No. 12-398

IN THE

Supreme Court of the United States

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, *et al.*,

Petitioners,

v.

MYRIAD GENETICS, INC., *et al.*,

Respondents.

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

BRIEF FOR THE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

ANTHONY F. LO CICERO
First Vice-President
CHARLES R. MACEDO
Co-Chair, Committee on Amicus Briefs
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
c/o AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 Park Avenue
New York, NY 10016
(212) 336-8000

MATTHEW B. MCFARLANE
Counsel of Record
RONALD M. DAIGNAULT
ROBINS, KAPLAN, MILLER & CIRESI L.L.P.
601 Lexington Avenue
Suite 3400
New York, NY 10022
(212) 980-7400
mbmcfarlane@rkmc.com

Attorneys for Amicus Curiae New York Intellectual Property Law Association

(Additional Counsel Listed on Signature Page)

246503

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

TABLE OF CONTENTS

Table of Contents

TABLE OF CITED AUTHORITIES

Page

CASES

Page

Page

STATUTES

RULES

OTHER AUTHORITIES

Page

Page

NYIPLA'S *AMICUS* BRIEFS

INTEREST OF *AMICUS CURIAE*

The New York Intellectual Property Law Association ("NYIPLA" or "Association") respectfully submits this brief *amicus curiae* in support of Respondents, Myriad Genetics, Inc. *et al.* ("Myriad").[1]

The arguments set forth herein were approved on March 12, 2013 by an absolute majority of the officers and members of the Board of Directors of the NYIPLA, including any officers or directors who did not vote for any reason, including recusal, but do not necessarily reflect the views of a majority of the members of the Association, or of the law or corporate firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer or director or member of the Committee on *Amicus* Briefs who voted in favor of filing this brief, nor any attorney associated with any such officer, director or committee member in any law or corporate firm, represents a party in this litigation. Some officers, directors, committee members or associated attorneys may represent entities, including other *amici curiae*, which have an interest in other matters which may be affected by the outcome of this litigation.

The NYIPLA is a professional association of approximately 1,300 attorneys whose interests and

1. Petitioners consented to the filing of *amicus curiae* briefs in support of either party or neither party in a docket entry dated January 2, 2013, and Respondents consented to this filing in correspondence dated February 27, 2013. Pursuant to Sup. Ct. R. 37.6, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than NYIPLA, its members, or its counsel made a monetary contribution to its preparation or submission.

practices lie in the area of patent, trademark, copyright, trade secret and other intellectual property law. The Association's members include a diverse array of attorneys specializing in patent law, from in-house counsel for businesses that own, enforce and challenge patents, to attorneys in private practice who represent inventors in various proceedings before the United States Patent and Trademark Office ("PTO").

A substantial percentage of the Association's member attorneys participate actively in patent litigation, representing both patent owners and accused infringers. The NYIPLA's members also frequently engage in patent licensing matters on their clients' behalf, representing both patent licensors and licensees.

The entities served by the Association's members include inventors, entrepreneurs, venture capitalists, businesses, universities, and industry and trade associations. Many of these entities are involved in research, patenting, financing and other commercial activity relating to biotechnology generally, and a significant number in such activities relating to the important narrower areas of genomic research and the modification of genetic material.

The NYIPLA's members and their respective clients have a strong interest in the issues presented by this case because their day-to-day activities depend on the consistently-applied and longstanding broad scope of patent-eligible subject matter under the Patent Act in general. Because of the vital and increasing importance of biotechnology and the modification of genetic material to the economy, moreover, the NYIPLA and its members have a particularly strong interest in ensuring that their

reasonable expectation that those principles continue to be consistently applied in those important areas.[2]

The NYIPLA's members demonstrably have a strong interest in ensuring that the Court does not disturb the current, clearly-defined framework governing the patent eligibility and patentability of inventions relating to modified genetic material that Congress enacted and that this Court has previously construed. In view of the enormous strides made in the related science of genomics since the initial discovery of Watson and Crick in 1953, it is equally important to the Association that this Court confirm that application of 35 U.S.C. § 101 to the technology of genetic modification should not unduly be conflated with considerations of patentability under Sections 102, 103 and 112.

STATEMENT

1. *Amicus* respectfully submits that the question presented—"Are human genes patentable?—is inextricably intertwined with issues that this Court already has considered and settled.

Since this Court has confirmed at least twice within the past 33 years that compositions of matter and

2. The technological and financial importance of claims to modified living genetic material were highlighted before this Court during oral argument on February 19, 2013 in *Bowman v. Monsanto Co., et al.* (No. 11-796) ("*Bowman v. Monsanto*"). Indeed, the significance of those issues to its members led the NYIPLA's Board to authorize the filing of a brief *amicus curiae* in that proceeding. *See* Brief for the New York Intellectual Property Law Association as *Amicus Curiae* in Support of Respondents, *Bowman v. Monsanto Co.* (No. 11-796) (filed January 22, 2013).

manufactures derived from living things are patentable under Sections 102, 103 and 112 of the Patent Act, *a fortiori* they necessarily are patent-eligible under Section 101. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 147 (2001) (concluding that a "composition of matter" . . . . includes living things"); *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980) (concluding that Congress has "recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions").

Indeed, the holding of *Chakrabarty* must be read to include a determination that a composition of matter or manufacture is patent-eligible when it incorporates naturally-occurring hereditary units analogous to human "genes." 447 U.S. at 305 n.1, 306, 307.

