No. 12-398

IN THE
Supreme Court of the United States

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 TARGET DISCOVERY, INC. AS *AMICUS CURIAE* IN SUPPORT OF AFFIRMANCE

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*

Target Discovery, Inc. is a diagnostics company that discovers, validates, and uses a new class of biomarkers (protein isoforms) to improve clinical diagnosis and management of disease.[1] Target Discovery's initial product focus is oncology with assays that better guide therapeutic choices and lower the overall costs of cancer treatment.[2] Target Discovery has numerous issued or allowed U.S. patents covering its unique platforms for protein isoform biomarker discovery, validation, and clinical application. All of these technologies are more broadly applicable for discovery biology and life sciences research. Two of these technologies have won industry recognition as seminal breakthroughs in their fields. Target Discovery believes that a strong patent system, including protection for

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[1] In accordance with U.S. Supreme Court Rule 37.6, amicus curiae states that this brief was not authored, in whole or in part, by counsel for a party, and that no party made any monetary contribution to the preparation or submission of this brief other than the amicus curiae or its counsel. After reasonable investigation, Target Discovery, Inc. believes that (i) no member of its Board or Amicus Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation, (ii) no representative of any party to this litigation participated in the authorship of this brief, and (iii) no one other than Target Discovery, Inc., or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

[2] All of the parties have consented to filing of this amicus brief through their counsel. *See* U.S. Supreme Court Rule 37.3(a).

biotechnology inventions, is essential for the development of new diagnostics and therapies.

If the Court is to make major changes in the law, it should not do so based on erroneous facts, irrelevant legal arguments, or controversial policy theories. This case does not justify the radical change advocated by petitioners or the government.

SUMMARY OF ARGUMENT

The isolated DNA molecules claimed by Myriad are not "genes." What is actually claimed are chemical compositions that differ markedly in structure and function from genes as they exist in the human body. 44-45a, 51-53a, 56a ("[I]solated DNA is a tangible, man-made composition of matter defined and distinguished by its objectively discernible chemical structure."); MBr.44-45.[3] They are never produced in nature, but rather exist only when made by humans. Many of petitioners' arguments are irrelevant to whether these novel man-made chemical compounds are eligible for patents under § 101, but are instead based on erroneous scientific and legal assumptions and on controversial policy arguments. Surprisingly, the government's brief also contains errors of law and fact, possibly due to the absence from the brief of the U.S. Patent and Trademark Office ("PTO"), the agency with scientific and patent law expertise.

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[3] Abbreviations: MBr. is Brief for Respondents, PBr. is Brief for Petitioners; GBr is Brief for the United States as Amicus Curiae in Support of Neither Party; JA is Joint Appendix; numbers followed by "a" are pages of Petitioners' Appendix.

Petitioners' proposal that isolated DNA molecules are not eligible for patenting under § 101 would upset settled expectations and invalidate thousands of patents, sending an entire segment of the U.S. economy into uncertainty. 61-62a; 86-89a (Moore, J., concurring); MBr.14-15, 33, 38-39; GBr.29-30. Whether these useful, novel, man-made molecules that never existed in nature are eligible for patenting under § 101 should be decided based on the facts about what is actually claimed, and not on disputed controversial policy arguments.

The government's implication that *all* molecules isolated from biological sources (and not just isolated DNA molecules) are unpatentable under § 101 because they are "products of nature" would overturn the practice of over 100 years. Patenting of isolated chemicals from natural sources has brought enormous benefits by making available valuable compounds that were not before accessible to the public. Elimination of these patents would have a drastic effect on the biotechnology, pharmaceutical, and numerous other industries.

Courts have occasionally mentioned a "products of nature" exception to patent eligibility in dicta, without analyzing it in depth. This case illustrates the difficulty of going beyond simple hypothetical examples to deal with modern technology. A better course would be to view *all* compositions of matter as patent eligible, as stated in the statute: "Whoever invents or discovers *any* new and useful . . . composition of matter . . . may obtain a patent therefor, *subject to the conditions and requirements of this title*." 35 U.S.C. § 101 (emphases added). Thus, while leaves plucked from

trees and kidneys removed from bodies would be patent *eligible* because they are compositions of matter, they would clearly *not be patentable* because they would not satisfy the other "conditions and requirements of this title," namely, the requirements for novelty and nonobviousness." Interpreting the statutory language in this way would also be consistent with the 100-year old practice of granting patents to certain compositions isolated from natural sources, thus making those compositions and their benefits accessible to the public.

Evidence suggests that the Myriad patents have not inhibited research on the *BRCA* genes and are not an impediment to developing methods of whole gene sequencing. If needed, Congress is the appropriate forum and can pass focused legislation to remedy actual problems. Patents, including patents to isolated DNA molecules and other biological molecules, can provide incentives for the development of diagnostics and treatments for cancer and other diseases.

ARGUMENT

I. Petitioners and Government Mix Erroneous Scientific and Legal Arguments

A. Petitioners Misinterpret the Claims

As an initial matter, petitioners' arguments ignore the basic rules of claim construction. This Court has long recognized that "[u]nder the statute, it is the claims of the patent which define the

invention." *Altoona Publix Theatres v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 487 (1935). The validity of each claim must be evaluated independently. *Id.* Furthermore, disclosure in the specification cannot be imported into the claims. *R.R. Co. v. Mellon*, 104 U.S. 112, 118 (1881)("[T]he scope of letters-patent should be limited to the invention covered by the claim, and that though the claim may be illustrated, it cannot be enlarged by the language used in other parts of the specification."); *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908)("[T]he claims measure the invention. They may be explained and illustrated by the description. They cannot be enlarged by it.").

