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 OF THE ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, JANIS CHESTER, M.D., AND GRAHAM L. SPRUIELL, M.D., AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTIONS PRESENTED

1. Does the Court exceed its Article III powers by answering the Petitioners' Question Presented instead of limiting the Section 101 analysis to the Patent Claims, as issued?

2. Does the creation of a judicial exception to Section 101 of Title 35 violate the Bicameral and Presentment Clauses as well as the Patent Clause?

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

CONSTITUTION AND STATUTES

AUTHORITY

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INTERESTS OF *AMICI CURIAE*[1]

Amicus Association of American Physicians & Surgeons, Inc. ("AAPS"), is a national nonprofit association of thousands of physicians. Founded in 1943, AAPS has been a litigant in this Court and in other appellate courts. *See, e.g.*, *Cheney v. United States Dist. Court*, 542 U.S. 367, 374 (2004) (citing

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[1] This brief is filed with the blanket written consent of the Petitioners, and the filed written consent of Respondents. Pursuant to Supreme Court Rule 37.6, counsel for *Amici Curiae* authored this brief in whole, and no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *Amici* or *Amici's* counsel make a monetary contribution to the preparation or submission of this brief.

Association of American Physicians & Surgeons v. Clinton, 997 F.2d 898 (D.C. Cir. 1993)); *Association of American Physicians & Surgeons v. Mathews*, 423 U.S. 975 (1975). In addition, this Court has expressly made use of *amicus* briefs submitted by AAPS in high profile cases. *See, e.g.*, *Stenberg v. Carhart*, 530 U.S. 914, 933 (2000); *id.* at 959, 963 (Kennedy, J., dissenting); *District of Columbia v. Heller*, 554 U.S. 570, 704 (2008) (Breyer, J., dissenting).

Amicus Janis Chester, M.D., privately practices psychiatry in Delaware, serves as chair of the Department of Psychiatry at a community hospital, is a member of the faculty at Jefferson Medical College and has held a variety of positions with organized medicine and psychiatry, locally and nationally.

Amicus Graham Lindley Spruiell, M.D., is in private practice in Massachusetts and specializes in forensic psychiatry and psychoanalysis.

The motto of AAPS is "*omnia pro aegroto,*" which means "all for the patient." The individual physician *Amici*, Drs. Chester and Spruiell, are likewise devoted to the best interests of their patients. Advancing patients' interests means supporting and defending incentives for medical innovations. *Amici* oppose categorical judicial exclusion of certain medical inventions from patentability because that will reduce incentives for these innovations, and result in fewer advances for patients.

As physicians and a physician's organization, *Amici* have a strong interest in defending full patentability for medical innovations so that inventions will improve the care of patients by physicians.

PRELIMINARY STATEMENT

Petitioners have asked the Court to resolve an abstract legal question, the question of whether a human gene is patentable subject matter under 35 U.S.C. § 101.[2] That gives the Court a Hobson's choice: either to issue a non-justiciable advisory opinion or to exercise legislative power by creating a judicial exception to 35 U.S.C. § 101 in violation of the Bicameral, Presentment and Patent Clauses of the Constitution of the United States. U.S. CONST. art. I, §1, U.S. CONST. art. I, §7, cl. 2, and U.S. CONST. art. I, §8, cl. 8, respectively.

To prevent such a dilemma, *Amici* suggest that the Court narrow its focus to the claims contained in the issued patents, *i.e.* to determine whether Claims 1, 2, 5, 6, and 7 of U.S. Pat. No. 5,747,282 ["('282 Patent)"], Claims 1, 6, and 7 of U.S. Pat. No. 5,837,492 ["('492 Patent)"], and Claim 1 of U.S. Pat. No. 5,693,473 ["('473 Patent)"] (cumulatively, "Respondents' Claims") contain patentable subject matter under Section 101. Respondents' Claims refer to "isolated DNA". They do not refer to: "native DNA"; "human DNA"; or the "human gene." By narrowing its focus to the claims as issued, the Court reaffirms its constitutionally assigned role: to resolve an actual case or controversy.[3]

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[2] In this brief, the word "Section" refers to a section of Title 35 unless the brief specifies otherwise.

