No. 12-398

IN THE
Supreme Court of the United States

THE ASSOCIATION OF 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 OF AMICUS CURIAE FEDERAL CIRCUIT BAR ASSOCIATION IN SUPPORT OF RESPONDENTS

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STATEMENT OF INTEREST

This brief is submitted by the Federal Circuit Bar Association ("FCBA") as *amicus curiae* in support of Respondents to urge the Court to affirm the judgment of the court of appeals and reject the attempt of Petitioners and certain *amici* to narrow the scope of patent eligibility under 35 U.S.C. § 101.[1] The FCBA is a national bar organization with nearly 2,500 members from all geographic areas of the country. The FCBA offers a forum for discussion of the common concerns between bar and courts, litigators and corporate counsel. One of the FCBA's purposes is to render assistance to the courts in appropriate instances, both in procedural and substantive practice areas.

The FCBA has no interest in any party to this litigation or stake in the outcome of this case. Neither the decision to file this brief nor the views articulated in it are expressive of, or binding upon, those members of the Board of Governors of the FCBA who are employees of the Federal Government.

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[1] In accordance with Supreme Court Rule 37.3(a), the FCBA states that counsel for Petitioners filed a general consent to the filing of *amicus* briefs on January 2, 2013. Respondents granted consent on March 3, 2013, via electronic mail, a copy of which has been filed with the Clerk. Pursuant to Supreme Court Rule 37.6, the FCBA 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 FCBA or its counsel.

SUMMARY OF ARGUMENT

The single question presented by Petitioners embeds at least five misleading assumptions. As an initial matter, the question incorrectly suggests that § 101 of the Patent Act is a catch-all provision designed to weed out patent claims that are defective for a variety of reasons, including overbreadth. In fact, that section is narrowly directed at the question of patent eligibility. Other misleading aspects of the question suggest that the Court's ruling in this case will affect only patents claiming human genes. In fact, a ruling for Petitioners would cast doubt on numerous DNA patents that are not drawn to human genes. Another misleading aspect of the question is that it suggests that all claims directed to human genes present the same issue of patent eligibility. In fact, the claims now before the Court include both full-length isolated genes as well as cDNAs, genes that are created by humans from messenger RNA transcripts. A final misleading assumption is that a gene is the same as an isolated gene. All the claims now before the Court are directed to ***isolated*** DNA molecules, which are chemically distinct from their natural counterparts and, in consequence, have tremendous diagnostic and therapeutic utility that natural genes lack. (Section I.)

Even under the narrowest interpretation of this Court's cases, claims to isolated DNA molecules are patent-eligible. They are novel, man-made creations that are chemically distinct from naturally-occurring DNA. Further, they greatly enhance the utility of the DNA in its natural form, a fact that should

weigh heavily in favor of their patent-eligibility under a proper reading of 35 U.S.C. § 101. Many of Petitioners' complaints about the claims relate to asserted flaws that are unrelated to the patent-eligibility of the claims and raise issues that are not properly before the Court. (Section II.)

The questions before the Court are highly controversial and involve questions of significant medical and scientific complexity. These questions should be addressed to the political branches of government. In fact, Congress has recently considered these questions and has chosen not to make isolated genes ineligible for patenting. In enacting Section 33 of the Leahy-Smith America Invents Act, Pub. L. No. 112-29 (2011), Congress expressly declined to limit the patent eligibility of DNA molecules. Congress has also refused to pass other legislation addressing the very policy issues raised by Petitioners. (Section III.)

ARGUMENT

I. PETITIONERS' QUESTION MISLEADINGLY SUGGESTS AN INCORRECT ANSWER.

Petitioners have presented the question, "Are human genes patentable?" The question subtly suggests the wrong conclusion, because it embeds at least ***five*** misleading assumptions.

1. The first is that the relevant inquiry is about ***patentability***, not simply ***patent eligibility***. As explained in Section II.C. below, the inquiry under § 101 is confined to whether an invention or discovery is eligible for patenting at all. Whether a patent-eligible invention is "patentable," on the other hand, depends on the "conditions and requirements" of other sections of the Patent Act, as also discussed below. *See* 35 U.S.C. § 101.