Moreover, the crucial distinction this Court drew in *Chakrabarty,* "between products of nature, whether living or not, and human-made inventions," logically must be read to govern the patent eligibility of the inventions that Myriad claimed. *Id.* at 313. On the one hand, "human genes" as they are found in the human body are (and should be) ineligible for patent protection. On the other, extracted and isolated deoxyribonucleic acid ("DNA") obtained by human intervention from a naturally-occurring source must be deemed patent-eligible. *Id.* at 309 (noting that "Congress intended statutory subject matter to include anything under the sun that is made by man.") (internal quotation marks and citations omitted).

Myriad's claims cover patent-eligible subject matter under Section 101. If those claims satisfy all other statutory requirements including, importantly, Sections

102, 103 and 112, then Myriad is entitled to exclude others during the term of the patent (1) from making or using the claimed inventions for commercial benefit, and (2) from selling modified genetic material. But the claims cover and would therefore exclude only isolated and extracted DNA that would not exist in the first place without human intervention.

Enforcement of Myriad's claims will not prevent or preempt the use of any human genetic material as found in the human body. Given the broad statutory grant which protects "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," subject matter that would not exist without human intervention should be found patent-eligible under Section 101 of the Patent Act. 35 U.S.C. § 101; *Chakrabarty*, *supra*; *J.E.M.*, *supra*.

2. DNA is a chemical compound that exists in nature as two separate chains, bound together to form a double helix structure. Pet. App. 14a-15a. Each chain is a polymer formed from a set of four monomeric nucleotides—adenine ("A"), guanine ("G"), cytosine ("C") and thymine ("T")—each unique by virtue of a different nitrogen-containing base. Those bases have the unique property of selectively pairing to other bases according to a simple rule: A always pairs with T, and C always pairs with G. One strand of double-helical DNA will be the complement of the other, a structure determined and stabilized by base-pairing between those two antiparallel strands.

In humans, DNA is organized into twenty-three pairs of chromosomes. Pet. App. 18a-20a. Each chromosome contains a single double-helical molecule formed from millions of nucleotide monomers. Naturally-occurring

human chromosomal DNA is therefore a specific single chemical, accurately identifiable only by its precise ordered nucleotide sequence. Different DNA sequences may have different functions that may, as in the BRCA1 and BRCA2 genes in this case, correlate with potential susceptibility to certain diseases in the organism that expresses them. Pet. App. 20a-21a.

In addition to its specificity, chromosomal DNA is also a special chemical because, *inter alia*: (i) specific nucleotide sequences in a DNA molecule may be attributed to and responsible for a particular cellular function, and (ii) those sequences, and their attendant functions, are heritable from generation to generation.

A "gene" is an organizing principle that accounts for the various functional properties exhibited by chromosomal DNA. Pet. App. 13a-17a. One important cellular function of genes is to encode proteins through a dual process of DNA transcription to form ribonucleic acid ("RNA"), and RNA translation to form proteins—the "central dogma" of molecular biology. For this function, a "gene" is defined spatially as that discrete region of chromosomal DNA responsible for the synthesis of a particular protein. This region is not necessarily continuous, however, as exons, the portions of the "gene" encoding the protein are flanked and interrupted by introns, or non-coding sequences. Other non-coding sequences are responsible for a gene's *in vivo* function by modulating its transcription rate. Those non-coding sequences may serve vitally important and dynamic control functions within the gene and between different genes. Therefore, a "gene" as a functional entity reflects the complex participation of both coding and non-coding DNA sequences as they are found in naturally-occurring chromosomal DNA.

3. The claims-in-suit do not cover "human genes." For example, claim 1 of U.S. Patent No. 5,747,282 ("the '282 patent") is a representative claim that recites:

> 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

'282 patent, col. 153 ll. 55-58. The term "isolated" in the claim is significant because it immediately identifies a DNA molecule within the scope of the claim as distinct from a DNA molecule that might exist naturally in a human based on its separation from chromosomal DNA. *See* '282 patent, col. 19 ll. 8-12 (defining an "isolated" DNA as "one which is substantially separated from other cellular components which naturally accompany a native human sequence").[3]

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3. On their face, the claims at issue do not involve "human genes" as in the question presented, and also avoid the potential written description issues involved in simply claiming a "gene" without further elaboration on the sequences covered. For example, in a claim directed to a "gene comprising SEQ ID NO:1,"

> [a] determination of what the claim as a whole covers may result in a conclusion *that specific structures* such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (*e.g.*, promoters, enhancers, coding regions, and other regulatory elements) which are also included.

Manual Pat. Examining Proc. ("MPEP") § 2163 (emphasis supplied).

In another application, the "isolated DNA" of the representative claim above could correspond only to the exons—that subset of the full gene that specifically encodes the BRCA1 polypeptide. For example, claim 2 of the '282 patent recites:

> 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.

'282 patent, col. 153 ll. 59-60. SEQ ID NO:1 corresponds to the nucleotide sequence excluding the non-coding introns and flanking portions. As discussed above, those excluded sequences are prominent features of the naturally-occurring gene that almost certainly play a role in the normal functioning of that DNA sequence *in vivo*. SEQ ID NO:1 represents a different chemical species, a complementary DNA ("cDNA") molecule that, as with the isolated DNA molecule of claim 1, does not exist in nature and can only be created by purposeful human activity. Pet. App. 267a-269a.

