No. 12-398

IN THE
Supreme Court of the United States

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

v.

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

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

BRIEF FOR THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF AFFIRMANCE BUT IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*

The American Intellectual Property Law Association ("AIPLA") submits this brief as amicus curiae in support of affirmance (but in support of neither party on the ultimate merits of the case), in order to present its views on the correct rule of law that applies to patent eligibility.[1] AIPLA is a national bar association of approximately 14,000 members engaged in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. AIPLA members represent both owners and users of intellectual property, thus representing the interests of both plaintiffs and defendants in IP litigation. AIPLA has no stake in any of the parties to this litigation or in the result of

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[1] In accordance with Supreme Court Rule 37.6, amicus curiae states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the amicus curiae or its counsel. After reasonable investigation, AIPLA 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 AIPLA, 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.

this case other than its interest in the issue of patent-eligible subject matter, which is vital to most, if not all, of AIPLA's members.[2]

SUMMARY OF ARGUMENT

The question presented is: "Are human genes patentable?" This question, however, does not capture the issues in this appeal.

Myriad's patents do not claim "human genes" as they exist in the body. Rather, the claims cover "isolated" DNA molecules—man-made, discrete chemical entities that differ markedly from genes as they exist in the human body. Those inventions, not any human genes, are the proper focus of the section 101 analysis required in this appeal. Genes in their native form, as part of human chromosomes, build and maintain cells. Myriad's isolated DNA molecules do not and cannot perform the functions of native genes. Rather, they can serve as functional biological tools that allow health care practitioners to identify individuals at significant risk of breast and ovarian cancer, to tailor existing treatment options for highest likelihood of therapeutic success, and to develop new anti-cancer treatments specifically designed to combat these devastating diseases.

These differences distinguish the claimed isolated DNA molecules from patent-ineligible

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[2] In accordance with Supreme Court Rule 37.3(a), the parties have consented to the filing of this amicus brief in support of neither party. The consents are submitted herewith.

"products of nature" under this Court's prior decisions in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), and *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931). Each of those cases focused the patent eligibility inquiry on whether the claimed subject matter had markedly different characteristics compared to nature's handiwork, as well as on the subject matter's potential for significant utility. Applying those standards, the Federal Circuit correctly held that the claimed isolated DNA molecules passed muster under section 101. *See* Pet. App. 2a-119a.

To be sure, "human genes" as they exist in the body are not "patent eligible" under 35 U.S.C. § 101; they also are not patentable under other provisions of patent law. For instance, human genes are not "new" and therefore a claim to a human gene would be anticipated by naturally occurring human genes in contravention of 35 U.S.C. § 102. "Patentability," however is not at issue in this case. "Patentability" refers to compliance with all statutory provisions that govern whether a patent is valid and enforceable, including those directed to, *inter alia*, obviousness, anticipation, enablement, and written description. The focus of this appeal is solely on 35 U.S.C. § 101, the gatekeeper provision that determines what subject matter is ***eligible*** for patent protection.

This Court's recent ruling in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* does not require reversal of the Federal Circuit's decision. In *Prometheus*, a law of nature—namely,

the relationship between certain levels of a drug metabolite and its safety and efficacy—was deemed central to the method claim at issue. 566 U.S. __, 132 S.Ct. 1289, 1294 (2012). This Court therefore looked to its precedents involving methods that implicate laws of nature and abstract ideas, including *Parker v. Flook*, 437 U.S. 584 (1978), and *Diamond v. Diehr*, 450 U.S. 175 (1981). Applying a test discerned from those cases, the Court examined Prometheus's method claims to determine whether they "do significantly more than simply describe [the] natural relations" at the heart of those claims. *Prometheus*, 132 S.Ct. at 1297.

Prometheus did not overrule any of the cases, including *Chakrabarty*, that the Federal Circuit relied upon to find that Myriad's isolated DNA products fall within the scope of section 101. Nor did *Prometheus* introduce a new test for patent eligibility that would conflate section 101 with sections 102, 103, and/or 112—they are separate. The test set forth in *Chakrabarty* and applied by the Federal Circuit properly governs the section 101 inquiry with respect to Myriad's claims to isolated DNA molecules. *See* Pet. App. 48a-52a.

