No. 12-398

IN THE
Supreme Court of the United States

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, *et al.*,
Petitioners,
v.
MYRIAD GENETICS, INC., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR *AMICUS CURIAE* CROPLIFE INTERNATIONAL SUPPORTING RESPONDENTS

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QUESTION PRESENTED

As they occur in nature, biologics (such as genes) exist in complex milieux. They are intimately and inherently associated with a wide range of other naturally-occurring materials. Biologics can be presented in isolated forms, but only through human handiwork and intervention. These "isolates" are freed from other cellular materials. Isolates are therefore capable of exploitation for the betterment of humankind in innumerable desired, controlled, and often novel ways, none of which are ever seen in nature.

Given the foregoing, should biological isolates be considered new and useful compositions of matter that are distinct from their naturally-occurring counterparts and, therefore, eligible for patent protection under 35 U.S.C. § 101?

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BRIEF OF *AMICUS CURIAE* CROPLIFE INTERNATIONAL SUPPORTING RESPONDENT

INTEREST OF *AMICUS CURIAE*[1]

CropLife International (CropLife) is a global federation representing the plant science industry and a network of regional and national associations in 91 countries. CropLife also has company members, including BASF,

[1] Pursuant to this Court's Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part, that no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person or persons other than *amicus* and its counsel made such a monetary contribution. Petitioners' consent to the filing of all *amicus* briefs is on file with the Clerk's office and respondents' consent to the filing of this brief was obtained from respondents' counsel on February 25, 2013 by e-mail correspondence, which is being lodged with the Clerk.

Bayer CropScience, Dow AgroSciences, DuPont Pioneer, FMC, Monsanto, Sumitomo, and Syngenta. These companies are committed to sustainable agriculture through innovative research and development in the areas of crop protection, pest control, and seed and plant technologies.

The innovations provided by CropLife member companies include, or are based on, isolated biologics, including isolated DNA molecules, cultures of isolated microorganisms, and other isolated substances found in nature. For example, isolated DNA molecules are used to bioengineer plants to have one or more novel properties, while cultures of isolated microorganisms are used, *e.g.*, as biocontrols to protect plants from various forms of pathogen infestation. With access to biologics such as these, crop yields increase and our dependence on pesticides, herbicides, water, and nutrients decreases. This benefits the environment, farmers, and the public. Consumers benefit too; they receive access to crop-based foods that, *e.g.*, are richer in nutrients or exhibit other salutary features. Plants engineered for increased production (of products like foods, oils, and fibers) and for decreased dependence on scarce resources (*e.g.*, water), are of self-evident benefit. This is especially true in countries experiencing deprivation. To recoup the investments made in these research and development efforts, CropLife's member companies rely on the exclusivity afforded by patents, including patents on isolated DNA molecules and other substances having counterparts in nature.

SUMMARY OF ARGUMENT

This case is about *patent-eligibility* under §101, not patent validity under other sections of the Patent Act. This Court has recognized § 101's breadth, characterizing it as reaching "anything under the sun that is made by man." *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980) (internal quotations omitted). Myriad's claims easily satisfy that standard. Other concerns regarding those

claims' validity, even if possibly meritorious, are irrelevant here; all that has been litigated, and all that this Court should decide, is whether their subject matter is patent-eligible.

1. Myriad's claims cover "isolates" of particular human genes. These are man-made versions of genes that are freed from the cellular components that associate with genes as they exist in humans. Nothing about Myriad's claims (or claims to any other biological isolate) attempts to cover nature's handiwork. Although this case formally focuses upon isolates of *human* genes, the reason that Myriad's claims satisfy § 101 also applies to any type of biological isolate, be it a non-human gene, another substance (such as a protein or an antibiotic), or a microorganism.

2. The patent-eligibility of biological isolates has generated extraordinary benefits to society. The isolated BRCA genes at issue here represent one end of the spectrum of biologics. They can save or sustain the lives of women predisposed to breast or ovarian cancer, typifying the "personalized medicine" revolution occurring in health care. Isolates of microbial origin, at the other end of the spectrum, are likewise revolutionizing agriculture, and thereby generating more for the world's people, at lesser cost, with higher quality, and often with substantial environmental benefits. Isolated versions of microbial genes can confer on plants desirable traits that they do not naturally possess, such as enhanced flavor, higher nutritional value, or the capacity to withstand adverse conditions, both before and after harvest. Such inventions have considerably improved agricultural development, and have even saved some staples—like the Hawaiian papaya—from extinction.

The benefits of biological isolates are extraordinary, and the short summary provided here understates their scope and import. Their patent-eligibility is what has

spurred those in the agricultural sector—and in other sectors—to make the investments necessary to create these new developments.

Whether to strip isolated biologics of patent-eligibility is, therefore, a policy question of great importance. But it is one for Congress, which is well aware of their being patented; it has chosen, however, only to eliminate patent-eligibility for a "human organism," and has rejected proposals to deny patent-eligibility to any other biologic. Any further changes to the standards of patent-eligibility should come from Congress, not the courts.

3. The posture of this case—arising with a scant summary-judgment record—also justifies caution. The Court should reject petitioner's attempt to introduce highly contested "evidence" that isolated versions of the BRCA genes *do* exist in nature.[2] No source supports this assertion, and logic refutes it; human genes in nature, unlike Myriad's isolates, are invariably associated with additional cellular components.

Similarly, petitioner tries to smuggle a question more properly addressed by § 112 into this § 101 case—he claims that Myriad's claims are too broadly written. And he attempts to solicit this Court in an extra-*Markman* claim-construction exercise, arguing theories about the claims' scope that improperly and unfairly distort the legal question before the Court. Because these issues were not litigated below, they should be ignored in favor of a case that properly presents them and, unlike this case, is brought by a petitioner with unquestionable standing.