4. It is significant that the question presented asks whether human genes are "patentable." This Court has recognized that the Patent Act require distinct "Conditions for Patentability" for validly issued patents. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. __, 131 S.Ct. 2238, 2242 (2011) (recognizing that 35 U.S.C. § 282(b)(2) provides a defense that a patent is invalid for failing to meet any ground specified as a condition for patentability); *Diamond v. Diehr*, 450 U.S. 175, 189 (1981) (noting that "[s]pecific conditions for patentability follow [Section 101] and § 102 covers in detail the conditions relating to novelty"); *id.* at 191 & n.13 (noting Congress' deliberate division between statutory subject matter in Section 101 and other conditions for patentability in Section 102); *see*

also H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952) (stating that a "person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled").

Patentability refers to a holistic analysis of *all* conditions for patentability, including, *inter alia*, novelty under 35 U.S.C. § 102, non-obviousness under 35 U.S.C. § 103, and adequate disclosure and definiteness required by 35 U.S.C. § 112. Indeed, determining whether human genes may be patented at all—*i.e.*, whether human genes constitute patent-eligible subject matter under Section 101—is only a "threshold" analysis. *See Bilski v. Kappos*, 561 U.S.___,130 S. Ct. 3218, 3225 (2010) ("The § 101 patent-eligibility inquiry is only a threshold test."); *id.* at 3236 (Stevens, J., concurring in the judgment) ("Section 101 imposes a threshold condition."); *Diehr*, 450 U.S. at 188.

5. This Court has consistently framed the general principles that govern patent-eligible subject matter under 35 U.S.C. § 101 based on two questions:

> 1) Does the claimed subject matter fall within one of the four statutory categories of patent-eligible subject matter: (i) process, (ii) machine, (iii) manufacture, or (iv) composition of matter (or any improvement thereof)?
>
> 2) If so, is the claimed subject matter directed to one of three so-called "fundamental principles," *i.e.*, laws of nature, natural phenomena or abstract ideas, that are exceptions to patent-eligible subject matter?

See Bilski, 130 S. Ct. at 3225; *Diehr*, 450 U.S. at 185 (synthesizing, *inter alia*, *Chakrabarty*, 447 U.S. at 309 (1980); *Parker v. Flook*, 437 U.S. 584, 589 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

6. In *Mayo*,[4] this Court relied on the notion that if a process claim is broad enough to preempt all uses of a fundamental principle, then the claim must be deemed patent-ineligible. That approach has been criticized in the literature,[5] and the NYIPLA respectfully submits that, as discussed *infra*, the better view should be to reserve the analysis of process claim breadth to the separate patentability analysis under Section 112.

An emerging concept in recent lower court analyses considers whether claim is adequately described and enabled for its "full scope," often referred to as the "commensurateness" principle. *E.g.*, *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380-81 (Fed. Cir. 2011) (Rader, C.J.) ("Enablement serves the

4. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. ___, 132 S.Ct. 1289, 1294 (2012) (noting that precedent warns "against upholding patents that claim processes that too broadly preempt the use of a natural law") (citations omitted).

5. Joshua D. Sarnoff, *Patent-Eligible Inventions After* Bilski*: History and Theory*, 63 Hastings Law Journal 53, 91 (2011) ("Concern over 'preempting' applications by patenting claims to applications of science, nature and ideas is both misleading and unhelpful. Preemption is a misleading concept because the scope of a claimed invention simply is *not* the relevant question for eligibility. . . . Preemption is unhelpful because it changes the focus from the nature of the invention for which patent protection is sought, and from the requisite judgments of human creativity or similarity, onto the consequence of granting protection; that is, it puts the cart of the conclusion before the horse of one of its premises.") (internal citations omitted) (emphasis in original).

dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention."); *id.* at 1381 ("The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.") (quotation and citations omitted).[6]

If Myriad's claims were construed as broadly as Petitioners argue, they might indeed fall within an exception to patent eligibility. But the claims before the Court are directed to isolated DNA molecules: specific, identified chemicals that do not exist in nature. Human intervention is required to convert a full-length naturally-occurring DNA molecule within human cells into the claimed chemical compounds which are patent-eligible under Section 101 as compositions of matter and manufactures.

SUMMARY OF ARGUMENT

The patents in this case are not patents on life. The claims at issue do not patent or preempt any individual's naturally-occurring DNA. Nor can the claims be infringed by a human's mere existence. Rather, the claims are limited to specific chemical compounds that can only be produced by purposeful and directed human activity. Those "pioneer" patents, which occasionally appear, certainly should not be deemed patent-ineligible simply because their disclosures are important and comprehensive.

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6. So long as a process claim contains sufficient limitations to facilitate the requisite analysis under Section 112 as required by *MagSil*, it should pass muster under Section 101.

The considerable public debate and deeper philosophical analysis that has surrounded the facts of this case are largely irrelevant to this Court's interpretations of the Patent Act. The legal precedents that should govern the analysis under Section 101 broadly confer patent eligibility upon non-naturally-occurring compositions of matter and manufactures such as the DNA molecules claimed by Myriad's patents.

This Court's precedent has established clear rules governing the scope of patent-eligible subject matter—rules that should inform the disposition of this case. Inventions covering compositions of matter and manufactures may be patented provided that the invention does not cover a patent-ineligible fundamental principle. The claims at issue are directed to human-made molecules that are not found in nature. Whether the claims at issue may ultimately suffer from other defects that preclude patentability is an issue not now before the Court. But the inventions recited, as a threshold matter, under *Chakrabarty*, are directed to patent-eligible subject matter.