2. The second misleading assumption is that there is something special about human genes, as opposed to genes of other organisms. (This case does not implicate the principle, discussed below in Section III, that a patent may not claim a whole human organism.) Many non-human genes are patented and, like human genes, are commercially important. For example, various bacterial genes are critical for the production of amino acids, and murine (mouse) genes can be used as immunological targets or probes. Petitioners' question appears to suggest that there is a conceivable basis for ruling that human genes are not patent-eligible, while leaving the question of other genes for another day. However, any ruling by this Court that human genes

are not patent-eligible logically would extend to all gene patents, not just patents drawn to human genes.

3. The third misleading assumption is that there is something special about genes, as opposed to other regions of DNA. Many DNA patents are drawn to sequences that are not genes and do not encode proteins. Nevertheless, these patents provide important protections for many innovations in the manufacturing of biologic drugs and other therapies. For example, numerous patents are drawn to control sequences of DNA, sequences that, when isolated from their natural context, can enhance production of desired therapeutic or other products. An example of such a control sequence is the promoter-regulatory region of human cytomegalovirus. In the early 1980s, a scientist at the University of Iowa isolated and patented this region, which was broadly licensed by the biotechnology industry for the production of biologic drugs. *See* U.S. Patent No. 5,385,839; *see also* University of Iowa, *Stinski to Receive UI's First Distinguished Inventor Award* (Sept. 30, 2004), http://news-releases.uiowa.edu/2004/september/093004stinski-award.html. The reasoning underlying Petitioners' arguments against gene patents apply equally to patents covering other regions of DNA. Thus, any ruling in favor of Petitioners would likely destroy any rationale for the patent eligibility of these important inventions as well.

4. The fourth misleading assumption is that the term "human genes" presents a single issue to this Court. In fact, as discussed in the Federal Circuit's

opinion, that term embraces both full-length genes having the full sequence of a corresponding natural gene, including intron sequences that do not encode amino acids; and cDNAs, which are genes obtained by manipulating messenger RNA to create a truncated gene that does not contain the natural intron sequences. *See Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1311-13 (Fed. Cir. 2012); *see also* Brief for *Amicus Curiae* Eric S. Lander in Support of Neither Party at 20-21 (hereinafter "Lander *Amicus* Brief"). Even *amicus* Eric Lander, who largely criticizes the reasoning of the Federal Circuit, agrees with that court that cDNAs are human creations that should be patent-eligible. Lander *Amicus* Brief at 21. However, the sweeping question presented by Petitioners lumps both kinds of genes into a single category. This is particularly problematic in view of the fact that several of the claims now before the Court (*e.g.*, claims 2 and 7 of U.S. Patent No. 5,747,282) are expressly drawn to cDNAs, while certain others might be interpreted as being so limited during a claim construction proceeding.

5. The fifth misleading assumption is that the claims are drawn simply to "human genes," not ***isolated*** human genes. Petitioners' question—"Are human genes patentable?"—suggests that the isolated DNA molecules of the claims are the ***same*** as genes in their natural context, and that all that differentiates one from the other is the act of "simply … removing … genes from the body." Pet. Br. at i. The notion that such a removal is a simple or un-inventive process is untrue.

As an initial matter, the process of isolation requires the application of some of the most ground-breaking technologies developed in the 20th century. These technologies enable the extraction of nucleic acids from cells, the cutting of nucleic acids into fragments, the analysis of the nucleotide sequence and functions of those fragments, the replication or synthesis of nucleic acid molecules, and the transfer of such molecules into plasmids or other vehicles for their storage and use.

Early projects to isolate human genes required months of painstaking laboratory work. Indeed, isolating a gene is a misnomer for the lengthy experimental process required. The process is not a simple extraction or purification, but rather a complex series of steps to create an isolated DNA molecule having the same genetic information as—but a different chemical structure from—a natural DNA of interest. Those steps, at least in the early years of isolating genes, included the extraction of undifferentiated RNA molecules from cells, the creation of cDNA molecules corresponding to those RNA molecules, the insertion of the cDNA molecules into plasmids after engineering both the cDNA molecules and the plasmids so that the insertion could be performed, the transformation of thousands or millions of bacterial cells with those plasmids, the production of polypeptides using those cells, the search for polypeptides bearing desired characteristics from among thousands of polypeptides produced by the cells, the sequencing of DNA fragments from cells producing the desired polypeptides, and the combining of separate sequenced fragments into a full-length isolated DNA