4. Relying on a series of this Court's cases, petitioner

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[2] Although this case is purportedly brought by multiple "petitioners," only one petitioner (Ostrer) has been held to have adequate standing, and that is tenuous at best. See Pet. App. 41a. Accordingly, *amicus* will describe arguments advanced by the petitioner, in the singular.

seeks to demonstrate why human gene isolates cannot be patent-eligible. But any biological isolate would satisfy the key case, *Chakrabarty*. The other cases relied upon are inapposite, and, if anything, actually favor Myriad. *Funk* dealt with what is now called "obviousness," not patent-eligibility itself, which the Court acknowledged. *American Fruit Growers* dealt with whether a treated citrus fruit qualified as an "article of manufacture," but that has nothing to do with biological isolates, which are "compositions of matter." Finally, this Court's recent decision in *Mayo* does not resolve this case, because Myriad has not patented a natural phenomenon or a law of nature. Its claims only cover genes to the extent they are presented in an *isolated* form, compositions of matter that are otherwise unknown in nature.

ARGUMENT

Isolated Biologics, Whether Human Genes Or Otherwise, Are Patent-Eligible Under § 101

Under *Chakrabarty*, anything that is the product of man's intervention and is distinct from what is found in nature is patent-eligible. This case does not ask whether the claims at issue are valid under all provisions of the Patent Act and across their entire breadth; it simply asks whether they are patent-eligible under 35 U.S.C. § 101 to the extent they cover particular subject matter: isolated genomic and cDNA versions of human genes. Under § 101 and this Court's cases, the answer to that question must be "clearly, yes."

Providing a biologic in an isolated form so that it is freed from the components it inextricably associates with in its natural milieu meets the *Chakrabarty* and, therefore, the § 101, test. Beyond being freed from cellular components they naturally associate with, isolated genes, as a class of biologics, are further distinct from their naturally-occurring counterparts in that they are unique

chemical entities, liberated from chromosomes and, hence, freed from the covalent bonds that connect their naturally-occurring counterparts to neighboring chromosomal DNA.

The DNA molecules at issue here, taking the forms of *isolates*, necessarily steer clear of covering genes as they occur in the human body. Neither a DNA molecule nor any other *isolated* biologic is a "natural phenomen[on]." Cf. *Mayo Collaborative Servs.* v. *Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2011). To the contrary, they take a form that does not exist in nature and would not exist at all without man's intervention and handiwork. This Court should affirm the judgment below.

A. This case addresses the patent-eligibility of isolated versions of any biologic, not just isolated human genes

Petitioner frames the issue in this appeal as one concerning the patent-eligibility of isolated versions of *human* genes. See, *e.g.*, Pet. Br. i (question presented), 3, 55. But no logical basis exists for treating these isolates differently from any other kind of biological isolate, at least with respect to the threshold question of patent-eligibility under § 101—they are all equally isolates, and hence distinct, because of man's handiwork. Cf. Resp. Br. 60-61.

The Court should recognize, therefore, that any biological isolate satisfies the basic requirements of § 101. The patent-eligibility of biological isolates—which can range from genomic or cDNA versions of human genes, such as the BRCA genes covered by the claims at issue here, to non-human genes and microorganisms—matters a great deal to our society and to humanity at large. Because the patent-eligibility of many biologics is premised on their isolated state, depriving isolated human genes of patent-eligibility would have cascading negative conse-

quences in many fields beyond health care that rely on the patentability of other types of natural biologics to spur their innovations.

1. Biological isolates are compositions of matter that are never found in nature and only exist through man's handiwork

a. Any biological isolate is a composition of matter that is man-made—that is, one that only comes into existence as a result of man's intervention and handiwork. That is because all biologics are present in nature in an environment that has other naturally-occurring materials present with which they associate. Through intervention and handiwork, man must either: (a) retrieve a sample from nature that harbors the biologic of interest and employ techniques to remove these "naturally-occurring contaminants," or (b) produce the biologic in the laboratory, employing conditions and techniques that ensure that the biologic is freed from such "contaminants," thereby creating something that never exists in nature.

b. A human gene is but one example of a biologic and is the class the petitioner has framed this appeal around. That is because the claims at issue are directed to isolated DNA molecules that contain nucleic acid sequences found in the BRCA genes present in human chromosomes. Petitioner asserts that, since the claims are so broad as to cover all isolated genomic and cDNA versions of these genes, they essentially cover the genes as they exist in human body, which are unpatentable.[3]

c. But the concept of a biologic extends well beyond

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[3] Genomic and cDNA versions of the BRCA genes share in common the fact that they both contain the coding sequences for the BRCA proteins. But the two versions differ in that the cDNA version only contains coding sequence, while the genomic version also contains "introns," or non-coding sequences interspersed within the coding sequence. See generally Pet. App. 15a-19a.

human genes. It embraces genes from any organism, such as other animals, plants, and from microorganisms, such as bacteria, fungi, and yeast. It also embraces the proteins encoded by genes and microorganisms themselves. Insofar as the agricultural sector is concerned, a sector of particular interest and concern to CropLife's members, a range of innovations have been developed that, at their core, rely on isolated genes from microorganisms and plants (*e.g.*, to impart novel traits to crops) as well as microorganisms themselves (*e.g.*, to serve as inoculants that protect crops from various pathogens). See Section B.2, *infra*.

d. The Federal Circuit properly held that the claims at issue in this appeal do not impermissibly cover the BRCA genes as they occur in nature. By virtue of being limited to *isolated* DNA molecules—which, through man's intervention, are removed from the cellular milieu in which human genes are found—the claims are directed to molecules that are distinct from the BRCA genes as found in humans. Pet. App. 51a-55a.

2. The question presented by petitioner implies a limitation—to "human" genes—that law and logic cannot accept

The springboard for this appeal is a set of claims directed to isolated DNA molecules that collectively cover isolated versions of the human BRCA genes. Given that scope, petitioner has couched the Question Presented as whether such claims are impermissibly covering human genes as they occur in the body. But as demonstrated above, nothing logically distinguishes human genes from other biologics in this context. The Court's decision thus could have a profound impact on a wide range of biologics that are providing innovative solutions in areas outside of health care that are critical to our welfare and survival.

B. Patent-eligibility for biological isolates has generated extraordinary achievements in many contexts

Recognizing the patent-eligibility of isolated human genes fulfills Congress's objective of liberally encouraging human ingenuity. The same is true of all other biological isolates.