Some of petitioners' arguments ignore these cardinal rules. For example, they assert that "none of the claims is limited to cDNA." P.Br.23. Yet claim 2 of U.S. Patent No. 5,747,282 ("the '282 patent") unambiguously claims a cDNA.[4] JA779 ("MOLECULE TYPE: cDNA"). This error is relevant because the government and all three Federal Circuit judges held that cDNA molecules are eligible for patenting. Petitioners explain that "[b]ecause the patents define the term 'DNA' used in this claim identically to claim 1 to include all versions of the nucleotide sequence (and more), the sequence referenced is solely illustrative." PBr.14. This impermissibly reads terms from the specification into the claim. The claim is not "solely illustrative."

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[4] Claim 2 of the '282 patent reads: "The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:l." JA822.

It precisely defines one specific DNA molecule, a cDNA molecule.

Petitioners also import language from the specification into the claims when they argue that the claims encompass RNA and DNA chemically modified by methylation. PBr.30-31. These elements are absent from the claims. The broad definitions in the patents (JA754-55) are speculations about all the embodiments that Myriad hoped to patent. Indeed, subject matter described in the specification but not claimed is dedicated to the public. *See Miller v. Brass Co.*, 104 U.S. 350, 352 (1881); *McClain v. Ortmayer*, 141 U.S. 419, 423-24 (1891).

B. Human Genes Are Fundamentally Different Than the Claimed Isolated DNA Molecules

Petitioners use the terms "genes" and "isolated DNA" interchangeably. *E.g.*, PBr.9, 19, 44. Using the terms interchangeably confuses the most basic assumption at issue—whether the challenged claims are in fact human genes. The patented claims are directed to isolated DNA sequences that are structurally and functionally distinguishable from their native gene counterparts. The isolated DNA molecules in dispute are not human genes as they exist in the body, and they are more than mere segments of DNA as petitioners contend. *See* PBr.4 n.1. Rather, they are man-made chemical compounds that do not exist in nature. 44-45a, 50-55a. The terms are, therefore, not interchangeable.

According to the government, cDNA[5] claims are patent eligible, whereas the other isolated DNA claims are ineligible because they are allegedly "isolated but otherwise unmodified human DNA." GBr.9. The government thus reasons that the physical changes that occur when isolating human genomic DNA "do not significantly alter the structure or function of the relevant DNA segments." *Id.*

The government implies that the only structural difference between isolated DNA and native DNA is the isolated DNA's "snipped" ends. *Id.* As set forth below, the isolated gene is not simply "snipped" out of its *in vivo* chromosomal context. The government fails to acknowledge that the process required to isolate the *BRCA* genes from the native cellular environment significantly alters the chemical structure, size, and function of the molecules.

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[5] Molecules of cDNA, as the government correctly observes, are "synthesized nucleotide sequences that contain only the exons of a naturally occurring gene." GBr.18. These "artificial DNA molecules" are patent-eligible inventions requiring "significant manipulation and alteration of naturally occurring genetic materials." *Id.* But the chemically isolated DNA macromolecules and fragments are patent eligible for the same reasons.

1. Isolated DNA Molecules Are Structurally and Functionally Distinct from Genes

Isolating a DNA sequence from its native environment does not produce a product that is structurally identical to the precursor but for its lack of association with cellular components. Isolating DNA chemically manipulates it to yield a markedly different structure than its native counterpart. 52a. For instance, the isolated DNA sequence is no longer covalently bonded to adjacent nucleotides in the chromosome. 51a. Breaking the covalent bonds, as is done as a first step in isolating the genomic DNA sequence, converts the genomic DNA molecule into a different chemical entity. The new molecule formed by breaking covalent bonds is structurally and chemically different than the original molecule. It no longer contains at least two phosphodiester bonds, and contains a hydrogen (H) atom and hydroxyl (-OH) group that were not present when it was in its native molecule.

Petitioners would like the Court to discount these basic structural and chemical differences because the native and isolated molecules both function to provide "information content" needed to make a protein. PBr.9. They contend that the isolated DNA molecules' loss of covalent bonds is insufficient to render the molecule markedly different. Judge Lourie, who holds a doctorate in chemistry, found the covalent bonds, which are the "defining boundary between one molecule and another," to be particularly important in

distinguishing isolated DNA as a different chemical molecule from chromosomal DNA. 54-55a.

Petitioners err for two reasons. First, they focus on a single difference between the isolated molecule and the genomic, native DNA instead of acknowledging all of the other differences. 55a. Second, the physiological use or benefit of an isolated DNA sequence, while perhaps relevant to method claims, is *not* relevant to the patent eligibility of *compositions of matter* claims. *Id.* Chemical compositions are claimed by their structure and not by their use.

As it is undisputed that a gene is a "material[] having a chemical nature," *id.*, the proper lens through which to assess patent eligibility under 35 U.S.C. § 101 is a structural analysis. Here, comparing the structure of the isolated DNA molecule to the structure of genomic DNA shows significant differences—at the least, in the lack of two phosphodiester bonds linking nucleotides to one another. There are other structural differences, such as the loss of epigenetic modifications in the isolated molecules. Fragments of DNA such as probes and primers have enormous differences in size compared to a gene. 51a. Thus, isolated DNA molecules are structurally markedly different from their native genomic counterparts.

2. The Process Used to Isolate Genomic DNA Results in a Markedly Different Compound Than That Which Is Found in Nature

Additionally, physically extracting chromosomal DNA from a cell is only the first of many steps in creating the claimed isolated sequences. Once removed from the cell, the extracted chromosomal DNA is used by scientists to create "genomic libraries" or to mechanically amplify the sample to extract the isolated sequence of interest. To create the initial genomic DNA library, scientists cleave the chromosomal DNA into short fragments. The fragments are individually inserted into "vectors" (vehicles used to transfer DNA sequences to a target cell), which are transformed into cells that are grown in culture in the laboratory. As the cells multiply and proliferate, the DNA fragment replicates so that the grown culture contains multiple copies of the DNA fragment. The engineered collection of cells is thus termed a "genomic DNA library," where the short stretches of DNA in the vectors have been produced synthetically via replication. The final step in the isolation process is screening the library and selecting a clone that contains a vector having a sequence of interest. If the DNA sequence of the gene of interest has already been determined, scientists can use more convenient mechanisms, such as polymerase chain

reaction (PCR) amplification,[6] to mechanically synthesize a large number of copies of the molecule of interest. *See* Harvey Lodish et al., Molecular Cell Biology 231-33 (3d ed. 1995); JA749, 7:53-8:4 (describing how *BRCA1* gene was isolated from yeast and bacteria artificial chromosome (YAC and BAC) vectors).