Moreover, Congress has had ample opportunity to consider whether patents directed to naturally-occurring DNA sequences, like human genes, should continue to enjoy patent protection. So too has Congress had the opportunity to legislatively adjust the judicially created exceptions to patent-eligible subject matter. Yet Congress has consistently declined to adopt the position that Petitioners seek through the judicial imprimatur of this Court.

Based on the points below, NYIPLA respectfully submits that the Court should confirm the patent eligibility

of compositions of matter and manufactures created by human intervention. As this Court has recognized, patent eligibility is only a threshold question, and the ultimate conclusion as to an inventor's right to exclude should be reserved for the holistic analysis of all conditions of patentability required by the Patent Act.

In reaching this conclusion, the Court also will endorse and reaffirm the decades-old practice of the PTO respecting the broad scope of patent-eligible subject matter germane to the critical biotechnology, pharmaceutical and health care industries. Those engaged in research and development in those industries, and the financing thereof, expect and deserve a clear statement from this Court that their innovations will continue to benefit from the value created by patent protection.

ARGUMENT

I. Well-settled principles governing patent-eligible subject matter should be applied to the claims at issue.

For more than thirty years, this Court has consistently applied a two-step inquiry as the standard for determining the patent eligibility of an invention under Section 101. The first step is to determine whether the subject matter of the claimed invention falls within one of the four categories of patent-eligible subject matter set forth in 35 U.S.C. § 101: processes, machines, compositions of matter, or manufactures. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 483 (1974) ("[N]o patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within the express categories of patentable subject matter.").

The second step is to determine whether the claimed subject matter is directed to one of the three so-called "fundamental principles:" "laws of nature, natural phenomena and abstract ideas." *Chakrabarty*, 447 U.S. at 309 (citations omitted); *see Bilski*, 130 S. Ct. at 3225 (2010) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

This Court has consistently applied this standard since *Chakrabarty*, and reaffirmed it most recently in *Mayo*. 132 S. Ct. at 1293.[7] In fact, the *Mayo* Court rejected "shortcuts" like the Federal Circuit's "machine-or-transformation" test as a suitable proxy for the two-step patent eligibility analysis commanded by precedent. *Id.* at 1303 (confirming that the Court has "neither said nor implied that the ["machine-or-transformation"] test trumps the 'law of nature' exception").

The Association respectfully submits that this standard is a clear and logical application of the Congressional purpose in enacting and codifying the Patent Act. It meets the settled expectations of practitioners, on the one hand, and those of patentees and their industries on the other. It has functioned well for over thirty years, permitting a broad scope for examining patent applications covering useful inventions that have advanced Science and useful Arts at an unprecedented rate. At the same time, the standard safeguards access to information and supports the public's expectation of continued innovation.

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7. The PTO likewise applies this Court's two-step inquiry as the standard for determining patent-eligible subject matter under 35 U.S.C. § 101. *See* MPEP § 2106.

A. The claimed inventions cover man-made compositions of matter and manufactures, satisfying the first step of the Section 101 analysis.

The isolated DNA molecules of the claims at issue are "compositions of matter," which this Court has defined as a composition of two or more substances or a composite article, whether the result of chemical union or of mechanical mixture, and whether of gas, fluid, powder or solid. *Chakrabarty*, 447 U.S. at 308 (quoting *Shell Development Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957), *aff'd*, 252 F.2d 861 (D.C. Cir. 1958) (per curiam)); *see P.E. Sharpless Co. v. Crawford Farms, Inc.*, 287 F. 655, 658 (2d Cir. 1923) (further stating that there is "no restriction as to the nature of the composition which may be patented"); *see also* Pet. App. 48a (noting that the "parties and the government appear to agree that isolated DNAs are compositions of matter, they disagree on whether and to what degree such molecules fall within the exception for products of nature").

The isolated DNA molecules of the claims at issue are also "manufactures," which this Court has defined, consistent with its dictionary definition, as "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or machinery." *Chakrabarty*, 447 U.S. at 308 (quoting *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)).

The claimed subject matter thus satisfies the first step of the Section 101 analysis by fitting into at least one of the statutory categories.

B. No judicial exception to patent eligibility applies to the claims at issue.

Claimed subject matter that falls within at least one of the four statutory categories, may not be patent-eligible if it is directed to a law of nature, a natural phenomena or an abstract idea—the only judicially-created exceptions to patent eligibility. *Chakrabarty*, 447 U.S. at 309. With regard to products of nature, however, *Chakrabarty* confirms that new products having "markedly different characteristics from [those] found in nature" are patent-eligible discoveries that are "not nature's handiwork," but that of the inventor—in other words, human-made and patent-eligible. *Id.* at 310.

1. DNA molecules made through human intervention cannot be products of nature.

In this case, the lower courts disagreed as to which characteristics of isolated DNA are relevant to determine patent eligibility. The district court focused on the DNA *sequence* to reach its conclusion that the claimed isolated DNA molecules did not represent "a change that results in the creation of a fundamentally new product." Pet. App. 320a-21a, 336a, 344a.

The court of appeals, however, focused on the DNA chemical structure to reach its conclusion that the claimed isolated DNA molecules were "markedly different" from their naturally-occurring counterparts, and patent-eligible composition that have "distinctive characteristics" resulting from human intervention. Pet. App. 50a-53a.