1. *Human genetic developments, like those in this case, portend a new era of personalized medicine*

The isolation of the human BRCA genes, and the identification of specific sub-sequences of these genes as biomarkers for breast and ovarian cancer, represent exactly the kind of human activity and ingenuity contemplated by Congress as meriting patent protection. See *Chakrabarty*, 447 U.S. at 309. These advancements benefit society at large, and could never be made without human intervention and ingenuity. Mutations in these genes are predictive of breast and ovarian cancer in a significant number of humans; being able to employ the claimed DNA molecules to detect these genes, particularly the markers for cancer that they bear, unquestionably saves lives. Indeed, the search for such mutations is so important to human health that it has become a priority for the National Institutes of Health (NIH).[4]

The human BRCA genes were among the earliest human genes to be cloned and identified as carrying markers for cancer. The identification and cloning of these two genes and the mapping of their markers were no small feats and represent true human ingenuity.[5] The

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[4] See, *e.g.*, National Institutes of Health, Fact Sheet—Cancer (2010), available at http://report.nih.gov/NIHfactsheets/Pdfs/Cancer(NCI).pdf.

[5] See, *e.g.*, Miki et al., A strong candidate for the breast and ovarian cancer susceptibility gene BRCA1, 266 Science 66-71 (Oct. 7, 1994), available at www.ncbi.nlm.nih.gov/pubmed/7545954; and Tavtigian et

DNA isolates disclosed and claimed by Myriad, which include genomic and cDNA versions of the BRCA genes, enable testing for these markers in high-risk patients, which has become the standard of care in the medical profession.[6]

It is all too easy to breezily suggest that claims like those at issue are not patent-eligible because they impermissibly cover natural phenomena. After all, the DNA molecules claimed cover isolated versions of human genes found in nature. But the discovery of such genes, their relationship to disease (*e.g.*, cancer), and their utility in diagnosing and treating disease represents a critical advance in the important art of making those predisposed to developing diseases healthy. Where a tool for identifying those who are at risk of developing a disease is discovered, it represents a true advance in the art of medicine and technology. Moreover, as reflected in Section D.1.b, below, when a claim clearly calls for a DNA molecule as an "*isolate*," such claim language should suffice to render the claimed subject matter patent-eligible under §101—even if it extends to covering isolated versions of a human gene.

2. Biological isolates being developed and patented in the agricultural sector confer useful traits to plants and are important to plant cultivation

The discovery, development, use, and patenting of biological isolates is extensive. It extends far beyond human

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al., The complete BRCA2 gene and mutations in chromosome 13q-linked kindreds, 12 Nat. Genet. 333-337 (Mar. 1996), available at www.ncbi.nlm.nih.gov/pubmed/8589730.

[6] See, *e.g.*, Biesecker et al., Genetic counseling for families with inherited susceptibility to breast and ovarian cancer, 269 Journal of the American Medical Association 1970-1974 (No. 15, Aug. 18, 1993), available at www.ncbi.nlm.nih.gov/pubmed/8352830.

genes useful for cancer diagnostics. Indeed, some of the most important isolates, and those of particular interest and concern to CropLife's members, are of microbial origin, consisting of isolated bacteria, fungi, viruses, and genes derived from them. The range is remarkably wide, but at each point throughout the range, these isolates provide innovative and often environmentally-friendly solutions to meeting many of society's most basic needs. These biologics are helping, and, if not impeded, will continue to help, feed, fuel, and clothe our ever-expanding population, which has reached, or soon will reach, seven billion.[7]

Various isolated versions of microbial and plant genes have been used to confer desirable traits on crops. In addition, genetic DNA markers have been identified in plants that can be used to select crops, produced through selective breeding techniques, possessing certain traits. The range of traits genetically engineered into plants includes enhanced flavor, higher nutritional value, longer shelf-life, and resistance to various conditions, such as drought, extreme heat or cold, and herbicide and pesticide treatment.[8] The list of plants modified with such

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[7] See Soils, Society & Global Change, Proceedings of the International Forum Celebrating the Centenary of Conservation and Restoration of Soil and Vegetation in Iceland 53 (2007), available at http://eusoils.jrc.ec.europa.eu/esdb_archive/eusoils_docs/other/EUR23784.pdf.

[8] See, *e.g.*, the following patents, claiming the following gene isolates: U.S. Patent No. 7,947,867 (USDA) (a DNA molecule that can increase a fruit's shelf-life); U.S. Patent No. 7,932,434 (USDA/WARF) (a polynucleotide that can confer disease resistance to solanaceous plants); U.S. Patent No. 7,439,419 (USDA) (a nucleic acid molecule that can reduce the bitter taste of certain vegetables); U.S. Patent No. 8,278,505 (Dow AgriSciences) (a polynucleotide that can confer herbicide-resistance to plants); U.S. Patent No. 8,299,324 (Bayer Cropscience N.V.) (DNA that can confer insect-resistance to plants).

traits includes important food staples, such as soybeans, tomatoes, corn, canola, squash, potatoes, alfalfa, papayas, and sugar beets, as well as fiber-producing plants such as cotton.

These innovations, which depend on the ability to identify and isolate non-human genes and use them to impart novel traits to plants, generate exceptionally beneficial consequences. As one concrete example, this ability essentially saved the papaya, a key Hawaiian export, from extinction there. Papaya is a subtropical-tropical fruit grown year-round in Hawaii. Rich in both vitamins A and C, it is a healthy staple for many worldwide. But in 1992, Papaya ringspot virus (PRSV) broke out in Hawaii and, within six years, ravaged production to the point that the annual papaya yield was less than half its pre-1992 level. See Biotechnology Industry Organization, Healing, Fueling, Feeding: How Biotechnology Is Enriching Your Life 66-67 (2010) ("Healing, Fueling").[9]

Salvation for the Hawaiian papaya came from isolating the gene that encoded the virus's coat protein and using that isolate to create a PRSV-resistant papaya. See Healing, Fueling, *supra*, at 67. Cornell University and the University of Hawaii jointly performed this work and hold a patent relating to this technology, which claims an isolated nucleic acid molecule encoding the PRSV coat protein—indistinguishable for legal purposes from the claims at issue in this case. See U.S. Patent No. 7,553,668. With the benefit of the resistance conferred by the PRSV coat protein gene, papaya is the second largest fruit crop grown in Hawaii. See Healing, Fueling, *supra*, at 67.