Among the misleading charges made by those who would exclude this subject matter for patent protection is the contention that scientists and researchers would be barred from examining and experimenting with the claimed material. This contention, however, fails to recognize the long-standing experimental use exception that immunizes non-commercial research with patented material; it also fails to recognize the statutory provision

permitting uses of patent inventions for conducting clinical testing necessary for obtaining FDA approval. 35 U.S.C. § 271(e)(1).

In sum, discrete, man-made chemical entities that serve as important medical tools are exactly the type of invention that the patent laws and their underlying policies are designed to incentivize and protect. Those policies are, as they should be, blind to the raw materials from which significant technological advances spring. Indeed, the USPTO, the courts, and Congress have recognized that inventions derived from naturally occurring substances but imbued with different characteristics and uses constitute protectable "compositions of matter" or "manufactures" under section 101. To reverse course and now deem the claimed isolated DNA molecules ineligible for patent protection without an express directive from Congress would disrupt not only well settled law but also the expectations of patent owners and inventors.

ARGUMENT

I. MYRIAD'S CLAIMED DNA MOLECULES ARE NOT PRODUCTS OF NATURE

An analysis under section 101 must start with an understanding of what is—and what is not—claimed. *See In re Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008), *aff'd*, 130 S. Ct. 3218 (2010)("[c]laim construction … is an important first step in a § 101 analysis"). By way of example, claim 1 of U.S. Patent No. 5,747,282 ("the '282 Patent") states:

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

2J.A. 822, '282 Patent at col. 153, ll. 55-58. SEQ ID NO:2 sets forth the amino acid sequence of the BRCA1 protein. Pet. App. 10a-11a. Claim 1 does not recite the phrase "human gene." Nor does it cover "human genes," which are integral portions of the intact, native human genome. It does, however, recite "DNA," albeit in "isolated" form.

A. Human DNA Is Complex in Both Structure and Function

DNA refers to a large class of compounds all sharing a common chemical backbone.[3] Pet. App. 14a. Each DNA molecule has chemical components called nucleotides, or nucleotide bases, which are referred to for ease of reference as A, T, C, and G. Pet. App. 14a. The term "DNA," as it refers broadly to a chemical class, encompasses both native, genomic DNAs (as found in the body) as well as DNAs that are wholly designed and synthesized by man. Pet. App. 18a-20a.

In the human body, the entire genome consists of twenty-three pairs of chromosomes, each of which is a complex structure comprising a single DNA molecule wrapped around proteins called

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[3] The Federal Circuit has provided an excellent summary of the technology involved in this case. We address certain pertinent points here.

histones. Pet. App. 18a-19a. Native chromosomes have at least 80 million nucleotides. Pet. App. 51a. The order of the nucleotide bases in a DNA molecule is called the "sequence," but what the "sequence" actually represents is the precise configuration of the component chemical nucleotides that make up a single, large chemical compound.

Each native DNA molecule consists of a long chemical chain of millions of nucleotide base pairs, and different portions of the DNA have different functions. Certain regions of the DNA chain are known as "genes" and hold the genetic code for the various proteins required to sustain life. Pet. App. 257a-259a. The human genome comprises a vast number of such genes along with other sequences, or portions of the DNA molecule interspersed. *See* Pet. App. 18a-19a; Pet. App. 259a ("25,000 genes in the human body make up the human genome."). A human gene, from a structural perspective, is simply one portion of a vastly complex, highly regulated chemical entity.

Most human genes contain both exons (the sequences that actually code for the protein) and introns (areas believed to contain non-coding sequences). Pet. App. 15a. The BRCA1 and BRCA2 genes are no exception. As they exist in the human body, each consists of tens of thousands of nucleotides, the vast majority of those being intron sequences. Pet. App. 51a-52a. Certain of the claimed isolated DNA molecules in Myriad's patent, however, contain just the coding exons, and no non-coding introns.

Not only are genes structurally complex, but they are functionally complex as well, instructing the human body on its growth and development. The BRCA1 and BRCA2 genes and the proteins they encode are part of the mechanism by which the genome repairs itself and are referred to as caretaker genes. But these two BCRA genes don't play that role by themselves. They are part of an intricate, highly regulated system that involves a variety of cellular components to both activate and effectuate the repair of the genome when it has been damaged.