Understanding the process by which genomic DNA is isolated shows that DNA molecules are not just "snipped" loose from a three-dimensional linear stretch of chromosomal DNA, GBr.22, but rather are made by scientists as fragments in the laboratory. Both the creation of genomic libraries and the amplification of a target DNA sequence convert what was a highly structurally complex chromosome into a stretch of DNA lacking structural complexity.

Epigenetic modifications, which "alter the activities and abilities of a cell without directly affecting and mutating the sequence of the DNA" also distinguishes the structure and function of isolated DNA from that of the native molecule. *See* Anders H. Lund & Maarten van Lohuizen, *Epigenetics and Cancer*, 18 Genes & Dev. 2315, 2315 (2004)("Lund"). Examples of epigenetic modification include DNA methylation, histone modification, and noncoding RNAs. *Id.* at 2315–35. Gene expression

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[6] PCR (polymerase chain reaction) amplification is a laboratory technique where a single copy of double-stranded DNA can be used as a template to create a large number of copies of a target sequence. *See* PCR, http://www.ncbi.nlm.nih.gov/projects/genome/probe/doc/TechPCR.shtml (last visited March 14, 2013); JA352-53.

that is controlled by epigenetic modification changes over time and differs from cell to cell within an individual as well as between individuals. Rudolf Jaenisch & Adrian Bird, *Epigentic Regulation of Gene Expression: How the Genome Integrates Intrinsic and Environmental Signals*, 33 Nature Gen. Supp. 245, 250-51 (2003). One common type of epigenetic modification, DNA methylation, results in the modification of cytosine residues in the nucleic acid sequence. Lund at 2315–20. DNA methylation is tightly connected to cancer development, and indeed, *BRCA1* hypermethylation has been observed in breast cancer tumors. *Id.* at 2320; Valgerdur Birgisdottir et al., *Epigenetic Silencing and Deletion of the BRCA1 Gene in Sporadic Breast Cancer,* 8 Breast Cancer Res. 1, 8 (2006), http://breast-cancer-research.com/content/pdf/bcr1522.pdf. Epigenetic modifications of chromosomal DNA are lost when genes are isolated,[7] and as such, genomic DNA in its native environment is structurally and functionally different than isolated genetic sequences.

Petitioners argue that genomic DNA and its isolated counterparts are not "markedly different" in structure or function by suggesting that when isolated DNA is reinserted into the cell, it maintains its previous function. PBr.9, 35. In support,

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[7] Although DNA methylation results in a methyl group covalently bonded to a cytosine and thus would be present in the initial chromosomally extracted DNA, *see* JA644–45, the methylation is lost during the PCR amplification necessary to create synthetic copies of the isolated gene. Yingying Zhang & Albert Jeltsch, *The Application of Next Generation Sequencing in DNA Methylation Analysis*, 1 Genes 85, 87 (2010).

petitioners cite to two "classic experiments" performed 65 and 27 years ago. *Id.* at 35. These experiments, conducted in *Streptococcus Pneumonia* bacteria and mouse fibroblast cells, illustrated that DNA is responsible for passing heritable traits from one generation to the next. JA649–53. It is overreaching, however, to suggest that these experiments show that if isolated human DNA sequences, such as those encoding *BRCA1*, could somehow be reinserted into the genome they would maintain their same function. Indeed, although the *theory* of human gene therapy has been around for decades, problems associated with transient gene expression, unpredictable gene insertion sites, and vector toxicity have rendered the promise of this technique largely unrealized. *See* Matthew Porteus et al., *A Look to Future Directions in Gene Therapy Research for Monogenic Diseases*, 2 PLoS Genet., 1285, 1285 (2006), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1584267/; *Gene Therapy*, Human Genome Project Information, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml (last modified Aug. 24, 2011). In short, for unknown reasons the reinserted DNA does not function in the same manner as the chromosomal gene it was meant to replace.

C. Simple Hypothetical Analogies Fail to Adequately Exemplify the Isolated DNA Molecules

Various hypothetical analogies to isolated DNA molecules appear in the briefs and in the Federal Circuit's opinion. PBr.2, 34, 56-57; GBr.22, 24-25; 59-61a; 102-04a, 107-08a, 109a n.4 (Bryson, J., dissenting); 84a (Moore, J., concurring). These analogies are oversimplified and lack the nuances that demonstrate the "intervention of man that created a new molecule." 82a n.3 (Moore, J., concurring); *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980). They are also not supported by science. *Cf.* Section I.A-B, *supra*. Isolated DNA molecules are not simply removed from their natural environment; the chemical structure of the isolated DNA molecules is not the same as those found in native DNA. These "analogous" separations miss this key feature of patent eligibility for isolated DNA molecules, namely that "isolating" DNA results in a new chemical entity!

These hypothetical examples compare isolated DNA molecules to removing things from their natural environment, such as removing a kidney from a body, snapping a leaf or limb from a tree, or plucking a plant from the ground.[8] PBr.2, 34;

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[8] Petitioners label the bacterial strains in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), as "isolated." PBr.32. While the bacteria were removed from their natural environment, PBr.32-33, they were not isolated analogously to isolated DNA molecules. Nor were they chemically altered like

MBr.55-56; GBr.22-24; 59-61a; 107-08a (Bryson, J., dissenting). Given the man-made nature of isolated DNA and its significant differences from molecules in nature, the better comparison would be, for example, using dissociated kidney or embryonic stem cells, or stem cells from the apical meristem of a plant, to grow *in vitro* isolated parts of the kidney (such as the glomeruli) or guard cells forming the stomata, respectively, that are never found alone in nature. No one familiar with kidney physiology or the components of a leaf would consider the resulting individual parts of the kidney or leaf to be equivalent to the whole.