The dual nature of isolated DNA as *both* a carrier of genetic information (sequence) and a specific chemical

compound (nucleotides) conflates these two positions—two sides of the same coin that support the conclusion that an isolated DNA molecule is patent-eligible under 35 U.S.C. § 101. Accordingly, however viewed, the Association respectfully submits that creating a useful, isolated DNA molecule is undeniably a product of human intervention—and therefore meets the standard for patent eligibility.

Isolation is a rational step that requires an informed decision of what nucleotide structural units (bases) to include in the molecule when cleaving it from its natural environment. Isolation is a significant and consequential step reflecting the handiwork of man, and thus creating a composition of matter, and a manufacture, that is neither a law nor a product of nature, and is therefore patent-eligible.

In light of the complex *in vivo* structure and function of a gene as it exists naturally in a unified chromosome, isolation of that gene—or a defined subpart of it—is an activity that falls on the patent-eligible side of the clear dividing line between patent-ineligible "natural phenomena" and patent-eligible "human-made inventions." *J.E.M.*, 534 U.S. at 130. *See Chakrabarty*, *supra*. This is especially so when the end result of isolation is the production of a distinct chemical compound that does not exist in nature and cannot be a "natural product," as in this case, as twice recognized by the court of appeals below.

Further, this Court has recognized that Congress specifically intended that patentable subject matter "include anything under the sun *that is made by man*." *Chakrabarty*, 447 U.S. at 309 (emphasis added) (quoting S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)). For the same reason, human activity generating

"newly developed plant breeds" falls within the ambit of Section 101, even though other statutes provide protection for plants. *J.E.M.*, 534 U.S. at 144 (identifying Section 101 and the Plant Variety Protection Act ("PVPA") as overlapping statutes that have effect because "many plant varieties that are unable to satisfy the stringent requirements of § 101 might still qualify for the lesser protections afforded by the PVPA").

Taken as a whole, this Court's precedent firmly establishes a product of human intervention as critical to expressly removing living subject matter from the category of patent-ineligible "natural phenomenon."

2. Isolated DNA is not a discovery of the handiwork of nature.

In *Mayo*, this Court asked whether an "inventive concept" existed in a process claim that "add[ed] enough" to a law of nature or natural phenomenon "sufficient to ensure that the patent in practice amounts to significantly more than a patent on the natural law itself." 132 S.Ct. at 1294, 1300. For a claimed process or method, this "inventive concept" is an analysis that delineates specific *human activity* as separate and apart from *natural activity* that standing alone is not patent-eligible.

By suggesting that human effort alone, without more, is insufficient to convert an invention from patent-ineligible to patent-eligible, Petitioners invite this Court to extend the "inventive concept" applicable to processes and methods to analyze the patent eligibility of compositions of matter and manufactures. *See* Pet. Br. at 36-37. The Association respectfully submits that the Court should decline this invitation.

When human intervention produces an isolated DNA molecule, it becomes a unique chemical that represents *direct evidence* of the human activity that the Court found lacking in the patent claims at issue in *Mayo*. 132 S. Ct. at 1302 (concluding that the additional steps in the claimed method "add nothing of significance to the natural laws themselves"). Isolated DNA molecules are not genes, human or otherwise, but are the end result of the applied human activity necessary to confer patent eligibility; thus, it would be redundant to turn to an "inventive concept" as a proxy for the human activity plainly present. In short, isolated DNA molecules are not nature's handiwork. *See Chakrabarty*, 447 U.S. at 310.

For this reason, Petitioners' reliance on *Funk Brothers*[8] is misplaced. *See* Pet. Br. at 37-38. There, the invention concerned the simple mixture of different strains of bacteria to create a composition of matter retaining the natural properties of each strain. In contrast, isolated DNA *does not* retain all of the naturally-occurring properties of its source. Removed from its native environment in the gene of the chromosome, isolated DNA is not subject to the complex genetic regulatory processes that confer full functionality of a gene *in vivo*. An isolated DNA molecule may possess some but never all of the naturally-occurring properties of a gene *in vivo*. Isolated DNA is always "markedly different" from the gene from which it was extracted. *Chakrabarty*, 447 U.S. at 310.

Like the pre-1952 claimed invention in *Funk Brothers*, the isolated DNA molecules of Myriad's claims fall squarely within the statutory definition for an "invention" as codified in 1952. In 35 U.S.C. § 100(a), the Patent

8. *Funk Bros. Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

Act expressly defines an "invention" as "invention and discovery." 35 U.S.C. § 100(a). This definition was retained in the 1952 Amendments. In fact, the originally proposed amendments contained the following description:

> Discoveries, as well as inventions, may be patented, *if the discovery can be expressed in terms of or embodied in a new and useful* art, machine, *manufacture or composition of matter*, or improvement thereof, and the term invention when used in this title includes such discovery.

H. Comm. on the Judiciary, 81st Cong., Proposed Revision and Amendment of the Patent Laws 11 (Comm. Print. 1950) (emphasis added). Converting a portion of a naturally-occurring gene into a distinct chemical entity—an isolated DNA molecule—is the conversion of a portion of a naturally-occurring gene into a useful composition of matter or manufacture through human intervention. This creates an invention within the scope of Section 101. The source material, which is not claimed, remains a fundamental principle ineligible for patenting.