[3] By staying within its constitutionally prescribed role, the Court avoids becoming embroiled in questions that are political, ethical, moral or metaphysical. It thereby avoids becoming a policy-maker.

Amici curiae strongly disagree with the Petitioners' major premise that the existence of Respondents' Patents thwarts innovation and research in the field of breast or ovarian cancer genetics. Petitioners' Brief at 2-4, 7-9, 24-25, 41-48, and 56-57. The converse is true. Rather, innovation has been promoted by the public disclosure of Respondents' patents. Respondents' Brief at 10. In fact, more than two dozen patents have been issued which have referenced the Respondents' '473 Patent (19 references),[4] the '282 Patent (9 references),[5] and the '492 Patent (3 references).[6] The referencing patents have been assigned to a variety of universities and medical schools, several commercial entities, and even the government of the United States. The fact that only two of the referencing patents are assigned to Myriad further establishes that Myriad's patents have not thwarted research and development in the field but actually have promoted such research and development.

SUMMARY OF THE ARGUMENT

This case is about the allocation of powers between and among the branches. It is not about what the law "ought to be."

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[4] *See* U.S. Pat. Nos. 7,897,356; 7,897,335; 7,534,565; 6,897,018; 6,875,592; 6,838,256; 6,686,163; 6,653,126; 6,596,481; 6,566,070; 6,492,109; 6,403,303; 6,344,320; 6,342,483; 6,306,628; 6,235,263; 6,030,832; 5,912,127; and 5,750,400.

[5] *See* U.S. Pat. Nos. 8,372,580; 8,110,185; 7,897,356; 7,781,199; 6,838,256; 6,686,163; 6,492,109; 6,342,483; and 6,258,536.

[6] *See* U.S. Pat. Nos. 8,076,065; 7,933,722; and 7,897,356.

The Separation of Powers Doctrine, as implemented by the language and structure of the Constitution, prevents the Judiciary from creating a judicial exception to Section 101, the legislated determination of patentable subject matter. The Patent Clause squarely places that responsibility in the hands of Congress. U.S. CONST. art. I, §8, cl. 8. The courts may not expand or contract what Congress says is patentable. Thus, a judicially created exception to the legislated definition of patentable subject matter is outside the scope of the Patent Clause and ignores the Presentment and Bicameral Clauses. Although the Executive Branch is similarly prevented from amending what Congress has legislated to be patentable subject matter, the Executive Branch, in its *amicus* brief, has abandoned its prior position that isolated DNA sequences are patentable. Such a complete reversal of position by the Executive Branch, without a change in the underlying authorizing legislation, is inconsistent with the Constitution because it creates a dispensing power in the Executive Branch.

Furthermore, this case is not justiciable. The scope of the subject matter to be considered by the Petitioners' "Question Presented" (*i.e.* Are human genes patentable?) is substantially beyond that contained in Respondents' Claims. The Respondents' Claims are for specified isolated DNA sequences. They are not for any human gene. In our claims-based patent system, an inventor's right to exclusivity extends no further than the claims granted. Consequently, this Court lacks and the courts below lacked the jurisdiction to determine whether a human gene is patentable. Courts may only determine if the claims, as granted, contain

patentable subject matter. In order for the Court to respond to the hypothetical question of whether a "human gene" is patentable subject matter, the Court would have to render an advisory opinion in violation of the Constitution.

This Court may not strike down the Respondents' Claims by creating a judicial exception to Section 101. A judicially created exception to Section 101 overrides the considered judgments of both Congress and the President which had enacted Section 101 and invades their constitutionally assigned roles, to make and faithfully execute the laws, respectively.

The evidence that isolated DNA is patentable subject matter is strong. First, Congress and the President have enacted laws with the understanding that DNA sequences may be claimed as patentable subject matter. Second, the United States Patent and Trademark Office ("PTO") has issued rules and published examination procedures regarding the patenting of DNA sequences. Third, the PTO considers DNA sequences patentable subject matter since it has granted numerous patents for such claims. Fourth, various departments and agencies within the federal government are assignees of patents for isolated DNA sequences. Fifth, the United States Department of Health and Human Services ("HHS") is an assignee of the '282 patent.