molecule. The starting materials were RNA molecules extracted from cells, not chromosomal DNA, and the specific DNA molecules investigated were cDNAs constructed using RNA. *See, e.g.,* R. Derynck et al., *Isolation and Structure of a Human Fibroblast Interferon Gene,* NATURE 285:542 (1980); J.T. Wilson et al., *Insertion of Synthetic Copies of Human Globin Genes Into Bacterial Plasmids,* NUCLEIC ACIDS RES. 5:563 (1978). As discussed above, such cDNAs are human creations and lack the non-coding DNA found in natural, chromosomal DNA.

While the processes for isolating genes became easier and were simplified over time, they still are anything but an elementary process of extraction or purification. For example, Myriad's inventors used techniques of genetic analysis to identify regions of chromosomal DNA associated with cancer. They isolated the genes of interest by analyzing a massive library of different cDNAs (again, created from RNAs, and thus different from chromosomal DNA) to find cDNAs associated with the suspect regions. They performed further sequencing analysis to identify the cDNAs having suspicious mutations in cancer patients, and they combined separate fragments of the genes of interest into full-length isolated DNA molecules.

Further, as the Federal Circuit made clear in its opinion, isolated DNA molecules are not natural phenomena. Once a gene has been isolated, it is a new and different chemical entity that is critically different from natural, chromosomal DNA. *Ass'n for Molecular Pathology*, 689 F.3d at 1328 ("Isolated

DNA has been cleaved (i.e., had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule.").

Amicus Eric Lander takes issue with the Federal Circuit's scientific premise, observing that DNA fragments may be found in the body separate from the chromosomes in which they originated. Lander's argument is carefully worded so as not to highlight its central flaw: that the DNA fragments that can be found in the body as a result of such processes as cell death are not cleaved exactly at the beginning or end of genes, but occur as random fragments. Thus, Lander argues that naturally occurring DNA fragments may "cover" the BRCA1 and BRCA2 genes. Lander *Amicus* Brief at 16. However, a large fragment that happens to include one of the genes of interest must still be cleaved—chemically altered—so as to yield the gene of interest. Smaller fragments must be joined to create a full-length gene. The fact that cells contain random DNA fragments also overlooks the difficulty, discussed above, of locating and identifying any particular DNA fragment, cleaving out a desired gene, and understanding what function its pieces may have and what parts may be missing from it. Thus, referring to a random, naturally occurring fragment as an "isolated" DNA assumes what must, but cannot, be shown: that a naturally occurring DNA fragment is the same as a gene that has been isolated from a natural context.

Petitioners attempt to paper over the fact that isolated genes differ from naturally occurring ones

by arguing that "the gene sequence, the information it includes, and the laws it embodies are the same whether in or out of the body." Pet. Br. at 9. However, the fact that DNA has a sequence does not mean that an isolated DNA ***molecule*** consists only of its sequence. Its other chemical attributes are critically important to its utility, which is why an isolated gene is simply not the same thing, or even a purified version of the same thing, as the chromosomal DNA to which it corresponds in sequence.

Petitioners' argument is like arguing that a novel drug compound is not entitled to patent protection because the elements by which it is constituted (oxygen, hydrogen, carbon, etc.) still have all the same protons, neutrons, and electrons that they have in nature. Such an argument is clearly wrong, but it is analytically indistinguishable from the argument Petitioners present to this Court. The Court should reject this oversimplified analysis.

II. ISOLATED DNA IS PATENT-ELIGIBLE UNDER § 101 OF THE PATENT ACT.

The FCBA urges the Court to rule that isolated genes are eligible for patenting. Section 101 of the Patent Act, 35 U.S.C. § 101, defines the inventions and discoveries eligible for patent protection:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a

> patent therefor, subject to the conditions and requirements of this title.

Isolated human genes are new and very useful compositions of matter and should be eligible for patent protection if claims drawn to them satisfy the other statutory requirements for patentability.