B. Myriad Claims Isolated DNA Molecules, Not Found in Humans, That Can Perform New Functions

A comparison between those human genome portions designated as BRCA1 and BRCA2 to what is actually claimed in Myriad's patent must begin with the claim language. Claim 1 of the '282 patent is a representative example.

The claim uses the term "isolated" to introduce its description of the DNA, which immediately indicates that the claim is directed to something other than human genes as found in the human body. *See* 2J.A. 755, '282 Patent at col. 19, ll. 8-19 (indicating "isolated" includes DNA that "has been removed from its naturally occurring environment"). Despite the impression that the term "isolated" may create for a lay person, it is not the case that one can hold down a DNA molecule and, using a scalpel, simply cleave off the portion that corresponds to the BRCA1 or BRCA2 gene.

Instead, to obtain an isolated DNA molecule, scientists extract chromosomal DNA from cells and then, using scientific methods, obtain shorter and shorter fragments. Pet. App. 2a, 51a-52a. These fragments have a variety of random lengths and composition, and they must be arranged and ultimately put in sequence order. Contrary to what some might imply, when the DNA is cut, it does not cleanly and neatly separate into individual genes, nor does the process simply cast aside the non-coding regions. Pet. App. 51a-54a.

This process results in the creation of a new chemical entity that did not exist before. Pet. App. 51a-54a. True, the new chemical has some nucleotides in the same order as found in DNA as it exists in the body. But the fact that a wholly new chemical is derived from, and even shares the same chemical units with, a chemical that exists in nature has never been the basis for excluding a claimed chemical compound from the scope of patentability in section 101. *See* Pet. App. 87a (Moore, J., concurring-in-part)(citing *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911), and comparing Myriad's isolated DNA molecules to adrenaline).

Claim 1 of the '282 patent, having required isolation, then continues: "DNA coding for a BRCA1 polypeptide." This describes a subclass of DNA molecules: those that have the precise chemical composition (*i.e.*, nucleotide sequence) corresponding to the amino acids that make up the BRCA1 protein. Those isolated molecules cannot function like the native DNA from which they are derived. They are

not part of a highly regulated genome that instructs the growth and development of humans. They cannot participate in the body's genomic repair mechanism, let alone regulate in the same fashion.

Instead, the newly created DNA molecules as claimed perform new functions that native DNA cannot perform. They can be used as biological tools to diagnose illness and are instrumental in tailoring treatment options to ensure therapeutic success. They can be used to develop new, carefully targeted anti-cancer treatments to benefit mankind. These are significant new utilities that flow directly from inventors' creation of a new composition of matter.

II. THE FEDERAL CIRCUIT APPLIED THE CORRECT TEST

A. Patent Eligibility of Isolated DNA Molecules, Which Are Compositions of Matter, Must Be Analyzed Under the Applicable Precedents

The Federal Circuit correctly recognized that this Court's decisions in *Chakrabarty* and *Funk Brothers* "set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules." Pet. App. 48a. The issue in *Chakrabarty* was whether a living organism—a bacterium created by scientists—was eligible for patent protection under the "product of nature" exception to section 101. *See* Pet. App. 49a (citing *Chakrabarty*, 447 U.S. at 305, 307). Through genetic engineering, the inventors created a

bacterium that did not exist in nature in the claimed form. It had four naturally occurring DNA molecules from different sources, each enabling the breakdown of a different component of crude oil. The new bacterium (with its four oil-eating DNA molecules) was more efficient in treating oil spills than any naturally occurring bacteria. Pet. App. 49a. This Court concluded that the man-made bacterium qualified as patent-eligible subject matter because it was a "product of human ingenuity" having "markedly different characteristics from any found in nature and one having the potential for significant utility." *Chakrabarty*, 447 U.S. at 309-10.

Funk Brothers and other Supreme Court decisions have likewise focused on the distinction between "products of nature, whether living or not, and *human-made* inventions." *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 130 (2001)(quoting *Chakrabarty*, 447 U.S. at 313)(emphasis added). In *Funk Brothers*, the patentee discovered a harmonious relationship between certain strains of naturally occurring bacteria. 333 U.S. at 131. When grouped together in a mixed culture, the combination had improved plant-protective properties as compared to any single bacterium. This Court, however, held that the bacteria's cooperative quality was the "work of nature" and thus not patentable. *Id.* at 130. Unlike the case in *Chakrabarty*, where the inventors created something entirely new and different from anything found in nature, the discovery in *Funk Brothers* resulted from merely observing a natural

phenomenon, not from any functional or structural improvement by human intervention.