Claims directed to isolated DNA molecules having a particular structure (*i.e.*, a specific sequence of nucleotide bases) or function (*e.g.*, capacity to encode and express a protein) necessarily evoke non-naturally-occurring subject matter. Under this Court's precedent, such claims are not directed to a patent-ineligible "fundamental principle," but are patent-eligible under Section 101.

3. Isolated DNA molecules, though patent-eligible under Section 101, may not meet the other conditions of patentability under Sections 102, 103 or 112.

Determining whether a patent-eligible claim is actually patentable—that is, satisfies the "conditions and requirements" of Title 35—necessitates an analysis separate from the patent eligibility inquiry. 35 U.S.C. § 101. *See Bilski*, *supra*.

Given the narrow ambit of the question presented to this Court on certiorari, and the fact that neither the district court nor the court of appeals has yet considered whether the isolated DNA claims at issue meet the other statutory conditions and requirements for patentability, it seems highly unlikely that this Court would wish to address patentability in this proceeding. Nevertheless, and despite the fact that Section 101 generally deals only with the threshold question of whether a claimed invention is patent-eligible, a few brief comments on three statutory criteria for patentability may be in order.

a. Sections 102 and 103

This Court's clear proscription in *Bilski* against conflating the patent eligibility and patentability inquiries is particularly important where rapid technological advances affecting the novelty and obviousness analyses can tempt the district courts to apply the prohibited technique. As this Court stated in *Diehr*,

> The "novelty" of any element or steps in a process, or even of the process itself, is of no

> relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

450 U.S. at 188-89. *See id.* at 193 n.15 (concluding that "the fact that one or more of the steps in respondents' process may not, in isolation, be novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter *eligible* for patent protection under § 101") (emphasis in original).

In this case, moreover, neither the district court nor the court of appeals has yet considered the question of whether the isolated DNA claims at issue failed to meet the conditions for patentability set forth in Sections 102 and 103.

The NYIPLA recognizes that in the three decades since *Chakrabarty* the levels of ordinary skill in the arts of biotechnology and the isolation and modification of genetic material have increased dramatically. Indeed, advances in laboratory technologies have enabled procedures once considered worthy of the Nobel Prize to be assigned to non-degreed workers in contemporary laboratories. The improved processes for carrying out the polymerase chain reaction ("PCR") represent one example.[9] Courts

9. Kary B. Mullis shared the 1993 Nobel Prize in Chemistry for his development of an improvement to the polymerase chain reaction ("PCR") made at Cetus Corporation ("Cetus") in 1983. Kary B. Mullis, Nobel Lecture: The Polymerase Chain Reaction (Dec. 8, 1993) (available at http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1993/mullis-lecture.html) (last accessed Mar. 13, 2013). As might be expected, a number of patents were issued to Cetus on various aspects of this development. *See*

and commentators alike also have noted that (a) near completion of the massive efforts to sequence the human genome and (b) widespread university and private corporate efforts to assign potential functionalities to certain isolated DNA molecules corresponding to genes could render claims directed to those functionalities obvious under Section 103. *See*, *e.g.*, *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (holding a claim directed to a gene obvious where "the prior art [taught] the protein of interest, a motivation to isolate the gene coding for that protein, and illustrative instructions . . . for cloning this gene"); Christopher M. Holman, *Trends in Human Gene Patent Litigation*, 322 SCIENCE 198, 199 (2008) (noting the steep decline in human gene patents and applications following the human genome's publication in 2001).

Nevertheless, in this case as in *Funk Brothers*, the lower courts did not hear facts relating to novelty or obviousness at all, limiting the factual record below and restricting the court of appeals analysis to patent eligibility under Section 101.

Brief Of New York Intellectual Property Law Association As *Amicus Curiae* In Support of Petitioner at 22 n.31, *Merck KGaA v. Integra Lifesciences, Ltd.*, 545 U.S. 193 (2005) (No. 03-1237), 2005 WL 460873. *See also* the discussion of *Taq* polymerase in Susan McBee and Bryan Jones, The Supreme Court should be mindful of naturally derived products other than nucleic acids when deciding Myriad, SCOTUSblog (Feb. 7, 2013, 10:16 AM), http://www.scotusblog.com/2013/02/ the-supreme-court-should-be-mindful-of-naturally-derived-products-other-than-nucleic-acids-when-deciding-myriad/.

b. Section 112

Likewise, Petitioner's argument repeatedly refers to the breadth of the claims at-issue, characterized as extending "to the genes themselves and reach all structures and uses of the gene" that would include both known and unknown variations. *See* Pet. Br. at 3, 11-16. But breadth necessarily implicates an issue sometimes referred to as "commensurateness": whether a claim is adequately described or enabled throughout its "full scope." *See* 35 U.S.C. § 112(a) ("The specification shall contain . . . the manner and process of making and using [the invention]."). *See also Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353-54 (Fed. Cir. 2010) (en banc) (stating that the written description requirement ensures that "the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification") (quotation and citations omitted); *MagSil*, *supra*. This too the courts below neither considered nor determined.

The NYIPLA respectfully submits that the "patentability" of the claims at issue can only be resolved, and the patentability of the isolated DNA from a human gene, can only be established by considering *all* potential grounds for invalidity. This holistic approach allows each of the conditions for patentability to properly limit the claimed inventions to those that Congress intended should enjoy protection. It would be both improper and impractical to graft aspects of substantive patentability analyses onto the threshold consideration of patent eligibility under Section 101. *See Bilski*, 130 S.Ct. at 3225.