Our country's dependence on isolated genes to modify crops is even more extensive than the foregoing example might suggest. As of 2009, over 158 million acres were

[9] Available at http://www3.bio.org/news/publications/ValueofBiotech.pdf.

devoted to cultivating not only genetically-modified papayas, but also soybeans, maize, cotton, canola, squash, alfalfa, and sugar beets, making the United States the world's top producer of genetically-modified crops. See Healing, Fueling, *supra*, at 57, Fig. 3.

The isolation of non-human genes and genetic modification of crops with such genes play prominent roles in the "green revolution," which has enabled farmers to increase their crop yields while simultaneously reducing the environmental footprint of their activities. Indeed, between 1992-2008 alone, the use of genetically-modified crops translated into a 352 million-pound reduction in the amount of herbicide and pesticide used to treat crops. See Healing, Fueling, *supra*, at 78. See also CropLife International's *amicus* brief to the Federal Circuit in this case, at 14 (highlighting how environmentally-unfriendly tilling practices have been significantly reduced with the use of genetically-modified crops).

Genetically modifying plants and seeds is not the only way those active in the agricultural sector are meeting society's basic needs. They are also developing and patenting inoculants, akin to those featured in *Funk*, that rely on, *e.g.*, isolated cultures of microorganisms to stimulate crop growth, augment crop yields, and combat various forms of infestation.[10] Hundreds of such biologics are currently in use just in North America. See http://www.cdpr.ca.gov/docs/pestmgt/ipminov/bensup.pdf.

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[10] See, *e.g.*, the following patents claiming isolated microorganisms: U.S. Patent No. 6,210,953 (U. Wy./AGERI) (strains of the bacterium *Bacillus thuringiens* for use as pesticides); U.S. Patent No. 7,001,755 (USDA/OURF) (strain of the bacterium *Bacillus sp.* NRRL B-30212 to prevent head blight caused by fungi); U.S. Patent No. 7,579,183 (USDA) (strain of the yeast *Pichia anomala* for controlling various types of bacterial and fungal pathogens); U.S. Patent No. 5,955,348 (Novartis AG) (strain of the bacterium *Pseudomonas fluorescens* for treating various fungal pathogens).

This survey is, of course, grossly abbreviated. But it leaves little room for doubt that biological isolates in the agricultural sector are providing enormous benefits to the public.

3. Patent protection for such innovations spurs investment in these developments

Those active in the agricultural sector expend hundreds of millions of dollars annually, paying for a massive workforce to research, develop, market, and sell innovative products like those described above. The potential to secure patent protection for these new developments is a chief means for recouping those investments and ensuring that innovations are brought to the public. Patent-eligibility provides a key incentive for agricultural concerns to hire employees and expend the time, energy, and resources necessary to bring valuable innovations to market. Put simply, patented isolated biological compositions of matter stimulate the economy and create American jobs.

The United States Government certainly recognizes this in its own practices. The promise of patent protection has incentivized federal agencies, like many universities, to bring about the very types of innovations described above. Recognizing that such patent estates can provide significant royalty streams, the U.S. Department of Agriculture has devoted an entire webpage to promoting the out-licensing of its own patent holdings in this field.[11] Indeed, the bulk of the patents listed in footnotes 8 and 10, *supra*, are held by governmental or educational institutions, not by corporations.

Hence, this Court's holding has the potential to either advance or hinder the discovery and development of, and the public's access to, extraordinary new inventions of

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[11] *E.g.*, http://www.ars.usda.gov/business/docs.htm?docid=763&page=5; http://www.ars.usda.gov/business/docs.htm?docid=763&page=5.

tremendous social, economic, and environmental value.

4. Congress has already indicated which biologics should be patent-eligible; if patent-eligibility requires further modification, that is a policy matter for Congress

The Constitution endows Congress with the authority and responsibility to enact laws that promote "Science and useful Arts." U.S. Const. art. I, § 8, cl. 8. Over more than two centuries, Congress has enacted various patent acts that define what subject matter is eligible for patent protection. When Congress has deemed man's acts of ingenuity to come too close to nature's own handiwork, or, for some other reason, to be improper as a policy matter, it has limited the scope of subject matter eligible for protection—but not by banning the patenting of all biologics.

These enactments governing patent-eligibility for biological patents are specific and limited. In this regard, Congress adopted language in the Leahy-Smith America Invents Act of 2011 (AIA), that prohibits the patenting of "a claim directed to or encompassing a human organism." See Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

Notably, that bar is expressly limited to patenting "a human organism." It does *not* prohibit patenting *non*-human organisms, such as plants and microbes, much less non-human genes, or even human biological material, such as a gene found in a "human organism."

The distinction—a "human organism" versus all other biological subject matter—is noteworthy. It demonstrates that Congress expressly recognized that biological patents are possible and thereby subject to specific regulation. Congress is well aware that a broad range of biologics is being patented, and in 2007 even considered a bill intended to prohibit the patenting of human genes, but not non-human genes. See H.R. 110-

977. Nonetheless, that bill died in committee. See http://www.govtrack.us/congress/bills/110/hr977. No statute justifies denying isolated human genes—much less isolated *non*-human genes or microorganisms—basic patent-eligibility.

Congress was clear about what should not be patent-eligible—the "human organism." It declined to go further, choosing not to deny patent-eligibility to the very subject matter at issue here—human genes (much less any other biologic). If Congress thought that, before the America Invents Act, § 101 could permit patent-eligibility for the "human organism" itself, thereby necessitating legislation, it would defy logic to conclude that § 101 already denies patent-eligibility to other biologics.

The foregoing underscores that Congress is not only the arm of government best suited to enact policy changes, but also that it takes that responsibility seriously. This Court should refrain from forcing Congress's hand and adopting a position that would disturb the current practice and understanding that biological isolates are, as a general matter, patent-eligible.