Applying that framework to the present case, the Federal Circuit correctly held that Myriad's isolated DNA is not nature's handiwork, but that of Myriad's scientists who used skill and ingenuity to produce compositions of matter not found in the body. *See* Pet. App. 48a, 50a-51a. The Federal Circuit thus properly applied the *Chakrabarty* inquiry to determine whether Myriad's claimed compositions have "markedly different" or "distinctive" characteristics when compared to compositions found in nature. Pet. App. 48a-54a.

In so holding, the Federal Circuit took particular note of the substantial differences in size and structure between the native genome and Myriad's claimed isolated DNA molecules. Pet. App. 51a. For example, in contrast to human chromosomes having at least 80 million nucleotides, each of the isolated BRCA1 and BRCA2 DNA molecules consists of about 80,000 nucleotides. But when non-coding introns are removed, the isolated DNA molecules shrink to 5,500 and 10,200 nucleotides respectively. Pet. App. 51a. Some of the claims at issue cover isolated DNA molecules having as few as fifteen nucleotides. Accordingly, the claimed isolated DNA molecules have chemical identities that are different from "human genes." And those differences were wrought by human intervention to both isolate discrete structures and produce utility. Pet. App. 51a-53a.

In sum, the Federal Circuit correctly recognized that Myriad's discovery of isolated DNA entails far more than identifying and observing a natural phenomenon as in *Funk Brothers.* Rather, Myriad's invention involved significant human effort to markedly transform DNA and then find new characteristics and uses for the isolated fragments. It thus meets the standards for patent eligibility established by this Court in *Chakrabarty.*

B. *Prometheus* Applies to Method Claims, Not to the Isolated DNA Molecule Claims at Issue Here

This Court's *Prometheus* decision reaffirmed that, while inventions covered by laws of nature, natural phenomena, and abstract ideas may not be patented on their own, a process that "applies" a fundamental principle in one of these categories may be patentable if it does "significantly more" than just recite a law of nature with instructions to "apply it." *Prometheus*, 132 S. Ct. at 1293-94.

Much of the *Prometheus* decision explored the "significantly more" quality that transforms an unpatentable principle into a patentable "application" of that principle. *Id.* This requirement of "significantly more" harmonizes the various approaches taken by the Supreme Court over the years. *See, e.g.*, *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972)(rejecting claims that "would wholly pre-empt the mathematical formula and in practical

effect would be a patent on the algorithm itself"); *Prometheus*, 132 S. Ct. at 1294.[4]

However, Myriad's method claims are not at issue here, so the criteria for patent eligibility set forth in *Prometheus*, which apply to method claims that implicate laws of nature, do not apply to composition claims such as Myriad's claims to isolated DNA molecules. *Prometheus* did not overrule *Chakrabarty* or its predecessors. Nor did it opine on the applicability of the rationale of such precedents to isolated biological materials.

C. Myriad's Claims May Not Be Patentable, But That Does Not Make Them Patent-Ineligible Under Section 101

As written, Myriad's isolated DNA claims potentially cover an enormous number of molecules. For at least this reason, patent practitioners can and do differ on the question of whether the claims at issue in this case on this record satisfy certain provisions of the patent laws pertaining to patentability, including those governing, for

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[4] Consistent with Supreme Court precedent as applied in *Prometheus*, the Federal Circuit properly concluded that one of Myriad's claimed screening methods (claim 20) included transformative steps that include "more than [an] abstract mental step" and do "not simply apply a law of nature" because the claimed method involved growing transformed cells and physically manipulating the cells to determine growth rates. Pet. App. 68a-69a.

example, obviousness, enablement and written description.[5] *See, e.g.*, *Diehr*, 450 U.S. at 188-89. But, whether those claims ultimately are valid and enforceable raises a question that is far different from whether they recite patent-eligible subject matter under section 101.