The question of whether a human gene is patentable can only be answered by Congress. It is a legislative question.

ARGUMENT

I. CONGRESS HAS THE POWER UNDER THE PATENT CLAUSE TO DEFINE PATENTABLE SUBJECT MATTER, A POWER WHICH MAY NOT BE EXERCISED BY THE OTHER BRANCHES WITHOUT AMENDING THE CONSTITUTION.

A. The Power To Define Patentable Subject Matter Is Legislative.

The Patent Clause provides: "The Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries...." U.S. CONST. art. I, §8, cl. 8. From the beginning of our nation, Congress has exercised this power. Indeed, the first Congress provided for the issuance of "letters patent." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (referring to Act of Apr. 10, 1790, ch. 7, §1, 1 Stat. 109). Today, the patent statutes are codified in Title 35 of the United States Code.

B. Legislative Power May Only Be Exercised by Congress in Accord with the Bicameral and Presentment Clauses.

It is black-letter law that Congress, and only Congress, may enact a law in accord with "a single, finely wrought and exhaustively considered, procedure" as prescribed by the Bicameral and Presentment Clauses. *Immigration and Naturalization Service v. Chadha*, 462 U.S. 919, 951 (1983) ("*Chadha*"); *Clinton v. City of New York*, 524 U.S. 417, 439-440 (1998) ("*Clinton*"); *Metropolitan Washington Airports Authority v. Citizens for*

Abatement of Aircraft Noise, Inc., 501 U.S. 252, 276 (1991) ("*MWAA*").

The Bicameral Clause vests federal legislative power exclusively in a bicameral Congress. The Bicameral Clause provides: "All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives." U.S. CONST. art. I, §1.

The Presentment Clause, U.S. CONST. art. I, §7, cl. 2, sets forth the precise procedures by which Congress is permitted to make a law. The Presentment Clause provides:

> Every Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes a law, be presented to the President of the United States; If he approve he shall sign it, but if not he shall return it, with his Objections to that House in which it shall have originated, who shall enter the Objections at large on their Journal, and proceed to reconsider it. If after such Reconsideration two thirds of that House shall agree to pass the Bill, it shall be sent, together with the Objections, to the other House, by which it shall likewise be reconsidered, and if approved by two thirds of that House, it shall become a Law…."

U.S. CONST. art. I, §7, cl. 2. These legislative steps are not empty formalities. Rather, they are commands which simultaneously require and limit the participation of the Senate, the House of Representatives, and the President in the lawmaking process. As such, they may be altered or evaded only by an Amendment to the Constitution. *See Clinton*,

524 U.S. at 449; *Chadha*, 462 U.S. at 958 n.23. In *Chadha*, this Court explained:

> Explicit and unambiguous provisions of the Constitution prescribe and define the respective functions of the Congress and of the Executive in the legislative process ... These provisions of Art. I are integral parts of the Constitutional design for the separation of powers ... "[T]he principle of separation of powers was not simply an abstract generalization in the minds of the Framers: it was woven into the document that they drafted in Philadelphia in the summer of 1787." *Buckley v. Valeo*, 424 U.S. at 124 .... [T]he Framers were acutely conscious that the bicameral requirement and the Presentment Clauses would serve essential constitutional functions .... It emerges clearly that the prescription for legislative action in Art. I, §§ 1, 7, represents the Framers' decision that the legislative power of the Federal Government be exercised in accord with a single, finely wrought and exhaustively considered, procedure.

Chadha, 462 U.S. at 945-951.

Executive power must faithfully execute the laws. *See* U.S. CONST. art. II, § 3. As this Court explained in *Youngstown Sheet & Tube Co. v. Sawyer*:

> In the framework of our Constitution, the President's power to see that the laws are faithfully executed refutes the idea that he is to be a lawmaker. The Constitution limits his functions in the lawmaking process to the

> recommending of laws he thinks wise and the vetoing of laws he thinks bad. And the Constitution is neither silent nor equivocal about who shall make laws which the President is to execute.