As this Court recognized in another patent case, *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, "Congress can legislate [a patent-law principle, such as the patent-eligibility of isolated biologics] out of existence any time it chooses. The various policy arguments now made by both sides are thus best addressed to Congress, not this Court." 535 U.S. 722, 733 (2002) (quoting *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997) (quotation marks omitted)). See also, *e.g.*, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (U.S. Patent & Trademark Office's Utility Guidelines, cmts. 2-5) (confirming the patentability of isolated genes).[12]

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[12] CropLife appreciates the serious questions petitioner raises regarding the alleged inaccessibility of Myriad's patented technology

C. The state of the record supports neither reversal nor entertaining issues beyond compliance with § 101

This case comes to the Court on a summary-judgment record. For pure questions of law—such as patent-eligibility of subject matter with undisputed properties—that is perfectly appropriate. But, at this late stage, petitioner seeks to bolster his case by introducing new evidence and engaging in a novel analysis about the reading and scope of these particular claims that is wholly improper. The Court should firmly reject that approach. It should confine its analysis to the legal question of whether isolates of biologics (or even just isolates of human genes), as described above, are patent-*eligible*, and, based on the record below, determine whether petitioner is entitled to the relief he now seeks. Furthermore, whether the claims are, despite their patent-eligibility, deficient for other reasons, is a question best left for a case that properly raises those issues.

1. Petitioner improperly seeks to introduce new evidence to support his § 101 argument that is substantively insufficient

One line of petitioner's § 101 argument is that the BRCA genes at issue here in fact exist in nature as fragments. But, by relying on evidence that is not in the Record, petitioner seeks to make this Court a tribunal of

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to certain patients, under certain circumstances. See, *e.g.*, Pet. Br. 8. To the extent incidents such as these require redress, the response should be properly tailored, directed at responding, in a proportional manner, to the underlying facts and circumstances responsible for them. Under *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006), access to the claimed subject matter can be provided where the equities, particularly the public interest, so dictate. But resorting to § 101—or indeed the patent laws at all—for a solution to what is fundamentally a healthcare issue is far too blunt and overreaching a response.

first look rather than final review. And, as it happens, even if that argument were assumed, *arguendo*, to be true, it still would not make his case.

Petitioner asserts that human DNA fragments can be found in human plasma and blood that "are identical to the fragments created by Myriad when it isolates the gene." Pet. Br. 10-11; see *ibid.* & nn.2-3. This is hardly an assertion unaccompanied by "no genuine dispute as to any material fact," Fed. R. Civ. P. 56(a), as required on a summary-judgment record.

None of the art petitioner cites to support this proposition teaches that any such "floating" DNA fragments actually correspond to a human BRCA gene and are otherwise freed from other cellular components. As described at length above, the "isolated" state of the gene is precisely what the § 101 inquiry must focus upon—and is a limitation present in the claims themselves. See *infra* Part D.1.b (describing why the claims cover only versions of the BRCA genes that are freed from other cellular components).

It would be imprudent, at best, to rely (as petitioner has) on mere conjecture or possibility in concluding that fragmented forms of the human BRCA genes, disassociated from the cellular components that accompany them in the cell, are inherently present in human plasma and blood and, hence, satisfy the "isolated" limitation of the claims-at-issue. Accord *Trintec Indus.* v. *Top-USA Corp.*, 295 F.3d 1292, 1297 (Fed. Cir. 2002); *W.L. Gore & Assocs., Inc.* v. *Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983). Indeed, *even if* there are BRCA "fragments" in human blood, any reasonable understanding would be that those fragments would be associated with other cellular components as in every other natural occurrence of the genes. That view is both consistent with science and is contrary to the one that petitioner requires to derive any value from his "fragment" argument.

2. Petitioner raises matters properly addressed under § 112 in the guise of § 101

Relatedly, petitioner also seeks to raise issues regarding the breadth of the claims that are unrelated to whether they effectively cover the BRCA genes as they exist in humans. He contends that the claims-at-issue are tantamount to covering *all* diagnostically-significant versions of human BRCA genes *as they occur in nature*. See, *e.g.*, Pet. Br. 14, 16.[13] This view is both analytically flawed and obscures the real question for the Court—whether those genes *as isolates* are patent-eligible. At best, it raises issues that should be addressed under the finer filter of § 112 of the Patent Act (which measures the claims' written support and enablement) rather than the coarse filter of § 101 (which focuses on patent-eligibility). See, *e.g.*, *Ultarmercial, LLC* v. *Hulu, LLC*, 657 F.3d 1323, 1326 (Fed. Cir. 2011); *Regents of the Univ. of Cal.* v. *Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997). Cf. *Bilski* v. *Kappos*, 130 S. Ct. 3218, 3235-3236 (2010) (Stevens, J., concurring in judgment). The fact that there *are* other mechanisms for properly aggrieved parties to test these issues is itself an important reason why the Court should confine its analysis to the core § 101 question.

Equally significant, Myriad's compliance with § 112 has not been properly preserved for appeal (much less litigated), and it is not before this Court for adjudication. See Pet. App. 60a. Hence, for this additional reason, petitioner's objections to the breadth of the claims should not be heard now.

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[13] Petitioner gives the impression that every claim-at-issue: (a) covers isolated genomic versions of the human BRCA genes; and (b) does not specify a DNA sequence for such isolates. That is incorrect. Claim 2 of the '282 patent, for example, is limited to a cDNA isolate having the coding sequence recited in SEQ ID. NO. 1, a specific sequence disclosed in the patent's specification. See Pet. App. 10a-11a.

3. Petitioner's argument amounts to offering claim constructions in a manner inconsistent with Markman

Petitioner's broad view of the claims trivializes expressly-recited claim language and distorts the scope of the claims. Indeed, by ignoring the language of the claims, petitioner ignores claim elements that explicitly limit the claimed DNA molecules to those bearing particular sequences. Moreover, petitioner's approach asks this Court to exercise the claim-construction authority that should be vested in the first instance in a district court under *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996). Petitioner has not litigated these present theories in the lower courts, least of all in a way that complies with *Markman*'s analytical framework. While no one disputes that the claims cover isolated versions of the BRCA genes limited by the sequences identified in the claims by "SEQ. ID" numbers, this Court should reject efforts—no matter how they are disguised—to arrive at other claim constructions like a court of first review.