Analogies comparing isolated DNA to things merely "carved out" or separated with no chemical transformation are flawed. The patentability of a "baseball bat" or "marble slab" is not analogous to isolated DNA. 108a, 109a n.4 (Bryson, J., dissenting); MBr.40-41; 84a & n.4 (Moore, J., concurring). The analogy of panning for gold is fatally simplistic as well. PBr.2, 34; MBr.55-56. While removing gold from a riverbed "isolates" the nugget from its surroundings, the nugget does not transform. And like the gold nugget, cleaning dirt off of a diamond, 104a (Bryson, J., dissenting), does not chemically transform that diamond into a human-made invention

Similarly, comparing isolated DNA to "coal beneath the earth, cotton fibers mixed with cotton

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the bacteria in *Diamond v. Chakrabarty*, 447 U.S. at 305, (or the isolated DNA molecules in this case). *Funk Bros.*, 333 U.S. at 129-30.

seeds, the stigmas of the saffron flower . . . . lithium, boron and barium" is flawed. GBr.24; *see also* 102-04a (Bryson, J., dissenting). Although these natural things are all physically separated to be "useful," they are not chemically transformed into different molecular entities. Isolating DNA molecules, however, does transform genomic DNA into a different molecular entity. The reason why all of these simple examples seem to be clearly unpatentable is not because they are "products of nature." It is because they are facially unpatentable under other provisions of the patent statute.

D. Petitioners Improperly Conflate § 101 Patent Eligibility with the Requirements for Patentability

As the Federal Circuit summarized, "[t]he issue is patent eligibility, not patentability." 43a, 44a ("[O]ther general questions relating to patentability and use of patents are issues not before us."), 62a, 70a. There is a distinct difference between subject matter eligibility, novelty, obviousness, written description, and enablement. For example, this Court stated that novelty "is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter." *Diamond v. Diehr*, 450 U.S. 175, 188-90 (1981); *see also Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1075 (Fed. Cir. 2011), *cert. denied*, 133 S. Ct. 973 (2013)(Rader, C.J., additional views)(noting that "[m]any litigation-spawned applications of section

101" improperly focus on "a question of patentability depending on prior art and adequate disclosure"). The substantive *requirements* for patentability under §§ 102, 103, and 112 apply only to inventions that have passed the antecedent question of § 101 patent *eligibility*. *See Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010).

The Federal Circuit explained that certain Supreme Court decisions are based on a "lack of novelty, not patent-eligible subject matter," 48a n.10, identifying *American Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. 566, 596 (1874), and *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884). Petitioners rely on these cases in arguing the patent ineligibility of Myriad's claims. PBr.39, 51-52.

Petitioners, and in certain instances the government, continue to conflate novelty with subject-matter eligibility. They argue that the claims are ineligible for patentability because Myriad "did not invent" the subject matter of the claims. PBr.37-39 (discussing "inventive concept"). In so doing, however, they rely on cases concerning novelty, where the claims covered prior art compositions of matter.[9]

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[9] Reliance on early case law highlights the nuances between § 101 and the conditions for patentability, in part because separate standards for assessing patents did not exist until the 1952 Patent Act. *See generally* MBr.23-25 (describing *Funk Bros.*, 333 U.S. 127, as an obviousness—not § 101—case); *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 14-15 (1966)(describing the 1952 Act).

For example, certain pre-1952 cases were cited where claims for "substantially pure tungsten having ductility and high tensile strength," and for ductile vanadium were respectively found invalid and not allowed. PBr.38-39; GBr.25. The purified metals existed in the art and the claims covered only natural and inherent characteristics of those known metals. *See Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 642-43 (3d Cir. 1928); *In re Marden*, 47 F.2d 958, 958-59 (C.C.P.A. 1931)("Vanadium . . . has been known to exist by metallurgists for more than a century."). Those cases rested not on lack of patent eligibility but rather on the lack of novelty of the claimed subject matter assessed against the prior art.[10] Similarly, in *In re Merz*, 97 F.2d 599, 600-01 (C.C.P.A. 1938), the compound ultramarine was well known in the prior art, which rendered "artificial ultramarine" unpatentable. PBr.39. Petitioners also rely on *Ex parte Latimer*, 1889 Dec. Comm'r Pat. 123, 126, where a claim to fibers extracted from pine needles was rejected because "[t]here is no chemical combination . . .by which the fiber becomes something new or different from the fiber in its natural state." In that case too, the claimed characteristics were known in the art and lacked any new or useful property. *Id.*

Not only do petitioners conflate inventive concept and novelty, but they also maintain improper arguments about the breadth and scope of

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[10] *See also* Kevin Noonan, *An Antidote to the Politics of the Human Gene Patenting Debate*, SCOTUSBlog (Feb. 6, 2013) http://www.scotusblog.com/2013/02/an-antidote-to-the-politics-of-the-human-gene-patenting-debate.

the claims' reach under § 101—arguments properly reserved for a § 112 or claim construction analysis. *See* 60a; PBr.31, 40. In arguing that Myriad's claims are not patent eligible, petitioners proffer preemption arguments resembling enablement arguments. They argue that "[a]ll of the claims reach all uses of the genes in DNA, cDNA, or RNA form and all variants and fragments of the genes, including future uses not yet identified or technically achievable." PBr.41. But they cite *O'Reilly v. Morse*, 56 U.S. 62 (1853), a case concerning § 112 written description. *Morse* explains that a patentee "can lawfully claim only what he has invented and described, and if he claims more his patent is void." *Id.* at 121; *see Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1359 (Fed. Cir. 2010)(Newman, J., additional views)(citing *Morse* as concerning adequate disclosure under § 112).