343 U.S. 579, 587 (1952).

Judicial power is likewise limited. Judicial power is limited to resolving an actual case or controversy. Courts do not resolve policy debates:[7]

> The constitutional role of the courts, however, is to decide concrete cases – not to serve as a convenient forum for policy debates. *See Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982) ("[Standing] tends to assure that the legal questions presented to the court will be resolved, not in the rarified atmosphere of a debating society, but in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action").

Massachusetts v. E.P.A., 549 U.S. 497, 547 (2007) (Roberts, C.J., dissenting).

Indeed, the Court below emphasized the point that courts should not address policy arguments.

> Under the statutory rubric of § 101, isolated DNA is a tangible, man-made composition of matter defined and distinguished by its objectively discernible chemical structure.

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[7] *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997) ("The various policy arguments now made by both sides are thus best addressed to Congress, not this Court").

> Whether its unusual status as a chemical entity that conveys genetic information warrants singular treatment under the patent laws as the district court did is a policy question that we are not entitled to address. *Cf. Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S.Ct. 2566, 2579 … (2012) ("[*W]e possess neither the expertise nor the prerogative to make policy judgments. Those decisions are entrusted to our Nation's elected leaders, who can be thrown out of office if the people disagree with them.*"). Congress is presumed to have been aware of the issue, having enacted a comprehensive patent reform act during the pendency of this case, and it is ultimately for Congress if it wishes to overturn case law and the long practice of the PTO to determine that isolated DNA must be treated differently from other compositions of matter to account for its perceived special function. We therefore reject the district court's unwarranted categorical exclusion of isolated DNA molecules.

Association for Molecular Pathology v. Myriad Genetics, Inc., 689 F.3d 1303, 1330-31 (Fed. Cir. 2012) (Slip op. at 49-50) (emphasis added).

C. Legislative Power May Not Be Ceded to or Aggrandized by the Judicial Branch.

Our Constitution diffuses power in several ways. First, power is divided between the federal sovereign and the state sovereigns. Second, power is further diffused among the three branches of the federal government, *i.e.* the Legislative Branch, U.S. CONST. art. I, the Executive Branch, U.S. CONST. art. II, and

the Judicial Branch, U.S. CONST. art. III.[8] The Bicameral Clause further diffuses federal legislative power by dividing Congress into two separate chambers, the Senate and the House of Representatives. U.S. CONST. art. I, §1.

The Court has repeatedly held "the lawmaking function belongs to Congress, U.S. CONST. art. I, § 1 and may not be conveyed to another branch or entity." *Loving v. United States*, 517 U.S. 748, 757 (1996) (internal citation omitted). Accordingly, "Congress manifestly is not permitted to abdicate, or to transfer to others the essential legislative functions with which it is … vested." *Panama Refining Co. v. Ryan*, 293 U.S. 388, 421 (1935). "[I]t is a breach of the national fundamental law if Congress gives up its legislative power and transfers it to the President, or to the Judicial branch …." *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 406 (1928); *see also Youngstown Sheet & Tube Co.*, 343 U.S. at 655 (Jackson, J., concurring) ("The Executive, except for recommendation and veto, has no legislative power"); *Field v. Clark*, 143 U.S. 649, 692 (1892) ("That Congress cannot delegate legislative power to the President is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the Constitution").

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[8] *Muskrat v. United States*, 219 U.S. 346 (1911) ("That by the Constitution of the United States, the government thereof is divided into three distinct and independent branches, and that it is the duty of each to abstain from, and to oppose, encroachments on either").

Concerns of encroachment and aggrandizement of legislative power, as well as the abdication of legislative power by Congress, have been an integral part of this Court's separation of powers jurisprudence. *Mistretta v. United States*, 488 U.S. 361, 382 (1989) ("It is this concern of encroachment and aggrandizement that has animated our separation of powers jurisprudence and aroused our vigilance against the 'hydraulic pressure inherent within each of the separate Branches to exceed the outer limits of its power'").