This Court in *Prometheus* did not announce a wholesale conflation of section 101 with sections 102 (novelty) and 103 (non-obviousness). Rather, applying *Bilski*, *Flook*, *Benson*, and *Diehr*, the Court explained that it had resisted any "temptation to depart from case law precedent." *Prometheus*, 132 S. Ct. at 1298-02. As *Diehr*, for instance, makes clear, "[t]he 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter." *Diehr*, 450 U.S. at 188-89. Indeed, whether one or more steps in a process is "novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter *eligible* for patent protection under § 101." *Id.* at 193, n.15.

Consistent with precedent, novelty and non-obviousness are and should remain separate, independent requirements, each with its own distinct elements, proofs, and precedents. Both of those requirements for patentability can entail complex legal, technical, and factual inquiries

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[5] AIPLA takes no position on the patentability of the claims at issue here.

regarding the state of the art, the contents of the relevant scientific literature, the inventor's work, and the invention's development and success. And over many decades and hundreds of decisions, the courts have developed a rich body of decisions to guide both of those separate patentability inquiries. Thus, an analysis that imports the requirements of novelty and non-obviousness into section 101 would risk turning determinations of patent eligibility into unmanageable exercises, dislodged from long-established and well-understood principles.

It may be appropriate to consider how Myriad produced the claimed subject matter in order to determine whether it is man-made and to better understand the extent to which it differs from products of nature. However, it is not germane to ask whether those methods should be deemed "routine," "conventional," or "well-understood," if those terms are synonyms for lack of novelty under section 102 or obviousness under section 103.

III. PATENT PREEMPTION DOES NOT PRECLUDE THE PATENTABILITY OF THE CLAIMED SUBJECT MATTER

Laws and phenomena of nature are not entitled to patent protection as they are "free to all men and reserved exclusively to none." *Funk Bros.*, 333 U.S. at 130. Another expression of the same exclusionary principle is that patent claims may not "preempt the use of a natural law." *Prometheus*, 132 S. Ct. at 1294.

However, a concern for that kind of "preemption" should not be allowed to undermine the legitimate "preemption" that is an essential feature of any patent system—an award of exclusive rights for a limited time granted to one who creates a new and nonobvious invention. This Court has recognized that "too broad an interpretation of this exclusionary principle could eviscerate patent law." *Id.* at 1293.

A. The Importance of Broad Patent Eligibility

Congress envisioned Section 101 as broad, flexible, and adaptable to new technologies and advances in knowledge. *See Bilski*, 130 S. Ct. at 3225 (citing *Chakrabarty*, 447 U.S. at 308). "Congress took this permissive approach to patent eligibility to ensure that 'ingenuity should receive a liberal encouragement.'" *Bilski*, 130 S. Ct. at 3225 (citing *Chakrabarty*, 447 U.S. at 308-09 (quoting 5 The Writings of Thomas Jefferson 75-76 (H. Washington ed., 1871))). In keeping with that legislative directive, each advance in technology—from the Industrial Age through the Information Age and beyond—has been spurred on and rewarded by robust patent protection. And in every age, the ultimate beneficiary of patent exclusivity has been the public.

Few would dispute that a company that discovers, tests, and brings to market a novel lifesaving therapy, while risking hundreds of millions of dollars, should be free from competition for a limited period, and thus be able to recoup its

enormous investment costs, fund additional research, and expand its business.[6] That patents provide such market exclusivity has never been a basis for denying or curtailing patent protection for worthy inventions. It is, in fact, the bargain established in the Constitution in order to "promote the Progress of … useful Arts, by securing for limited Times to … Inventors the exclusive Right to their … Discoveries." U.S. CONST. ART I, § 8 ¶ 8.

Significantly, patents spur even more innovation. The fundamental *quid pro quo* of the patent grant is the requirement that inventors fully disclose their inventions so their knowledge, insights, and achievements become available to everyone, especially to competing innovators, who can then use the patent disclosure to push the frontiers of science even further. Indeed, there is every indication that the availability of patent protection for isolated genes (and similar compositions of matter based on structures found in the human body) has fueled an explosion of

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[6] The investment required for biologic treatments can reportedly exceed $1 billion, and is still rising. *See* Press Release, Tufts Center for the Study of Drug Development, Rising Clinical Trial Complexity Continues to Vex Drug Developers (May 5, 2010), *available at* http://csdd.tufts.edu/news/complete_story/pr_ir_may-jun_2010; Tufts Center for the Study of Drug Development, *Research Milestones: Drug Policy and Strategy Analyses to Inform R&D and Strategic Planning Decisions*, http://csdd.tufts.edu/research/research_milestones (last visited Jan. 22, 2013)(referring to a 2006 study that estimated the average cost of developing a new biotechnology product as $1.2 billion).