In relying on cases that do not distinguish between patent eligibility and patentability, petitioners confuse § 101 with other legal theories that have not been asserted and are not at issue in this case.[11]

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[11] Petitioners also rely on *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931), asserting that this Court rejected the patenting of an orange coated with borax. PBr.29 (citing *id.* at 11-12). But the issue in that case was whether the borax-coated oranges fit within one category of patent eligible subject matter, an article of manufacture, and not whether they were "products of nature." There, the process claims were reversed as anticipated by an earlier patent. *Am. Fruit Growers*, 283 U.S. at 11-14; *see also* GBr.20 n.6 (citing *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985)(rejecting claims as anticipated under § 102)).

II. A Better Approach: Consider All Compositions of Matter Eligible for Patenting, and Apply the Statutory Requirements of Patentability

This case illustrates the great difficulty of applying a "products of nature" standard to the eligibility for patenting of compositions of matter. The uncertainty is illustrated by the different conclusions reached by the parties and judges, by the tendency to conflate patent eligibility and patentability, and by the inadequacy of simple examples. As Justice Frankfurter wisely observed: "It only confuses the issue, however, to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation." *Funk Bros.*, 333 U.S. at 134-35 (concurring).

A better course would be to view *all* compositions of matter as eligible for patenting. This is consistent with the language of the statute: "Whoever invents or discovers *any* new and useful . . . composition of matter . . . may obtain a patent therefor, *subject to the conditions and requirements of this title*." 35 U.S.C. § 101 (emphases added). The narrow judicial exceptions to patent eligibility (laws of nature, abstract ideas, natural phenomena) do not fall in the patent eligible categories of § 101, but compositions of matter do.

Although they are compositions of matter, the simplest hypothetical examples discussed in the briefs (leaf from a tree, kidney removed from the body, etc.) would undoubtedly be unpatentable as

clearly lacking novelty and as obvious (35 U.S.C. §§ 102 and 103). A plant in the forest, gold in a stream, and electrons would all be anticipated under 35 U.S.C. § 102 based on their prior existence. While modestly modified by man, a leaf snapped from a tree or a kidney removed from the body would be anticipated and also invalid as obvious under 35 U.S.C. § 103.[12] Isolated DNA molecules should be patent eligible since they are compositions of matter and they do not fall within the three patent-ineligible exceptions—laws of nature, abstract ideas, natural phenomena. The patent law, however, would prohibit a claim to an isolated DNA molecule that was not novel, was obvious, or lacked sufficient support. Thus, there is no reason to fear improper patents preempting compositions of matter in the public domain. Instead, patents on compositions of matter would receive a sophisticated analysis of validity in the PTO and courts, instead of an uncertain and somewhat subjective "product of nature" rejection.

This analysis would also rationalize the 100-year old practice of granting patents to certain compositions isolated from natural sources, thus making those compositions and their benefits accessible to the public. Patenting of those molecules can be evaluated with the same approach

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[12] One requirement of § 101 does impact validity as opposed to patent eligibility, the requirement of utility. *Brenner v. Manson*, 383 U.S. 519, 530-36 (1966). Among other things, many isolated DNA molecules would be unpatentable for lack of a known use. 2001 PTO Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001).

as the well-developed patent law regarding inherency. "The fact that a version of the invention may have previously existed, unrecognized, unavailable, and unappreciated, should be irrelevant to patentability under either novelty or subject matter. The proper question is: did the inventor make available to humankind something we didn't have available before?" Dan L. Burk, *Anticipating Patentable Subject Matter*, 65 Stan. L. Rev. 109, 114 (2013); Dan L. Burk & Mark A. Lemley, *Inherency*, 47 Wm. & Mary L. Rev. 371 (2005).

III. Patent Eligibility Should Not Be Decided on Controversial Theories About Potential Effects of Myriad's Claims

A. Contrary to Petitioners' Assertions, the Claims in Myriad's Patents Do Not Preempt Use of the *BRCA* Genes

The Myriad patents do not preempt research using the *BRCA* genes. Any potential preemption is limited as the seven challenged patents expire prior to December 19, 2015. 58a. The Federal Circuit correctly recognized that any preemption is "very limited in the case of the present patents" and that "a limited preemption is inherent in every patent" by virtue of the right to exclude. 58-59a; *see also* GBr.17 ("This inquiry into preemptive effect is not an exclusive test of the patent-eligibility of a product."); MBr.46 ("'[P]reemption' is not a test for patent-eligibility.").

Petitioners allege that Myriad's patents foreclose any opportunity for researchers to use the native *BRCA* genomic sequence, preventing and deterring research. PBr.3, 43. The *BRCA* genes are only covered broadly because of Myriad's numerous claims in its portfolio. To properly assess this allegation and determine if the claims are invalid, Myriad's patent claims must be analyzed on a claim-by-claim basis. *See Altoona*, 294 U.S. at 487 ("[I]t is the claims of the patent which define the invention. . . . And each claim must stand or fall, as itself sufficiently defining invention, independently of the others."). However, without the benefit of claim construction and a claim-by-claim analysis for invalidity, petitioners' allegation cannot be resolved.

Despite the lack of claim construction in this matter, it is possible to observe that Myriad's patents do not prevent researchers from using *BRCA* genes. Since 2000, over 8,000 articles have been published reciting *BRCA1*,[13] with a spike in the publications occurring in 2012.[14] This large volume of work reflects researchers' perception that the *BRCA1* gene is accessible for research. This

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[13] Results from the search run in PubMed for "BRCA1" on March 10, 2013. NCBI PubMed, http://www.ncbi.nlm.nih.gov/pubmed (last visited March 10, 2013).