A. Isolated DNA Is Patent-Eligible Even Under the Narrowest Reading of This Court's Precedents.

This Court's cases addressing 35 U.S.C. § 101 have recognized that Congress intended the threshold patent-eligibility standard set forth in that section of the Patent Act to be construed broadly. *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 130 (2001) ("the language of § 101 is extremely broad") (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)). Congress used "expansive terms" in defining the four categories of inventions eligible for patent protection under § 101: processes, machines, manufactures, and compositions of matter. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Chakrabarty*, 447 U.S. at 308). In *Bilski*, this Court expressly noted that by using the comprehensive modifier "any," Congress "plainly contemplated that the patent laws would be given wide scope" and explained that "Congress took this permissive approach to patent eligibility to ensure that ingenuity should receive a liberal encouragement." *Id.*

However, this Court has also made clear that neither "laws of nature" nor "products of nature" are

patent-eligible under § 101. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. __, 132 S. Ct. 1289, 1293 (2012); *Chakrabarty*, 447 U.S. at 309. The Court's recent ruling in *Mayo* disapproved as "effectively claim[ing] the underlying laws of nature" a patent claim directed to determining blood levels of certain metabolites. 132 S. Ct. at 1305. Specifically, the claim was drawn to "determining" the level of resulting metabolites in the subject's blood, "wherein" a level below a certain threshold "indicate[d] a need" to increase the dose, while a level above another threshold "indicate[d] a need" to reduce the dose. *Id.* at 1295. In holding that these claim elements were "not sufficient to transform unpatentable natural correlations into patentable applications of those regularities," the Court explained that "the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id.* at 1298.

The Prometheus claims, with their almost passive observation of metabolite levels, stand in stark contrast to claims drawn to isolated DNA molecules. As discussed above in Section I, obtaining such a molecule requires significant human activity and results in a product that is not found in nature. In this respect, claims drawn to isolated DNA molecules are akin to the claims of "a typical patent on a new drug," a type of claim that the Court contrasted favorably with the Prometheus claims. *Id.* at 1302. The massive human effort

required to isolate or synthesize DNA molecules is completely unlike the passive observation of a natural relationship.

The *Mayo* decision has little relevance to claims drawn to isolated DNA molecules in any event, because those present a different issue: whether such molecules are patent-eligible "composition[s] of matter" or ineligible "products of nature." Thus, their patent eligibility is governed by this Court's prior cases on products of nature, two of which are particularly on point: *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) and *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

In *Funk Brothers*, just as in *Mayo,* the inventor discovered a natural phenomenon: that certain strains of nitrogen-fixing bacteria, in contrast to the norm, did not exhibit a mutually inhibiting effect on each other. 333 U.S. at 130. Thus, those select strains could be used together to obtain superior nitrogen fixation. The Court held that claims drawn to a mixture of mutually non-inhibitory bacteria were not patent-eligible, however, because each strain, and the mixture, were "the work of nature." *Id.* The problem with the claims was that, while they exploited a discovery about the qualities of the bacteria, they did not add anything to the natural phenomenon the inventor had observed: "[P]atents cannot issue for the discovery of the phenomena of nature." *Id.*

Claims to an isolated DNA molecule, on the other hand, resemble the claims held by this Court to be patent-eligible in *Chakrabarty*. There, as in *Mayo*

and *Funk Brothers*, the inventor discovered a natural phenomenon—that certain naturally occurring DNA plasmids (circular DNA molecules naturally present in bacteria) encoded enzymes capable of degrading oil. *Chakrabarty*, 447 U.S. at 305-06. Just as the *Funk Brothers* inventor reasoned that it would be advantageous to bring together multiple strains of nitrogen-fixing bacteria, Chakrabarty reasoned that bringing together several of the oil-degrading plasmids would be advantageous. Accordingly, Chakrabarty created a new organism that incorporated several of the oil-degrading plasmids. What distinguished Chakrabarty's creation from the *Funk Brothers* mixture was that Chakrabarty had created a new organism not found in nature. *Id.* at 309-10.