The Separation of Powers Doctrine does not merely protect each branch from encroachments by the other two branches. Rather, the doctrine protects the people from the undue concentration of power in any branch. *MWAA*, 501 U.S. at 272 ("The structure of our Government as conceived by the Framers ... disperses the federal power among the three branches - ... placing both substantive and procedural limitations on each. *The ultimate purpose of this separation of powers is to protect the liberty and security of the governed*") (emphasis added).[9]

D. A Judicially Created Exception to Section 101 Impermissibly Exercises Legislative Power.

A judicially created exception to Section 101 is legislative in character and effect as it essentially amends Section 101. Amending legislation, as well as repeal of legislation, is a quintessentially legislative

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[9] In *Buckley v. Valeo*, the Court indicated the system of separated powers and checks and balances was regarded by the Framers "as a self-executing safeguard against the encroachment or aggrandizement of one branch at the expense of the other." 424 U.S. 1, 122 (1976).

function requiring bicameral passage and presentment to the President.

Although not every Congressional action is subject to the bicameralism and presentment requirements, those requirements must be met when Congress exercises legislative power. Whether particular actions are an "exercise of legislative power depends not on their form but upon 'whether they contain matter which is properly to be regarded as legislative in its character and effect.'" *Chadha*, 462 U.S. at 952 (internal citation omitted).

The legislative character of an action may be established by an examination of the congressional action it supplants. This "Supplantation Principle" was used to analyze the constitutionality of the legislative veto in *Chadha,* 462 U.S. at 952 ("The legislative character of the one-House veto in these cases is confirmed by the character of the Congressional action it supplants"). The Court should extend this principle to apply to all non-Congressional exercises of legislative power including: "legislative actions" undertaken by departments and agencies within the Executive Branch, "legislative actions" undertaken by the Judicial Branch, and "legislative actions" undertaken by independent agencies.

In *Chadha,* the Court examined the constitutionality of the legislative veto found in section 244(c)(2) of the Immigration and Nationality Act of 1952. Public L. 82-414, 66 Stat. 163, 214 (1952). The Court found that §244(c)(2) had an essentially legislative purpose and effect. Despite acknowledging that §244(c)(2) authorized one house, by resolution, to require the Attorney General to

deport an alien whose deportation would otherwise be canceled under §244, the Court reasoned that "the House took action that had the *purpose and effect of altering the legal rights, duties, and relations of persons,* including the Attorney General, Executive Branch Officials and Chadha, all outside the Legislative Branch." *Chadha,* 462 U.S. at 952 (emphasis added).[10] The Court explained that absent the House's action, Chadha would remain in the United States. Chadha's deportation could be accomplished only by new legislation requiring deportation, if at all. *Chadha,* 462 U.S. at 953-954.

Creating a judicial exception to section 101 is legislative in both character and effect. The relief sought – to create a judicial exception to section 101 – is the equivalent of legislation because it, in effect, amends Section 101. It affects the legal rights, duties and relations of many persons.

The power to "amend" an existing law is unquestionably a legislative power, which the Constitution vests solely in Congress. U.S. CONST. art. I, §1. *See Chadha,* 462 U.S. at 954 and *Clinton*, 524 U.S. at 438. It cannot be stressed too much that the Constitution begins with the allocation of legislative power solely to Congress. The first clause of the Constitution states: "All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives." U.S. CONST. art. I, §1.

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[10] *See also MWAA*, 501 U.S. at 276 ("In short, when Congress '[takes] action that ha[s] the purpose and effect of altering the legal rights, duties, and relations of persons … outside the Legislative Branch,' it must take that action by the procedures authorized in the Constitution."). *See also id.* at 258 n.4.

Nothing is unclear or ambiguous about this language. "All" means "all".[11]

E. Considering *United States v. Symonds*, New Legislation Is Required for the Executive Branch To Reverse Course and Argue Isolated DNA Is Not Patentable Subject Matter.

1. Under *Symonds*, a federal agency may not issue an order or regulation that is inconsistent with the authorizing statute.