[14] Nearly all of the challenged Myriad patents issued during 1997 or 1998 except for U.S. Patent No. 6,033,857, which issued in May of 2000. Excluding the years 1998 and 1999 from the search, a PubMed search returned 8057 articles. Including 1998 and 1999, the PubMed search returned 8804 articles. 2012 has the highest number of articles regarding *BRCA1*, with 869 articles available on PubMed.

perception is shared not only by university researchers, but also by representatives of biotechnology and pharmaceutical firms.[15] *See* John P. Walsh, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in Patents in the Knowledge-Based Economy 285, 287 (Wesley M. Cohen & Stephen A. Merrill, eds., 2003)("Walsh").

Researchers were once concerned that a patent to an isolated DNA molecule would grant rights to the whole native gene or encoded protein on the patent owner, which would block access to these genomic research tools. *Id.* at 299. Both in theory and in practice, however, researchers now appreciate that isolated DNA molecule patents grant only limited rights to isolated DNA molecules; limited to the exact isolated DNA sequence that is claimed. *Id.* Likewise, biotechnology and pharmaceutical firms have not become lost in the patent thicket of isolated DNA molecule patents. [16] *Id.* at 298; *see generally* Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 Nat. Biotechnol. 1091, 1091-93 (2006). In fact, a survey reported that many patent-holding firms embrace university researchers working on the patented invention so long as the work is non-commercial. Walsh at 317. University researchers

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[15] The cited study reports the results of interviews with 70 individuals "at biotechnology and pharmaceutical firms and universities in considering the effects of research tool patents on industrial or academic biomedical research." Walsh at 287.

[16] *See id*. at 298 ("One biotechnology executive stated: 'I am hard pressed to think of a piece of research that we haven't done because of blocked access to a research tool.'").

benefit the patent owners by exploring the patented invention to develop increased understanding of the invention. *Id.* Even on the reportedly rare occasion that a patent owner sends a cease and desist letter to a university, the university appears to remain unencumbered by the threat. *Id.* at 317-18.

For at least the wide-spread use of *BRCA1* in research reflected in the understanding of the scientific community, the Court should not hold that Myriad's patents preempt the native DNA of the claimed isolated DNA molecules. The Court should not decide this controversial issue of gene patent validity on nearly expired and unconventional patents.

B. The Broad Claims in the Myriad Patents Are Not Representative of Modern Claims to Isolated Genomic Molecules

In the late 1990s when applications for the Myriad patents were filed, the study of the human genome was still developing as a new area of technology. In 2003, the Human Genome Project completed its goal of identifying all genes in human genomic DNA, and it was not until this accomplishment that the scientific community appreciated the volume of redundancy in the human genome. John Aach et al., *Computational Comparison of Two Draft Sequences of the Human Genome*, 409 Nature 856, 856 (2001). Accordingly, and in light of this lack of appreciation, claims to isolated DNA molecules filed before 2003 are likely overbroad.

After 2003 and the publication of the human genome sequence, researchers could draft their claims in light of the redundancies in the genetic code to more succinctly describe the invention. Instead of drafting claims to isolated DNA molecules themselves, patents frequently claim only cDNA.[17] Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. Rev. 563, 595 (2012)("Holman I"). The PTO became more experienced with examining claims to isolated DNA molecules because the human genome sequence was available as prior art. Lori Pressman, *DNA Patent Licensing Under Two Policy Frameworks: Implications for Patient Access to Clinical Diagnostic Genomic Tests and Licensing Practice in the Not-for-Profit Sector*, 6 Life Sci. L. & Industry Rep. (BNA) No. 6, at 329, 331 (Mar. 23, 2012). This ultimately led to the PTO issuing better claims to isolated DNA molecules.[18] Indeed, a study observes that DNA sequences available in GenBank

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[17] *See* Holman I, at 595 ("Most of these patents appear to have been filed based on the discovery of a protein-encoded cDNA, and with the intent of protecting the use of the cDNA in the recombinant production of the encoded protein, not as a subject of genetic testing.").

[18] "The announcement of a working draft of the human genome in 2001, and the completed sequence in 2003, is particularity critical in the context of WGS [whole genome sequence], because it strongly suggests that any patent filed since then cannot be both valid and infringed by WGS, at least by the conventional methodologies used in the initial sequencing of the human genome." Christopher M. Holman, *Debunking the Myth that Whole-Genome Sequencing Infringes Thousands of Gene Patents*, 30 Nature Biotechnol. 240, 242 (2012).

prior to the filing date of Myriad's patents might anticipate or render the claims obvious. Thomas B. Kepler, *Metastasizing Patent Claims on* BRCA1, 95 Genomics 312, 314 (2010). A broad reading of the claims might also implicate invalidity under 35 U.S.C. § 112. Holman I at 581.

C. Claims to Isolated DNA Molecules Do Not Preempt Genomic Sequencing

Patents to isolated DNA molecules do not prevent researchers from sequencing the human genome. For a method of DNA sequencing to infringe a claim to isolated DNA molecules, the method must use or make the isolated DNA molecule exactly as claimed. Christopher M. Holman, *Debunking the Myth that Whole-Genome Sequencing Infringes Thousands of Gene Patents*, 30 Nature Biotechnol. 240, 240 (2012)("Holman II"). Any partial sequences that contain some of the same nucleotide sequence as the isolated DNA molecule cannot infringe claims requiring a larger sequence. The traditional methods of sequencing a gene do not infringe the isolated DNA molecule patents. Using either traditional methods of sequencing or newer genome sequencing technologies, a claim to isolated DNA molecules will rarely be infringed. PBr.7, 41-45; Holman II at 242-43.