4. The Court's opinion should not address petitioner's expansive questions

All of these problems demonstrate the limits on deciding cases arising on a scant summary-judgment record. Such a factually under-developed record should dissuade the Court from relying on untested (yet highly contested) factual assertions by petitioner. It also counsels a prudential result—particularly if the Court has any questions about the patent-eligibility of isolated genes. If that is the Court's leaning, then it should exercise restraint and maintain the *status quo* at least until a proper case arises. Indeed, exercising such restraint is all the more appropriate considering that only one petitioner—and one with questionable standing—in reality remains in the case. See Pet. App. 41a; *supra* p. 4 n.2.

D. Recognizing the patent-eligibility of isolated human genes (or other biologics) is wholly consistent with this Court's case law

1. Chakrabarty*'s basic requirements are clearly met*

The claims at issue here satisfy *Chakrabarty*'s carefully enunciated test for patent-eligibility. The claimed isolates are made by man and do not exist in nature. That should be sufficient to resolve the § 101 question. The Federal Circuit, while reaching the correct result, deviated from this analysis, and the Court should correct that error in its opinion.

a. As reflected in *Chakrabarty*, Congress intended patent-eligible subject matter to "'include anything under the sun that is made by man.'" See 447 U.S. at 310 (quoting S. Rep. 82-1979, at 5 (1952); H.R. Rep. 82-1979, at 6 (1952)). To ensure that Congress's intention is fulfilled, the Court adopted a bright-line test for determining whether a composition of matter is patent-eligible: is the composition impermissibly directed to "nature's handiwork" or, instead, properly directed to a "human-made invention," *i.e.*, something created by man and, hence, that has a distinctive name, character, or use? See 447 U.S. at 309-310.[14]

At issue in *Chakrabarty* was the patent-eligibility of bacteria that had been genetically engineered with foreign DNA to be capable of digesting crude oil, a trait the

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[14] This is not to say that every man-made invention always differs *per se* from something that already exists in the prior art, including in nature. See, *e.g.*, the cases cited in nn. 10-11 of the Pet. App. 48a-49a. But it is the province of §§ 102 and 103 of the Patent Act, not § 101, to prevent the issuance of claims that, *although directed to patent-eligible subject matter*, lack novelty or non-obviousness. This case addresses only § 101, and a holding that Myriad's claims satisfy § 101 takes no position as to whether they satisfy any other provision of the Patent Act.

bacteria did not naturally possess. 447 U.S. at 305. This Court found such subject matter patent-eligible because the introduction of the foreign DNA into the bacteria was not a natural event but one brought about by man's handiwork. It was human intervention that gave the bacteria a "distinctive name, character [or] use." *Id.* at 309-310.

b. Although the Federal Circuit reached the correct outcome in this case, it strayed from *Chakrabarty*'s test. It introduced imprecision into the analysis by holding that the isolated versions of the BRCA genes were patent-eligible because they are "markedly different from" their naturally-occurring counterparts present in the body. See Pet. App. 40a, 45a, 50a, 52a.

Under *Chakrabarty*, that approach is unnecessary. Compared to the composition found patent-eligible in *Chakrabarty*, the compositions claimed here are equally distinctive and equally reflect the handiwork of man, not nature. This is evident from the claims' focus on *isolated* DNA molecules. For decades, the term "isolated" (like the term "purified") has been used in patent claims to distinguish isolates from genes as they occur in nature, which are associated with other cellular components such as proteins and other DNA molecules. See Pet. App. 18a-20a. The term "isolated" therefore reflects that, with the aid of human intervention, the claimed DNA molecules are molecules that: (a) are not part of human chromosomes, and, hence, not chemically linked to DNA sequences that naturally flank such molecules in their natural chromosomal environment in human cells; and (b) are freed from other components that co-exist with human genes in a cell.

The patent employs the term "isolated" in a consistent

fashion.[15] Hence, the requirement that the claimed DNA molecules take the form of "isolates" emphasizes their man-made quality and distinguishes them from the human BRCA genes found in nature. That crucial feature, and its distinctiveness, is all that is required under *Chakrabarty* to satisfy § 101.

To the extent the Government and other *amici* urge that patent-eligibility should turn on whether the isolated gene is in a genomic or cDNA form, that analysis is unsound and should be rejected. See U.S. Br. 18-20; Lander *Amicus* Br. 26-29. First, the distinction generally only has meaning with respect to genes found in higher organisms such as humans; lower organisms, such as those of interest to CropLife's members, typically lack introns. Hence, genomic and cDNA versions of the latter genes are essentially indistinguishable from each other in terms of their sequences. Second, the analysis is inconsistent with *Chakrabarty*, which allows *any* distinctiveness—attributable to man's handiwork—to provide a basis for patent-eligibility. Again, an isolated biologic, whether a genomic version or cDNA version of a gene or something else, meets that test: with the benefit of human intervention, the biologic is freed from the materials that its natural counterpart is associated with.

2. No precedent cited by petitioner impairs the patent-eligibility of isolated human genes or other biological isolates

Contrary to the foregoing analysis of *Chakrabarty*'s

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[15] The '282 patent, col. 19, ll. 8-18, defines "an isolated nucleic acid" as one "substantially separated from other cellular components which naturally accompany a native human [nucleic acid] sequence, *e.g.*, ribosomes, polymerases and many other human genome [nucleic acid] sequences and proteins. The term embraces a nucleic acid sequence * * * which has been removed from its naturally-occurring environment, and includes recombinant or cloned DNA isolates." J.A. 755.

core requirements, petitioner argues that claims covering isolated versions of a human gene do not pass muster under *Chakrabarty* and other precedents of this Court as patent-eligible compositions of matter. He asserts that such subject matter fails to satisfy any of the three alternative "tests" purportedly created by these precedents and against which a composition's patent-eligibility should purportedly be judged, namely: (a) does the claimed subject matter have markedly different characteristics from what is found in nature?; (b) is the claimed subject matter based on an inventive concept?; and (c) does the claimed subject matter preempt what nature has provided? See Pet. Br. § I.