innovation and biomedical advance. Thus, while a particular patent may temporarily preempt competition narrowly, the patent system promotes innovation and competition broadly. Of course, once the patent term expires, all are free to enjoy, commercialize, and improve the claimed inventions. The considerable public interest would not be well served by curbing patent protection at a time when the horizons of science have expanded by looking inward, to human biology, as part of a new age of innovation—the Biotech Age.

B. The Experimental Use Exception Allows For Some Uses of the Claimed DNA Molecules

In their brief on the merits, Petitioners argue that patent protection for Myriad's inventions "run[s] afoul of the First Amendment," "lock[s] up the body of knowledge" about BRCA1 and BRCA2, and will choke off "all study of them," which they allege conflicts with the Constitutional mandate that the patent law and policy should promote the progress of science and technology. Pet. Brief on the Merits, pp. 25, 40, 42.

These sweeping assertions are not true; they ignore the experimental use exception to a patent owner's exclusive rights. For nearly two centuries, the patent law has distinguished between experimenting "on" a patented invention for research or experimental purposes—which is not an infringing use—and using the invention for its stated purpose, thereby infringing the patent. *See Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass.

1813)(No. 17,600); *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y.1861)(No. 11,279). This experimental use exception applies to non-commercial research, such as that conducted in not-for-profit university laboratories. *Cf. Madey v. Duke Univ.*, 307 F.3d 1351, 1361-62 (Fed. Cir. 2002). Moreover, Congress expressly provided for an experimental use exception to cover profit-related uses related to developing information for U.S. Food and Drug Administration submissions. 35 U.S.C. § 271(e)(1). Thus, there is substantial room for scientific inquiry into DNA sequencing, even as patent protection rewards the inventors by excluding others from exploiting commercial uses of their inventions.

The principle of a research or experimental exemption has a long history in patent law. By 1861, the law was "well settled[] that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee." *Poppenhusen*, 19 F. Cas. at 1049. As Justice Story noted in the mid-nineteenth century:

> [I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its desired effects.

Whittemore, 29 F. Cas. at 1121.

Furthermore, the Federal Circuit recognized the viability of this exception as recently as last year:

> [P]atenting does not deprive the public of the right to experiment with and improve upon the patented subject matter. As discussed in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001), "[t]he disclosure required by the Patent Act is 'the quid pro quo of the right to exclude,'" quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974). It is not necessary to wait for the patent to expire before the knowledge contained in the patent can be touched.

In re Rosuvastatin Calcium Patent Litig., __ F.3d ___, 2012 WL 6217356, at *12 (Fed. Cir. Dec. 14, 2012). As academics have noted, the experimental use exception should apply equally to genomic inventions. *See* J.M. Mueller, *Facilitating Patent Access to Patent-Protected Genetic Testing*, 6 J. Bus. & Tech. L. 83, 95 (2011)(footnotes omitted).[7]

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[7] For a detailed history and analysis of the experimental use exception, *see* R. E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. Pat. Off. Soc'y 357 (1957) and L.C. Bruzzone, *The Research Exemption: A Proposal*, 21 AIPLA Q.J. 52 (1993).

The ability to perform research on a patented invention to understand the invention fosters further development and promotes the progress of the useful arts related to human genetics.

IV. Congress Has Recognized The Patent Eligibility of Isolated DNA Molecules

Congress repeatedly has recognized the patentability of isolated DNA molecules as inventions. Absent a clear directive to the contrary, it would be inappropriate for this Court to conclude otherwise.

In 1996, Congress enacted section 287(c) of the Patent Act to preclude actions for damages or injunctive relief against a medical practitioner certain arising out of medical activities that would otherwise be infringing. In providing a detailed recitation of the acts and subject matter covered, Congress expressly recognized the existence of "biotechnology patent[s]." *See* 35 U.S.C. § 287(c)(2)(A)(iii). The Conference Report for that legislation states that a "biotechnology patent" "includes … a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* at the cellular or molecular level" and includes "genetic materials, such as DNA and RNA that is obtained from within the cell." H.R. Conf. Rep. No. 104-863, at 855. It also explains that this term refers to *ex vivo* manipulation, which includes the "propagation, expansion, selection, purification, pharmaceutical treatment, or alteration of the biologic characteristics of these substances

outside of a human body." *Id.*; *see Chakrabarty*, 447 U.S. at 315 ("Congress, not the courts, must define the limits of patentability.").