Claims to isolated DNA molecules are patent-eligible, just like the new microorganisms in *Chakrabarty,* because they are novel creations that are chemically different from naturally-occurring DNA. The claim that isolating a gene is like "snapping a leaf from a tree," *see Ass'n for Molecular Pathology*, 689 F.3d at 1352 (Bryson, J. dissenting), is untrue, because the leaf remains a leaf, while an isolated gene is, as a matter of chemistry, not the same as a gene in natural context. As the Federal Circuit explained, chromosomal DNA is "intertwined with various proteins, including histones, to form a complex tertiary structure known as chromatin[.]" *Id.* at 1328. Random fragments of DNA, as discussed in Section I, are also not isolated genes, which have "been cleaved (*i.e.,* had covalent bonds … chemically severed) or synthesized to consist of just

a fraction of a naturally occurring DNA molecule." *Id.*

Thus, isolated DNA molecules are fundamentally unlike the purified, naturally-occurring chemicals found not to be patent-eligible in a series of appeals court cases. *See, e.g., Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928) (purified tungsten not patent eligible); *In re Marden*, 47 F.2d 957 (C.C.P.A. 1931) (purified uranium not patent eligible); *In re Marden*, 47 F.2d 958 (C.C.P.A. 1931) (purified vanadium not patent eligible); *In re Merz*, 97 F.2d 599 (C.C.P.A. 1938) (purified ultramarine not patent eligible). Petitioners cite these "purification cases" for the proposition that "courts must examine whether the composition and any characteristics specified in the claims were invented by the patentee or were the work of nature." Pet. Br. at 39. What differentiates isolated DNA molecules from DNA in nature is that they have a distinct chemical structure that enables them to be used for diagnostic and therapeutic purposes, among other things. Further, as discussed in Section I, a gene is not typically isolated by simply extracting it from the entire genome of the source organism, as one might pluck a leaf from a tree.

Isolated genes are also fundamentally unlike the borax-treated fruit ruled patent-ineligible in *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931). There, the Court reasoned that treating the fruit rind with borax did not impart to the fruit "a new or distinctive form, quality, or property…. There is no change in the name, appearance, or general character of the fruit." *Id.* at

11-12. The problem with the treated fruit claims was that the addition of borax to the rind did not effect a meaningful alteration from the natural fruit itself. The fruit was no more patent-eligible when treated with borax than it would have been when packaged in cellophane. Isolated genes, however, involve much more than a simple addition to a product of nature. As discussed in Section I, they are new molecules created by human intervention.

Thus, isolated genes are patent-eligible under the principles established in *Chakrabarty* and are fundamentally unlike the products of nature ruled patent-ineligible in *Funk Brothers,* the purification cases, and *American Fruit Growers*.

B. This Court's Prior Cases Do Not Support the Narrow, Rigid Test Proposed by Petitioners.

Citing *Chakrabarty*, 447 U.S. at 303, Petitioners urge this Court to hold that for a composition of matter to be patent-eligible, it ***must*** have "a distinctive name, character and use" and must also have "markedly different characteristics from any found in nature." Pet. Br. at 28-29. Although as set forth above, Petitioners misapply *Chakrabarty*, Petitioners' argument also fails in another crucial respect: nowhere does *Chakrabarty* hold that it sets forth the ***only*** test for patentability of compositions of matter under § 101. The Court in *Chakrabarty* simply held that because the bacteria there ***were*** markedly different from any found in nature, they ***were*** patent-eligible. *Chakrabarty* did not establish that a composition that is ***not*** "markedly different"

from its natural antecedents is ***not*** patent-eligible. Indeed, *Chakrabarty* did not establish any kind of rigid or exclusive test.

Rather, *Chakrabarty* emphasized that "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Id.* at 308; *see also id.* at 315 ("The subject-matter provisions of the patent law have been cast in broad terms[.]"). The Court "cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed." *Id.*

The Court sounded the same theme in *Bilski,* in observing that courts should avoid "adopting categorical rules that might have wide-ranging and unforeseen impacts." 130 S. Ct. at 3229. In *Bilski*, this Court rejected the Federal Circuit's "machine or transformation" test as the "sole" test for patent eligibility of process patents. Repeating its caution in *Chakrabarty* that courts should not read limitations into the Patent Act that were not expressed by Congress, the Court held that "adopting the machine-or-transformation test as the sole test for what constitutes a process … violates … statutory interpretation principles." *Id.* at 3226.

Applying the "markedly different" test as the exclusive basis for determining the patent eligibility of compositions of matter would also violate those principles. In fact, there is no meaningful difference between the rigid and exclusive tests advocated by

Petitioners and the machine-or-transformation test that this Court has already rejected. *See id.* 3226-27. Petitioners' arguments for the exclusive adoption of the factors articulated in *Chakrabarty* ignore this Court's guidance in *Bilski*.