But this Court has never held ineligible for patent protection a biologically-based composition of matter. Quite to the contrary, it has recognized the eligibility of such subject matter, finding the bacterial cultures claimed in *Funk* and *Chakrabarty* to be man-made compositions that are different from what occurs in nature. Petitioner has misconstrued these and other precedents and, in turn, has improperly applied them (and the foregoing "tests") to the subject matter now at issue. In fact, many of these decisions focus on entirely different issues and concerns than the question presented here: inventiveness/non-obviousness (*Funk*); what qualifies as an "article of manufacture" (*American Fruit*); and avoiding the preemption of a law of nature (*Mayo*).

a. Funk *solely concerns whether claims lacked "invention,"* i.e., *were "obvious," not whether they are patent-eligible*

The issue in *Funk* was not patent-eligibility but "lack of invention" (or what one might call "lack of inventiveness"). Such a deficiency is synonymous with our modern concept of "obviousness" under 35 U.S.C. § 103.

The claims in *Funk* were directed to combinations of

various strains of bacteria that can be used as "inoculants" to assist any leguminous plant in absorbing nitrogen. *Funk Bros.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 128-129 (1948).[16] The Court readily credited the patentee with making "a new and different composition" compared to what is provided by nature. *Id.* at 130. That is the § 101 inquiry. The Court found, however, that it "fell short of invention"—that is, that what was made was insufficiently inventive.[17] 333 U.S. at 131; see *id.* at 128, 132. *That* examination is wholly unrelated to § 101, which underscores that subject matter, like that in *Funk*, may simultaneously be patent-eligible yet invalid for "obviousness."

Hence, patent-eligibility was not the issue in *Funk*; obviousness was.[18] See also Pet. App. 49a (noting this

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[16] Prior art had taught that individual strains of bacteria could selectively work with a particular species of a leguminous plant and, further, that combining distinct species of bacteria to treat fields containing mixed leguminous crops generally did not work since the various strains tended to inhibit each other's nitrogen-fixing capabilities. *Funk*, 333 U.S. at 129-130. Hence, the patentee's invention was premised on the surprising discovery that certain species of bacteria could be successfully combined to treat any leguminous crop without producing an inhibitory effect on nitrogen-fixation. See *ibid.*

[17] To the Court, the discovery that certain bacterial strains were not mutually inhibitory of one another was nothing more than discovering nature's handiwork, *i.e.*, that nature had conferred compatibility among these bacterial strains for nitrogen-fixing. Relying on that "natural phenomenon" to combine such bacterial strains into prepackaged compositions convenient for sale and application to crops was not considered to be inventive activity on the part of the patentee. 333 U.S. at 131. Because condoning the *validity* of claims to such subject matter was viewed as effectively granting a patent on an *obvious application* of one of nature's heretofore unknown secrets, the Court invalidated the claims. *Id.* at 132.

[18] That the concept of "invention," as *Funk* called it, is synonymous with the modern concept of "non-obviousness," is underscored in the current Patent Act's legislative history. It makes clear that the re-

point). Indeed, the claimed mixtures of bacteria were clearly compositions created by man. Although the individual strains present in those compositions exist in nature, it was man, not nature, who uniquely took them and combined them together.

If *Funk* has any relevance here, it does not aid petitioner. *Funk* simply illustrates that the Patent Act has sufficiently powerful filters to remove claims even if they satisfy § 101's threshold—even those directed to compositions that in some fashion can be said to be based on or derived from what is otherwise found in nature.[19]

b. Petitioner relies on dicta *in* Chakrabarty *distinguishing man's handiwork from nature's—but isolated versions of a human gene respect that distinction*

As petitioner correctly observes, *Chakrabarty* cites *Funk* and notes that the genetically-engineered bacteria Chakrabarty created had "markedly different characteristics from the bacteria found in nature." 447 U.S. 310.

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quirement was a judicially created doctrine, which Congress was codifying for the first time as § 103. See S. Rep. 82-1979, at 4, 6; H.R. Rep. 82-1979, at 5, 7.

[19] Since the jurisprudence on obviousness has evolved since *Funk*, it is unlikely that the same result would be reached today. First, with the enactment of § 103, the concept of "inventiveness/non-obviousness" has been expanded such that patentability "should not be negatived by the manner in which the invention was made"—*e.g.*, drawing on a law of nature, as the patentees in *Funk* had. See 35 U.S.C. § 103(a). Second, subject matter is considered non-obvious under § 103 if it produces a result that could not have been predicted. See *KSR Int'l* v. *Teleflex, Inc.*, 550 U.S. 398, 416-417 (2007). Measured against this yardstick, the patentee in *Funk* went against the grain of conventional wisdom and surprisingly demonstrated that select strains of the bacteria could in fact be combined in a compatible fashion. Compare, *e.g.*, *In re Brimonidine Pat. Litig.*, 643 F.3d 1366, 1376 (Fed. Cir. 2011) (finding the compatibility between two ingredients in an eye-drop formulation to be non-obvious).

But this discussion is descriptive *dicta*, not a new test. It draws on the facts of *Funk*, an obviousness case, as a foil to dramatically illustrate that Chakrabarty's invention reflected man's handiwork, not nature's: genetically-engineering bacteria to possess the novel trait of being able to decompose crude oil necessarily reflected the hand of man, because Chakrabarty's bacteria were unlike any occurring in nature.[20]

Finding isolated versions of a human gene, such as the BRCA genes, patent-eligible respects the "man versus nature" distinction. *Patent-eligibility* for such subject matter *is not* predicated on discovering a heretofore hidden secret of nature, such as these genes' existence, their specific DNA sequences, or their ability to predict a predisposition to cancer. Rather, it is predicated on the fact that isolated versions of these genes, by virtue of man's intervention, are different molecules—different compositions of matter—than what exists in the body.

c. American Fruit *addresses "articles of manufacture," not "compositions of matter"*

The issue before the Court in *American Fruit Growers, Inc.* v. *Brogdex Co.* was whether the claimed subject matter (a citrus fruit, the rind of which was impregnated with borax to be resistant to fungal decay) qualified as an "article of manufacture," which was one of the statutory classes eligible for patent protection under former 35 U.S.C. § 31. See 283 U.S. 1, 11 (1931). The present case,

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[20] Although the patentee in *Funk* could not take credit for the claimed bacteria working in a cooperative fashion when it comes to nitrogen-fixing, the acts of assembling the bacterial strains into "all purpose" compositions reflects human handiwork and is, hence, sufficient for claims directed to the same to be patent-eligible. See *supra* Part D.2.a. Nothing in *Chakrabarty* detracts from that logic and disqualifies such acts as being sufficient to cross § 101's threshold.

of course, involves patent-eligibility for "compositions of matter," an entirely different statutory class of invention.