The principle that neither the Judiciary nor the President may unilaterally exercise legislative power applies equally to subordinate federal departments and independent agencies. Thus, the PTO may not issue regulations in conflict with Title 35, and the Department of Justice ("DOJ") may not advocate a position that is inconsistent with Title 35 and the regulations promulgated thereunder. The DOJ and PTO, like the President, must see that the laws are faithfully executed. Although the Court has generally allowed regulations as interstitial "lawmaking", *Wayman v. Southard*, 10 Wheat. (23

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[11] The "Plain Meaning Rule" is one of several canons of construction applied by courts to determine the meaning of statutory provisions. Courts typically turn to this canon before others. *Connecticut National Bank v. Germain*, 503 U.S. 249, 253-54 (1992) ("We have stated … that courts must presume that a legislature says in a statute what it means and means in a statute what it says there … When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'") (internal citations omitted). This canon should also be applicable to the interpretation of the Constitution, including its first word (*i.e.* the word "all").

U.S.) 1, 43 (1825) (Marshall, Ch. J.), it has struck down regulations which conflict with the authorizing statute. For example, in 1887, the Supreme Court struck down an order issued by the Secretary of the Navy that provided that a particular training vessel was not to be considered "at sea" in connection with the compensation of an officer for "sea service." The Court reasoned that the Secretary did not have the authority to declare something as "shore duty" that the statute requires the Navy to treat as "sea duty." The Court declared that the Secretary of the Navy only had authority to "establish regulations in execution of, or supplementary to, *but not in conflict with*, the statutes defining his powers or conferring rights upon others." *United States v. Symonds*, 120 U.S. 46, 48-49 (1887) (emphasis added).

Furthermore, when an agency or executive department picks or chooses which laws or regulations to "faithfully execute." it turns rulemaking or executive action on its head – agency or executive department actions would control legislation instead of the rulemaking or executive actions being controlled by the legislation. Such a doctrine – agency or department control of legislation – has no support in the Constitution. It asserts a principle which would provide the executive departments, independent agencies and the President with an unlimited power – "a power to control the legislation of [C]ongress and paralyze the administration of justice." *Kendall v. United States ex rel. Stokes*, 12 Pet. (37 U.S.) 524, 613 (1838).

2. The PTO has issued regulations, guidelines and practices recognizing DNA sequences as patentable subject matter.

Subsections 1.821 through 1.825 of the patent rules recognize that nucleotide sequences are patentable subject matter. 37 C.F.R. §§ 1.821-1.825. *See also* Manual of Patent Examination Procedures ("MPEP") §2422. The PTO's favorable policy towards the patentability of isolated DNA was recognized below. An opinion concurring in part below said:

> For more than a decade the Patent Office's policy has been that "[a]n isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because … that DNA molecule does not occur in that isolated form in nature …." 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) … The PTO concluded that isolated DNA is patentable because it is different from what is found in nature – the process of synthesizing it or isolating it changes it. While the PTO lacks substantive rule making authority, it is not without expertise in this area. The explicit statement of the Patent Office's position on isolated DNA, however, is simply a continuation of a longstanding and consistent policy of allowing patents for isolated natural products. *See id.* (noting U.S. Patent 141,072, claiming "[y]east, free from organic germs of disease," issued to Louis Pasteur in 1873); *cf. In re Bergstrom*, 427 F.2d 1394 (CCPA 1970) (isolated prostaglandins patentable).

> According to the Patent Office, isolated DNA is no different from the isolated natural products of *Parke-Davis*. *See* 66 Fed. Reg. at 1093 (quoting Parke-Davis).

Association for Molecular Pathology, 689 F.3d at 1343-44 (Moore, J., concurring) (slip op. at 14-15) (emphasis added). *See also* Resp. Brief at 3-5, 29-31, 37-38, and 49-50 (regarding the PTO's longstanding practice).

3. The PTO has recognized isolated DNA as patentable subject matter by issuing patents with claims for isolated DNA.

The PTO's recognition of the patentability of isolated DNA did not go unnoticed by the Federal Circuit. In his concurring opinion below, Judge Moore recognized the PTO's issuance of thousands of patents for isolated DNA. Considering *Symonds*, those patents could only have been issued if, and only if, isolated DNA is patentable subject matter. Judge Moore stated:

> Likewise, the United States Patent Office has allowed patents on isolated DNA sequences for decades, and, more generally, has allowed patents on purified natural products for centuries. There are now thousands of allowed patents with claims to isolated DNA, and some unknown (but certainly large) number of patents to purified natural products or fragments thereof…I believe we must be particularly wary of expanding the judicial exception to patentable subject matter where

> both settled expectations and extensive property rights are involved.