Indeed, this Court's patent cases, including those concerning issues other than patent eligibility, have repeatedly emphasized that narrow and rigid tests are particularly clumsy tools for assessing human innovation. "The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007). In *KSR*, just as in *Bilski,* this Court rejected a narrow, rigid test. 550 U.S. at 415 ("We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach[.]"). This Court should not begin to impose a rigid and inflexible test in the one area—patent eligibility under § 101—where Congress has unambiguously mandated breadth and flexibility.

Petitioners' inflexible approach also ignores the utility of isolated genes compared with natural DNA. Utility is a factor that this Court has pointed to in determining that an invention was patent-eligible. In *Funk Brothers*, for example, the Court pointed out that mixing the bacterial strains produced "no enlargement of the range of their utility." 333 U.S. at 131. The Court continued:

> Each species has the same effect it always had. The bacteria perform in their natural

> way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

Id. Thus, the inquiry should focus not only on the narrow criteria advanced by Petitioners, but also on differences in utility, and the fact that the intervention of humans created those differences. *See Chakrabarty*, 447 U.S. at 310 (in ruling transformed bacteria patent-eligible, noting their "potential for significant utility").

The isolation of a human gene allows it to be used to diagnose and treat diseases—uses to which it could not be put in its natural context. Petitioners concede that natural genes lack the utility of an isolated DNA molecule: "It is not currently possible to use genes, including looking at or sequencing them, without removing or 'isolating' them from the body." Pet. Br. at 9. This increase in utility results from human ingenuity and strongly suggests that isolated genes should be patent-eligible.

C. Although Isolated DNA is Eligible for Patenting, Other Statutory Restrictions on Patentability Still Apply.

Patent eligibility under § 101 is only one of many hurdles that a patent claim must surmount in order to be deemed worthy of patent protection. As this Court stated in *Bilski*, "The § 101 patent-eligibility inquiry is only a threshold test." 130 S. Ct. at 3225. As the language of § 101 expressly acknowledges,

other "conditions and requirements" of the Patent Act must also be met, including novelty (35 U.S.C. § 102), non-obviousness (§ 103), written description (§ 112), and enablement (§ 112). The limitations found in §§ 102, 103, and 112 "serve a critical role in adjusting the tension, ever present in patent law, between stimulating innovation by protecting inventors and impeding progress by granting patents when not justified by the statutory design." *Bilski*, 130 S. Ct. at 3229. As Justice Stevens cautioned in his concurrence in *Bilski*:

> Given the many moving parts at work in the Patent Act, there is a risk of merely confirming our preconceived notions of what should be patentable or of seeing common attributes that track the familiar issues of novelty and obviousness that arise under other sections of the statute but are not relevant to § 101.

Id. at 3238 (internal quotation marks and citation omitted).

In their brief, Petitioners fall right into the trap identified by Justice Stevens. For example, Petitioners argue that that the claims are overbroad, because they cover many different forms of the genes of interest: "The challenged claims cover all isolated forms of the naturally-occurring genes, whether previously identified or not." Pet. Br. at 41. Similarly, Petitioners argue that the Myriad patents "undermine the patent system by giving Myriad the right to any applications of isolated DNA without

disclosing them or even having done the work to develop them." *Id.* at 41.

Insofar as Petitioners' criticisms of the claims are correct, the claims can be challenged under the provisions of the Patent Act that protect against overly broad claims, such as 35 U.S.C. §§ 102, 103, and 112. Broad claims that encompass prior art run afoul of §§ 102 or 103. Claims that are overly broad compared to the inventors' actual discoveries are invalid for lack of written description under § 112. If the Myriad claims are overbroad, the solution is not to rule that all isolated genes are ineligible for patenting under § 101.