II. Congressional action and intent has repeatedly implied broad support for biotechnology, including patent eligibility for inventions involving human genes.

Congress has already set clear policy concerning biotechnology patents, including patents involving human genes. Such inventions should remain patent-eligible under Section 101 unless and until Congress indicates otherwise. Congress is fully capable of making statutory amendments that specifically exempt past and future activities from patent eligibility. *E.g.*, 42 U.S.C. § 2181(a) ("No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon."). By creating an exception for one category of subject matter, while failing to carve out "gene patents" in the same manner, Congress impliedly chose not to disturb the patent eligibility of isolated DNA molecules obtained by human intervention upon human genomic DNA—an activity the PTO has permitted for more than thirty years.

A. The Court has confirmed Congress' broad grant of subject matter eligibility.

The future direction of human innovation is impossible to predict. This limitation requires that the patent laws remain a "dynamic provision designed to encompass new and unforeseen inventions." *J.E.M.*, 534 U.S. at 135. Broad subject matter eligibility should remain a cornerstone of this dynamic approach to patentable inventions.

This Court recently concluded that a "categorical rule denying patent protection for 'inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law.'" *Bilski*, 130 S.Ct. at 3227 (quoting *Chakrabarty*, 47 U.S. at 315). The *Chakrabarty* Court confirmed this expansive view when it cited the Committee Reports accompanying the 1952 Patent Act as evidence of the intent of Congress to achieve broad subject matter eligibility consistent with Thomas Jefferson's "liberal encouragement" of ingenuity. 447 U.S. at 308-09 (quoting 5 Writings of Thomas Jefferson 75-76 (Washington ed.) 1871). More than a century before *Chakrabarty*, this Court had expressed the same general principle:

> The true policy and ends of the patent laws enacted under this Government are disclosed in that article of the Constitution, the source of all these laws, *viz*: 'to promote the progress of science and the useful arts,' contemplating and necessarily implying their extension, and increasing adaptation to the uses of society.

Kendall v. Winsor, 62 U.S. (21 How.) 322, 328 (1859).

Absent a clear statement from Congress to the contrary, the NYIPLA respectfully submits that this Court should continue to respect the broad patent eligibility for "anything under the sun that is made by man," which, as discussed above, would include the isolated DNA molecules claimed by Myriad.

B. Congress' acts and omissions suggest its continued support for patent eligibility for gene patents.

Beyond its holding that human-made compositions of matter and manufactures (versus products of nature) should be eligible for patent protection, *Chakrabarty* is a fitting cornerstone for this Court's analysis because its holding and the modern molecular biology revolution have matured in tandem. In the three decades since *Chakrabarty*, Congress has not taken any action that would limit the broad applicability of the Patent Act to reach biotechnology applications in general, and modified genetic material in particular. The NYIPLA respectfully submits that this case is not an appropriate vehicle for the Court to substitute its judgment for that of Congress'.

1. In 1995, Congress amended the Patent Act to address conditions of patentability related to "biotechnological process" patents. *See* Pub. L. No. 104-41, 109 Stat. 351-52 (Nov. 1, 1995). Congress defined "biotechnological process" broadly to cover fused cells and genetically altered organisms that express either: (*i*) an exogenous nucleotide sequence, (*ii*) an endogenous nucleotide sequence in a different manner than in that organism in nature, or (iii) non-naturally-occurring physiological characteristics, and methods of using the products produced by such processes. 35 U.S.C. § 103(b)(3). *See also* Biotechnology Patent Protection Act of 1991, S.654, 102nd Cong. (1991) (proposing amendment to 35 U.S.C. § 103 to reach a "biotechnological process," defined as "any method of making *or using* living organisms . . . for the purpose of *making or modifying products*") (emphasis added).

Importantly, the exogenous and endogenous nucleotide sequences referenced in Congress' definition do not exclude isolated DNA, let alone human genes, suggesting Congress' understanding at the time that patents, which the PTO had then been issuing for over a dozen years, should continue to issue covering isolated DNA and its use in biotechnological processes. It stands to reason that subject matter defined in the Patent Act necessarily should qualify as patent-eligible subject matter under Section 101.

2. In 1996, Congress amended the Patent Act again to limit medical practitioners' liability for patent infringement, specifically exempting infringement liability for "the practice of a process in violation of a biotechnology patent." 35 U.S.C. § 287(c)(2)(A)(iii); *see* 110 Stat. 3009-67. Congress specifically identified biotechnology patents as those making use of, *inter alia*, "genetic materials, such as DNA and RNA that is obtained from within the cell." 142 Cong. Rec. H11866 (daily ed. Sep. 28, 1996). Indeed, Senator Hatch specifically recognized that, under *Chakrabarty* and *Diehr*, Section 101 should be interpreted broadly to "encompass unforeseeable future developments." 142 Cong. Rec. S11844 (daily ed. Sep. 30, 1996). Therefore, Congress enacted Section 287(c) specifically knowing that future biotechnology patents might issue in a medical, *i.e.*, human, context, and specifically sought to shield medical practitioners from liability for infringement. This is a clear indication that Congress did not disapprove of biotechnology patents covering DNA and RNA obtained from naturally-occurring cells, like human cells, and that uses of such isolated DNA might infringe a patent in a medical context. Congress' acquiescence in this instance demonstrates its

understanding that the scope of patent-eligible subject matter under Section 101 is broad enough to reach isolated DNA molecules, including those corresponding to human genes in whole or in part.