Unlike the traditional methods of DNA sequencing, the next generation of genomic sequencing is unlikely to infringe isolated DNA molecule claims. These new sequencing technologies are faster and more likely to be used in the context of personalized medicine than traditional sequencing

methods. *See* W. Nicholson Price, II, *Unblocked Future: Why Gene Patents Won't Hinder Whole Genome Sequencing and Personalized Medicine*, 33 Cardozo L. Rev. 1601, 1606, 1624 (2012)("Price"); Holman I at 579-80. *See generally* Jonas Korlach et al., *Real-Time DNA Sequencing from Single Polymerase Molecules*, 472 Methods Enzymol. 431 (2010). Thus the Myriad claims do not prevent research of the whole genome or even the *BRCA* genes.

IV. Other Molecules from Biological Sources Should Not Be Unpatentable as "Products of Nature"

A. Isolated Biological Molecules Are Patentable

Isolated molecules from natural sources require human intervention even when the molecules are not changed chemically. The utility of the isolated or purified molecules can differ substantially from the molecules in nature. The patenting of isolated or purified molecules has been accepted for 100 years, and has contributed to the progress of medicine, biotechnology, and other fields. Patenting has not deprived the public of the use of those molecules, but instead has provided the commercial incentive to discover and make them available.

Patenting molecules from natural sources has a long history. 52-53a. In a leading case, *Parke-Davis & Co. v. H.K. Mulford Co.*, Judge Learned

Hand found that purification of adrenaline resulted in the same molecule that existed in the body, but the purified adrenaline was "for every practical purpose a new thing commercially and therapeutically." 189 F. 95, 103 (S.D.N.Y. 1911); *see also Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 161-64 (4th Cir. 1958)(purified composition of vitamin B-12 was patentable because the purification process resulted in a product that was therapeutically effective, whereas the natural form was not).

Prostaglandins, compounds important in major disease processes, are present in the body only in minute quantities. The patenting of pure prostaglandins, *In re Bergstrom*, 427 F.2d 1394, 1394 (C.C.P.A. 1970), made them available to researchers leading to progress in the understanding and treatment of many diseases, such as rheumatoid arthritis. *See, e.g.*, Sune Bergdtrom, Nobel Prize Lecture: The Prostaglandins: From the Laboratory to the Clinic (Dec. 8, 1982), *available at*: http://www.nobelprize.org/nobel_prizes/medicine/laureates/1982/bergstrom-lecture.pdf. Similarly, purified vitamin B-12, a natural product, was held to be patentable. *Merck*, 253 F.2d at 156. The court explained that purified vitamin B-12 was "far from the premise of the [naturally occurring] principle. . . . The new product, not just the method, had such advantageous characteristics as to replace the [naturally occurring] liver products. What was produced was, in no sense, an old product." *Id.* at 162-63; 77a.

Isolation gave these biological compounds important new uses. These were not "part of the

storehouse of knowledge of all men . . . free to all men." *Funk Bros.*, 333 U.S. at 130. No one had access to these valuable molecules until the inventors' ingenuity provided them. If a molecule never existed in nature in a pure or isolated form, then the pure molecule is "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" *Chakrabarty*, 447 U.S. at 309-10.

Accepting the government's view broadly, *see* GBr.24-26, would deprive patent protection needed for development of the next antibiotic, the next useful industrial enzyme from a bacterium, and myriad other useful chemicals. It would vastly reduce the financial viability of developing new therapies and decimate a growing sector of the United States workforce.

B. Congress Determines the Appropriate Scope of Patent Subject Matter Eligibility Under § 101

Notwithstanding the unique social implications of the current case, absent any clear and certain signal from Congress, this Court should not disrupt the widely accepted application of the patent laws and § 101.[19] *See* 61-62a; *see Deepsouth*

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[19] A reversal by this Court would upset the current practice of the lower courts, the PTO, and the biotechnology industry. Such a reversal would also place U.S. common law in dissonance with international standards. *See, e.g.*, EU Directive 98/44/EC (implemented by the European Patent

Packing Co. v. Laitram Corp., 406 U.S. 518, 531 (1972); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997). It is not up to the judiciary to narrow the "wide scope" Congress envisioned for § 101 or upset the long-standing practice of the PTO, which has "specific expertise in issues of patent law," and is charged with the task of examining and issuing patents. *Bilski*, 130 S. Ct. at 3225 (quoting *Chakrabarty*, 447 U.S. at 308); *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145 (2001); *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2242 (2011). Rather, Congress, beholden and answerable to the public, is best equipped to balance the policy considerations here at issue. *See Charkrabarty*, 447 U.S. at 303, 309, 317-18; PBr.54-55 ("It is not for the Court to balance policy considerations . . . ."). "Given the complicated technology and conflicting incentives at issue here, any change must come from Congress." *See* 94a (Moore, J., concurring), 57a.

Congress has recognized the significance and uniqueness of DNA-based patents.[20] It has often

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Convention and indicating that a nucleic acid corresponding to a gene may constitute a patentable invention if isolated from the human body or otherwise synthesized); *Cancer Voices Australia & Anor (ABN 93 322 703 42y) v Myriad Genetics Inc. & Ors.* [2013] NSD 643 (Austl.), *available at* http://www.austlii.edu.au/au/cases/cth/FCA/2013/65.html. (affirming the Australian court's position that isolated genetic material is patentable subject matter).

[20] *See* 92-94a (Moore, J., concurring)(indicating Congress has "explicitly declined to implement legislation to 'affect any of those current existing patents [on human genes]'" and that "it

provided special carve-outs to balance the public interest involving DNA-based inventions. The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), for example, carved out an exception to the safe harbor for inventions "primarily manufactured using recombinant DNA, [or] recombinant RNA," and set special conditions for the patent extension of an application for a product primarily using recombinant DNA technology. *See* 35 U.S.C. §§ 271(e)(1); 156(a)(5)(B). Section 271(g) established a specific cause of action for infringement where a foreign manufacturer uses a patented "process of preparing a DNA molecule comprising a specific genetic sequence," uses the DNA to make an unpatented protein outside the United States, and then sells the protein in the United States. *See Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1561 (Fed. Cir. 1996)(citing the Senate Report for the Process Patent Amendments Act of 1988). And more recently Congress created an abbreviated approval pathway for biologic products that are "biosimilar" to approved reference products, i.e. derived by recombinant DNA or controlled gene expression methods. *See* Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001–7003.