Petitioners react with outrage to the practical consequences of Myriad's patent monopoly. However, many of the problems Petitioners point to are illusory. Statutory and judicial exemptions to patent infringement protect many of the activities that Petitioners complain are being blocked by the Myriad patents. For example, uses of the patented technology may be protected if they are connected with seeking regulatory approval or are experimental. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005); *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

Petitioners' policy arguments that the Myriad patents block the development of "drugs, instruments, and treatment methods," Pet Br. at 44, completely ignore the critical importance of patent protection in the biotechnology industry. Many biotechnology drugs, including insulin (used to treat diabetes), human growth hormone (for growth

hormone deficiency), erythropoietin (for anemia), beta-interferon (for multiple sclerosis), and beta-glucocerebrosidase (for Gaucher's disease) are or were protected by gene patents. A ruling that gene patents are invalid would throw the industry into turmoil and would threaten the development of new "drugs, instruments, and treatment methods."

Indeed, Petitioners' arguments suggest a thoroughgoing disagreement with the patent system itself. However, § 101 should not be gutted simply because Petitioners disagree with the balance between innovation and monopoly established in Article I of the Constitution and by Congress.

In sum, claims drawn to isolated DNA molecules should "at the very least not [be] barred at the threshold by § 101." *Diamond v. Diehr*, 450 U.S. 175, 188 (1981). Whether such claims also meet the conditions of patentability imposed by §§ 102, 103, and 112 are questions that are not before the Court.

III. THE COURT SHOULD DEFER TO CONGRESS' POLICY CHOICE DECLINING TO LIMIT PATENT ELIGIBILITY OF GENES.

Congress has considered the patent eligibility of genes, including human genes, and has declined to limit their eligibility. Instead, Congress has made the policy choice that only human ***organisms*** should be patent-ineligible. Under Section 33 of the Leahy-Smith America Invents Act of 2011 ("AIA"), Congress limited the broad scope of § 101 to specifically exclude human organisms: "Notwithstanding any other provision of law, no patent may issue on a

claim directed to or encompassing a ***human organism***." Pub. L. No. 112-29 (2011) (emphasis added). Although Congress specifically considered the issue, as discussed below, it did not prohibit issuing patents on genes, including human genes.

Section 33 of the AIA, generally known as the Weldon Amendment, is derived from a series of amendments to appropriations bills since 2004. *See* 157 CONG. REC. E1177 (daily ed. June 23, 2011) (statement of Rep. Christopher Smith). *See generally* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435, 510-11 (2011) (detailing legislative history of Section 33). Notably, in floor debate introducing his amendment, Representative Weldon explained that "I recognize that there are many institutions … that have extensive patents on human genes, human stem cells. This would not affect any of those currently existing patents." 149 CONG. REC. 18998 (July 22, 2003) (statement of Rep. Weldon.); 149 CONG REC. H7274 (daily ed. July 22, 2003).[2]

Section 33 of the Leahy-Smith America Invents Act was itself introduced as an amendment to the AIA by one of its lead sponsors, Rep. Lamar Smith, the then-Chairman of the House Judiciary

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[2] These floor statements were incorporated as part of the Congressional Record accompanying the consideration of Section 33 of the AIA. 157 CONG. REC. E1177-1178 (daily ed. June 23, 2011) (statement of Rep. Christopher Smith) (submitting statements by Rep. Weldon into legislative record).

Committee, and the Representative after whom the AIA is named. 157 CONG. REC. H4451 (daily ed. June 22, 2011); *see also* Matal, *supra*, at 510-11. In supplemental remarks on behalf of the Committee on the Judiciary regarding the proposed amendment that eventually became Section 33 of the AIA, Chairman Smith explained:

> The Committee recognizes that the economic viability of the biotechnology industry requires that patents be available for the full spectrum of innovations that may be subject to commercialization. … The Committee also recognizes that continued innovation in the biomedical and biotechnological fields will lead to new kinds of inventions, and it expects that the overwhelming majority of such inventions will not raise any of the concerns that the present legislation addresses. In particular, nothing in this section should be considered to limit the ability of the PTO to issue a patent containing claims directed to or encompassing: 1. Any chemical compound or composition, whether obtained from animals or human beings or produced synthetically, and whether identical to or distinct from a chemical structure as found in an animal or human being, including but not limited to nucleic acids ….