Similarly, the Patent and Trademark Office has acted on this Congressional intent to grant thousands of patents claiming isolated DNA sequences and their use, and the biotechnology industry has long relied upon them. *See, e.g.*, Pet. App. 87a-89a (Moore, J., concurring-in-part). This Court should not change this interpretation of the patent statute without a "clear and certain signal from Congress." *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972). Indeed, with issues surrounding so-called "gene patents" in the forefront of scientific and policy debate, Congress recently amended the patent law, enacting the America Invents Act ("AIA"). Yet, in passing this sweeping overhaul of patent law, Congress did not exclude isolated DNA molecules from the scope of section 101. Indeed, rather than exclude DNA-related patents in the AIA, Congress explicitly recognized their existence. Pub. L. No. 112-29, § 27(a), 125 Stat. 338 (2011)(referring to "gene patents" in the context of requiring a study on genetic testing).

Both *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997) and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002), cautioned courts not to upset the settled expectations of the patent community absent a clear directive from Congress. In developing what is, literally, a multi-billion dollar industry, the U.S. biotechnology industry has relied on both Congressional action and inaction. The U.S.

biotechnology industry has led the field in the global economy in large part due to strong patent protection of DNA-based inventions. Such patent protection is critical to attracting investments and recouping the significant up-front expenditures for the type of skill, hard work, and ingenuity required to create and develop inventions such as those claimed in this case. *See* Melissa Wetkowski, *Unfitting: Gene Patent Limitations Too Tight For United States' Biotechnology Innovation and Growth in Light of International Patenting Policies*, 16 Sw J. Int'l L. 181, 198-99 (2010).

A ruling such as the one Petitioners seek in this case that isolated DNA molecules are not eligible for patent protection would deter investment in the biotechnology industry and put hard-won competitive market positions at risk. Worse, such a ruling would signal to inventors and investors working in other emerging biotechnologies that they cannot rely on the incentives and protections that have inspired and rewarded innovators from the earliest days of our republic. And, more devastatingly, it would not incentivize investors to look for new cures and diagnostics for disease. Given the stark effect such an abrupt change in the law would have on American biotechnology ingenuity and industry, Congress, not the courts, should initiate any dialogue about whether this settled law should be modified. *See* Nikos C. Varsakelis, *The Impact of Patent Protection, Economy Openness and National Culture on R&D Investment: A Cross-Country Empirical Investigation*, 30 Res. Pol'y 1059, 1066 (2001).

In this context, it is important to consider that: (1) patents have been granted on human genetics for a long time; (2) Congress has recognized and considered the availability of such protection and has chosen not to limit it in the context of enacting legislation; and (3) businesses are entitled to rely not only on Congressional action but also on Congressional inaction.

A. Moral and Ethical Considerations Are for Congress, Not the Courts

Those challenging Myriad's patents have invoked additional societal, moral, and ethical issues surrounding the exclusionary effects of purified, isolated DNA molecule patents. AIPLA is not unmindful of or unsympathetic to these concerns, but they require careful scrutiny in an appropriate forum.

Indeed, these issues, while important, are expressly reserved for Congress, not the courts, under its authority to enact laws that promote the progress of the useful arts. There has never been a "medical treatment/diagnostics" exception to Section 101. In fact, current patent policy should and does follow the Constitutional mandate to promote the next new advance lest researchers lack incentive to provide diagnostics and treatments because there is no protection for their inventions. And where Congress has spoken and set forth broad categories of patent-eligible subject matter, the courts should not narrow the scope of the patent laws based on their own balancing of ethical and moral considerations. *See Charkrabarty*, 447 U.S. at 317-

18 ("[U]ntil Congress takes [] action, this Court must construe the language of § 101 as it is.").

CONCLUSION

For the foregoing reasons, AIPLA urges the Court to affirm the judgment of the court of appeals.

Respectfully Submitted,

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