As a further example, Congress considered DNA-related inventions when it addressed surgical method patents. *See* 35 U.S.C. § 287(c). The bill originally sought to preclude certain surgical

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appears Congress also believes DNA is patentable")(citing the Congressional Record).

procedures from patentability. *See* Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. Pat. & Trademark Off. Soc'y 789, 789-801 (1996). As amended and enacted, however, the law balanced the interests of health care practitioners, the biotech industry, and the PTO. While the law ultimately limited infringement liability, it did not change patentability standards. In fact, Congressman Ganske reassured the PTO and industry groups that under the amendment, "[a]ll presently patentable new drugs will remain patentable," and clarified that the law "does not prohibit patents on gene therapy or other similar procedures." 104 Cong. Rec. H8277 (daily ed. July 24, 1996).

Contrary to the assertions of petitioners and the government, Congress is aware of this case, and is already addressing certain issues raised in this appeal. *Compare* 57a, *with* PBr.55, *and* GBr.28-29. Congress recently directed the PTO to "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," which directly responds to the "second opinion issue" raised by petitioners. PBr.8, 45. *See* Leahy-Smith America Invents Act ("AIA"), Pub. L. 112-29, 125 Stat. 338-39 at § 27 (Sept. 16, 2011).[21] The study is currently

[21] In the original amendment to the Bill, Representative Deborah Wasserman Schultz (D-FL), a breast cancer survivor, proposed a safe harbor for patent infringement for providers of second opinion genetic testing. *See* 157 Cong. Rec. H4433 (daily ed. June 22, 2011).

ongoing. In August 2012, after multiple public hearings and period for public comment, the Department of Commerce indicated "*the complexity and diversity of the opinions, comments and suggestions provided by interested parties, and the important policy considerations involved*," necessitated further review, discussion, and analysis before a final report could be submitted to Congress. *See* 77 Fed. Reg. 71,171 (Nov. 29, 2012)(emphasis added).

Accordingly, the PTO and Congress together are currently assessing at least one of the issues petitioners raise.[22] This Court, therefore, should not divest their efforts to assess these complex patent issues that implicate conflicting policies and diverse interests. *See Gottschalk v. Benson*, 409 U.S. 63, 72-73 (1972)(indicating § 101 raises issues that "only committees of Congress can manage, for broad powers of investigation are needed, including hearings which canvass the wide variety of views which those operating in this field entertain"); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1305 (2012)("[W]e must hesitate before departing from established general legal rules lest a

[22] Notably in § 33 of the AIA, Congress also addressed 35 U.S.C. § 101, demarcating a line for what constitutes patentable subject matter vis-à-vis a human being: "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism." During debates over the provision, Congress specifically considered the application of § 33 to DNA-based inventions. *See* 157 Cong. Rec. E1177–80 (daily ed. June 23, 2011)(Rep. Lamar Smith)(listing the types of subject matter § 33 does not apply to).

new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary.").

C. The PTO Position Is Legally Correct

It has been argued that that the PTO position has "been substantially undermined by the position the government has taken in this case." 118a; *see also* GBr.26-30; PBr.53-55. It is problematic, however, that the government agency with greatest scientific and patent law expertise, the PTO, did not participate in the briefing. The government theory on this important patent question was apparently developed with no public comment. This raises doubts as to the degree of deference that should be given to the "government position," especially in view of the apparent scientific and legal errors in the government's brief. *See* Section I, *supra.*

Although petitioners and the government argue that the Court is not *bound legally* by the earlier PTO position, the PTO is the agency with great expertise in science and patent law, and as such deserves—and often receives—great deference on issues of policy through judicial notice. While the MPEP and Examiner Guidelines "are not binding on this [C]ourt," they "may be given judicial notice to the extent they do not conflict with the statute." *In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005)(citations omitted); *see also* 117a (Bryson, J., dissenting). The PTO position that isolated DNA molecules are patent eligible should be adopted because it is based on a correct interpretation of the

law, and because those policies have succeeded in fostering growth of the pharmaceutical and biological industries. The biologics industry has, from humble beginnings, grown to a $52 billion industry, with the addition of recombinant technology. John R. Thomas, Cong. Research Serv., RL33901, Follow-On Biologics: Intellectual Property and Innovation Issues 1 (2009).

As Judge Moore correctly observed:

> [P]urifying or isolating natural products has historically been exactly the kind of discovery protected by the patent statutes. There is a century-long history of affirming patent protection for isolated and purified biological products ranging from hormones to vitamins to proteins to antibiotics. These inventions must have seemed miraculous at the time, providing previously unknown therapeutic options to treat sickness. The fact that these molecules might have existed in nature did not foreclose patent protection in view of the extraordinary benefits accessible to man after isolation.

94-95a (concurring). The Court should not "destroy long settled industry expectations for no reason other than a gut feeling that DNA is too close to nature to be patentable, an arbitrary decision based on a judge-made exception." 95a.

CONCLUSION

Petitioners seek radical changes in the law for the patenting of biotechnology inventions, based on unique circumstances, erroneous scientific assumptions, and irrelevant legal arguments. Some allegations of the consequences of Myriad's claims are controversial and unproven. The government's attempt at a compromise by excluding patents on all natural molecules would have even broader deleterious effects to the development of biotechnology, medicine, and many other fields.

Developing better diagnostics and treatments could be harmed if patenting of molecules found in nature or man-made molecules related to them (such as isolated DNA) is prohibited based on flawed factual and legal premises.

Respectfully submitted,

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