157 CONG. REC. E1183 (daily ed., June 23, 2011) (statement of Rep. Lamar Smith); *see also* Matal, *supra*, at 510-11.

The enactment of Section 33 of the AIA came just a few years after Congress considered, and rejected, much broader legislation, the Genomic Research and Accessibility Act ("GRAA"), that sought to make all genes patent-ineligible. The GRAA, introduced in 2007, provided that "no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies." H.R. 977, 110th Cong. (2007). Thus, it would have enacted exactly what Petitioners want: to withdraw patent eligibility for all genes and other DNA molecules, regardless of source. In remarks introducing the legislation, the bill's sponsor raised many of the policy issues that Petitioners raise before this Court regarding gene patents.[3] 153 CONG. REC. E316 (daily ed. February 9, 2007) (statement of Rep. Becerra).

Congress declined to strip isolated DNA of patent eligibility and did not pass the GRAA. Understood together, the fates of Section 33 of the AIA (which was passed into law) and the GRAA (which was not) indicate that whole human organisms are not patent-eligible, but isolated DNA is. The legislative history of Section 33 of the AIA confirms this intent. 157 CONG. REC. E1183 (daily ed. June 23, 2011) (statement of Rep. Lamar Smith).

Now that Congress has spoken, this Court should not read into the broad language of § 101 further

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[3] He also thanked Petitioner Association of Molecular Pathology for its support for the bill. 153 CONG. REC. E316 (daily ed. February 9, 2007) (statement of Rep. Becerra).

limitations that were considered, and rejected, by Congress. *See Andrus v. Glover Constr. Co.*, 446 U.S. 608, 616-17 (1980) ("Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent."). As this Court wisely advised less than a decade ago:

> There is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted. [This Court's] unwillingness to soften the import of Congress' chosen words even if we believe the words lead to a harsh outcome is longstanding. It results from deference to the supremacy of the Legislature[.]

Lamie v. U.S. Trustee, 540 U.S. 526, 538 (2004).

The complex medical and scientific issues at stake here, and the extensive disagreement among the scientific and medical community regarding the wisdom of gene patenting, further counsel that this Court should proceed cautiously and defer to Congressional judgment. "[W]hen a legislature undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad and courts should be cautious not to rewrite legislation." *Kansas v. Hendricks*, 521 U.S. 346, 360 n.3 (1997) (quoting *Jones v. United States*, 463 U.S. 354, 365 n.13 (1983)).

This Court has declined similar invitations to engraft its political or prudential views onto Congressional statutes. In *United States v. Rutherford*, 442 U.S. 544 (1979), for example, terminally ill cancer patients sought an exception to the premarketing approval requirements under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Specifically, the plaintiffs sought to exempt drugs used to treat terminally ill patients from the FD&C Act's regulatory requirements. *Id.* at 548-49. The lower courts agreed with the patients' arguments despite Congressional silence on the issue. *Id.* at 550-51, 554.

This Court reversed, explaining that "[u]nder our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy." *Id.* at 555. "Only when a literal construction of a statute yields results so manifestly unreasonable that they could not fairly be attributed to congressional design will an exception to statutory language be judicially implied." *Id.* This Court should follow its previous reluctance to read moral or political judgments into broadly worded statutes such as § 101 of the Patent Act. *See Chakrabarty*, 447 U.S. at 308 ("We have also cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed.").

In *Rutherford*, this Court was particularly careful not to reach past the FDA, the agency charged with implementing the FD&C Act. 442 U.S. at 553 ("[T]his Court has often recognized the construction of a statute by those charged with its administration

is entitled to substantial deference."). In fact, the Court ruled that deference "is particularly appropriate where, as here, an agency's interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives." *Id.* at 554. "Once an agency's statutory construction has been fully brought to the attention of the public and the Congress, and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned." *Id.* at 554, n.10; *see also Bob Jones Univ. v. United States,* 461 U.S. 574, 600 (1983) (declining to overturn agency interpretation of statute in view of unsuccessful legislation and Congress' "prolonged and acute awareness of so important an issue").

This case presents precisely the same kind of situation. As the Court counseled in *Chakrabarty*, "Whatever their validity, the contentions now pressed on us should be addressed to the political braches of the Government ... and not to the courts." *Chakrabarty,* 447 U.S. at 317.

CONCLUSION

For the reasons discussed above, the FCBA urges this Court to affirm the judgment of the court of appeals and reject the attempt of Petitioners' and certain *amici* to narrow the scope of patent eligibility under § 101.

Respectfully submitted,

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