The *American Fruit Growers* Court resolved the issue before it by consulting Century Dictionary's definition of "manufacture," and, based on that definition, concluded that articles of manufacture, per § 31, required producing materials with "'new forms, qualities, properties, or combinations.'" 283 U.S. at 11. Adding borax to a fruit rind was deemed not to "change the name, appearance, or general character of the" underlying fruit; the claims were thus held not to be directed to an article of manufacture within § 31's meaning.

The Court's analysis was performed solely to inform the inquiry of whether the former could be characterized as an "article of manufacture." That inquiry has nothing to do with this case, and recognizing isolated human genes as patent-eligible does not offend *American Fruit Growers* in the least. That is because isolated genes, being molecules, *i.e.*, "arrangements of atoms," squarely qualify under § 101 as "compositions of matter," a statutory class that is distinct from "articles of manufacture." See, *e.g.*, D.S. Chisum, Chisum On Patents § 1.02[2], p. 1-14 (2012). There is no need to test whether isolated human genes qualify as "articles of manufacture" under *American Fruit*.

Even, assuming *arguendo*, that the presence of a "marked difference" were a proper way to identify patent-eligible subject matter, isolated versions of the human BRCA genes would satisfy that test. Whereas genes as they exist in the human body serve only the function of encoding mRNA and/or proteins, the claimed isolated genes can be put to use for the very important, and life-saving purpose, of diagnosing breast and ovarian cancer. Genes, as they exist in nature, cannot serve this purpose. See Pet. App. 51a-52a, 82a; Resp. Br. 35. Even

petitioner concedes this point. Pet. Br. 34 n.9.[21]

d. Mayo *concerns the patent-eligibility of processes, but isolated versions of a human gene qualify as compositions of matter*

As previously noted, *Mayo* considered whether certain claimed processes were impermissibly directed to a natural law or properly directed to patent-eligible applications of those laws. 132 S. Ct. at 1294. This Court noted that, to be patent-eligible, a claim may only recite a law of nature if it recites "additional features that provide practical assurances that the [claimed] process is more than a drafting exercise designed to monopolize the law of nature itself." *Id.* at 1297. See also *Diamond* v. *Diehr*, 450 U.S. 175 (1981).

In contrast to the claims at issue in *Mayo*, the claims here are directed to DNA molecules, which, again, are compositions of matter. Cf. *supra* Part D.2.c. These claims do *not* recite a "natural law." Thus, there is no need to inquire into whether the claims recite language that ensures that they are directed to a patent-eligible application of a natural law, as opposed to just the law itself. See Pet. App. 44a.

To be sure, claims to a composition of matter can raise concerns parallel to these articulated in *Mayo*, *i.e.*, that product claims may impermissibly preempt natural phenomena. But by virtue of being directed to "isolates,"

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[21] Petitioner tries to negate such utility by noting that an isolate must be labeled, *e.g.*, via "fluorescence," in order to function as a probe. While that may be true, it is a distinction without significance. Such a probe still contains and employs the DNA isolate as a component and, hence, falls within the scope of the claims at issue. Moreover, even if petitioner were to argue that the sequence of the DNA isolate needs to be modified so that the label can be incorporated, that distinction similarly lacks any significance since petitioner has argued that the claims are broad enough to read on isolates with derivitized sequences. See Pet. Br. 13-14.

Myriad's claims exclude human genes as they naturally occur in the human body from their scope. In this respect, the claim limitation "isolated" serves an analogous function as claim elements do in a process claim that ensure that the subject matter being claimed is an application of the law of nature, and not the law itself; it ensures that human genes as they occur in nature are not being preempted. Critically, humans carrying the BRCA genes do not infringe such claims because they are not making, using, or selling *isolated* versions of such genes.[22] See Section D.1.b., *supra*.

Finally, other considerations further caution why *Mayo* should not be extended, as petitioner urges, to resolving whether a composition of matter claim is impermissibly directed to a natural phenomenon. Principally, such an extension would lead to an absurd result that conflicts with *Chakrabarty*. This can be readily appreciated considering the application of petitioner's position to claims directed to genetically-modified seeds and plants—subject matter of keen interest to CropLife's members.[23] If the gene isolate were deemed *per se* patent-ineligible as a natural phenomenon, one would only be left to point to generic language that refers to the seed or plant that bears the gene as conferring patent-eligibility to the claim. The generic concept of creating a seed or plant transformed by a gene could be viewed as

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[22] Petitioner repeatedly highlights that the claims cover any use of the isolated human BRCA genes, insinuating that the claims have an unjustified reach. See, *e.g.*, Pet. Br. 11. What petitioner fails to appreciate, however, is that *any composition claim* entitles the patent-holder to enforce it against *any use* of the subject matter it covers. See, *e.g.*, 35 U.S.C. § 271(a). Accord Pet. App. 58a-59a. Hence, the exclusionary power to which the claims-at-issue are entitled is no different than that conferred under any composition patent.

[23] A sample claim would be: "A seed/plant comprising a DNA molecule having the nucleic acid sequence of SEQ. ID No. X."

implicating "conventional" activity, which, per *Mayo*, is insufficient to take the claim across § 101's threshold.

And yet *Chakrabarty* clearly instructs that this threshold is successfully crossed when a substrate (a bacterium) is transformed with DNA (a plasmid) so as to impart a novel trait to it (oil digestion). As between extending *Mayo's* holding versus preserving the holding in *Chakrabarty*, the latter is the sounder course—especially since petitioner takes no issue with the manner in which *Chakrabarty* was resolved.

CONCLUSION

This Court's precedents regarding patent-eligibility under 35 U.S.C. § 101 have served the country well in advancing science and the useful arts and, if reaffirmed, will continue to do so. This Court should therefore maintain its broad interpretation of § 101 and affirm the Federal Circuit's judgment that the claims at issue in this case are patent-eligible under § 101. Isolated versions of human genes sufficiently reflect man's handiwork—per *Chakrabarty*'s interpretation of what subject matter Congress intended to be patent-eligible—that claims so directed merit the same protections afforded by the law to other new and useful inventions.

Respectfully submitted.

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