3. In 2007, Representatives Becerra (D-CA) and Weldon (R-FL) introduced the Genomic Research and Accessibility Act that proposed amending the Patent Act to prohibit patenting "human genetic material," providing:

> Notwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.

H.R. 977, 110th Cong. § 2(a) (2007). In introducing the bill, Rep. Becerra's extended remarks noted that the "practice of gene patenting, where private corporations, universities and even the Federal Government are granted a monopoly by the United States Patent and Trademark Office on significant sections of the human genome" has "dramatic, costly and harmful implications for every American." 153 Cong Rec. E316 (Feb. 9, 2007). Quoting *Chakrabarty*, the remarks identified the true nature of the problem to be addressed:

> Proponents of gene patenting have said they are not patenting genes but instead are patenting "isolated and purified" genetic sequences. This is mere wordplay. In practice, these patents are patents on products of nature.

Id.

After referring the bill to the House Judiciary Committee, and then to the House Subcommittee on Courts, the Internet, and Intellectual Property, Congress took no further action on the proposed legislation that would accomplish the very same outcome Petitioners seek from this Court. The Association respectfully submits that the courts should refrain from adopting policy positions that Congress specifically considered but declined to pursue.

4. In 2011, Congress passed the America Invents Act, which expressly excluded a "human organism" from patent eligibility. Pub. L. 112-29, Sep. 16, 2011 (H.R. 1249) § 33(a). This provision was consistent with the PTO's interpretation of Section 101 that a claim encompassing a human being is not patent-eligible. 1077 Off. Gaz. Pat. Office 24 (April 21, 1987); *see also* MPEP § 2105 (explaining that a patent claim should be rejected under 35 U.S.C. § 101 if, under its "broadest interpretation," the "claimed invention as a whole encompasses a human being"). Rep. Weldon, the sponsor, confirmed that this exclusion did not extend to gene patents. 157 Cong. Rec. E1178 (daily ed. Jun. 23, 2011) (speech of Rep. Weldon) ("I would like to add, Mr. Chairman, that this has no bearing on stem cell research or patenting genes, it only affects patenting human organisms, human embryos, human fetuses or human beings.").

Congress' intent is clear that "[c]onsistent with the current law, the genetic inventions that form the basis for . . . diagnostic tests *are eligible for patenting*. . . ." 157 Cong. Rec. E1183 (daily ed. Jun. 22, 2011) (remarks of Rep. L. Smith) (emphasis supplied). Notably, Rep. Weldon's human organism exception to patent eligibility had been pending for years in Congress when the district court's

decision below issued in 2009 invalidating the patents-in-suit.

Moreover in considering the Weldon Amendment, Congress' intent was clear that

> nothing in this section should be construed to limit the ability of the PTO to issue a patent containing claims directed to or encompassing:
>
> 1. *any chemical compound or composition*, whether obtained from animals or human beings or produced synthetically, and *whether identical to or distinct from a chemical structure as found in an animal or human being*, including but not limited to *nucleic acids*, polypeptides, proteins, antibodies and hormones. . . .

Id. (emphasis added). Congress therefore appreciated that it could have restricted patenting for isolated DNA molecules corresponding to human genes such as those claimed in this case, yet specifically chose to permit such patents to preserve "economic viability of the biotechnology industry." *Id.*[10]

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10. This legislation also provides for a PTO study on genetic diagnostic testing, and a report thereafter to Congress. According to the statute,

> [t]he Director shall conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist.

Pub. L. 112-29, Sep. 16, 2011 (H.R. 1249) § 27. Congress is already addressing the considerable public debate and deeper philosophical questions surrounding the facts of this case.

It is clear that Congress has long been in an ideal position to consider whether patents directed to isolated DNA molecules derived from a human gene should no longer enjoy patent protection. Congress' decisions not to act over the years, in the face of proposed legislation essentially raising the Question Presented, should be respected, suggesting that it might be improper for this Court to judicially create an exclusion under Section 101 where no intent exists from Congress to do so.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be affirmed.

Respectfully submitted,

ANTHONY F. LO CICERO
First Vice-President
CHARLES R. MACEDO
Co-Chair, Committee on Amicus Briefs
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
c/o AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 Park Avenue
New York, NY 10016
(212) 336-8000

MATTHEW B. MCFARLANE
Counsel of Record
RONALD M. DAIGNAULT
ROBINS, KAPLAN, MILLER & CIRESI L.L.P.
601 Lexington Avenue
Suite 3400
New York, NY 10022
(212) 980-7400
mbmcfarlane@rkmc.com

THOMAS J. KOWALSKI
Committee on Amicus Briefs
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
c/o VEDDER PRICE PC
1633 Broadway
47th Floor
New York, NY 10019
(212) 407-7700

ROBERT M. ISACKSON
Committee on Amicus Briefs
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
c/o ORRICK, HERRINGTON & SUTCLIFFE LLP
51 West 52nd Street
New York, NY 10019
(212) 506-5000

NOAH M. LEIBOWITZ
Committee on Amicus Briefs
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
c/o SIMPSON THACHER & BARTLETT LLP
425 Lexington Avenue
New York, NY 10017
(212) 455-2000

DAVID F. RYAN
Co-Chair, Committee on Amicus Briefs
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
c/o 1214 Albany Post Rd.
Croton-on-Hudson, NY 10520
(914) 271-2225

Attorneys for Amicus Curiae
New York Intellectual Property Law Association

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