Association for Molecular Pathology, 689 F.3d at 1343 (Moore, J., concurring) (slip op. at 13-14) (footnotes omitted). *See also* Resp. Brief at 3, 30.

While it is apparent that this Court's decision could have a substantial economic impact upon the inventors of patents for isolated DNA as well as upon investors in those patents, it is less apparent that an unrestrained opinion could have a devastating effect upon inventors and investors in other industries where the technologies depend upon the isolation, purification or distillation of molecules. Technologies involving: flavorings; fragrances; energy and petrochemicals; and vitamins and nutritional supplements are all at risk.

Any *post hoc* exclusion of subject matter would send a chilling, if not devastating, message to all inventors and investors who may have spent considerable time and/or money to obtain and commercialize a patent. Indeed, normal patent prosecution takes two to three years. Some patent prosecutions have lasted decades. *See, e.g. Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, LP*, 422 F.3d 1378, 1386, *amended*, 429 F.3d 1051 (Fed. Cir. 2005)) (Fourteen of Jerome H. Lemelson's issued patents were prosecuted over an 18-39 year period but were ultimately invalidated for prosecution laches).[12]

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[12] Like Lemelson's prosecution of his patent applications, the Petitioners herein have let many years lapse before bringing their Complaint to invalidate Respondents' patents.

4. Other federal departments and agencies recognize that isolated DNA is patentable subject matter because they are assignees of patents containing claims for isolated DNA.

Not only has the PTO issued thousands of patents for isolated DNA or nucleotide sequences,[13] but many of those patents have been assigned to other agencies and departments within the federal government including the Department of Health and Human Services[14] (including the Center for Disease Control[15]), and the Army.[16] The expressed position of the United States, as *amicus curiae*, is not consistent with the receipt of such assignments. U.S. Brief at 5, 10, 20-33. Those assignments belie any argument

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Consequently, relief should be denied under either a laches or failure to prosecute theory.

[13] S*ee* Resp. Brief at 28, 30.

[14] *See, e.g.*, U.S. Pat. No. 8,148,082, Claim 1 ("An isolated nucleic acid molecule that encodes a PTC taste receptor, or non-transmembrane fragment thereof, comprising at least 14 nucleotides of SEQ ID NO: 1 or SEQ ID NO: 3, wherein the nucleic acid molecule comprises nucleotide 145 of SEQ ID NO: 1 or SEQ ID NO: 3.").

[15] *See, e.g.*, U.S. Pat. No. 7,220,852, Claim 1 ("An isolated nucleic acid molecule consisting of the nucleotide sequence as set forth in SEQ ID NO: 1."); U.S. Pat. No. 8,119,788, Claim 1 ("An isolated nucleic acid molecule consisting of the nucleic acid sequence as set forth in SEQ ID NO: 1 or 2."); and Claim 13 ("An isolated nucleic acid molecule consisting of the nucleic acid sequence as set forth in SEQ ID NO: 1 or 2, wherein the nucleic acid is labeled.").

[16] *See, e.g.*, U.S. Pat. No. 7,029,853, Claim 1 ("An isolated and purified DNA fragment from chromosomal DNA of *B. anthracis* consisting essentially of the nucleotide sequence of SEQ ID NO:5.").

that "isolated DNA" is not patentable as a "composition of matter" pursuant to section 101.[17]

II. PATENT CLAIMS LIMIT AN INVENTOR'S EXCLUSIVITY RIGHTS AND JUDICIAL REVIEW OF THE PATENT.

The axiom that "claims claim," is a principle that is at the heart of the United States' patent system. This is evident throughout Title 35, throughout the rules promulgated pursuant to Title 35, and throughout the MPEP. It is also evident in the decisions of this Court and the Federal Circuit. Claims define what an inventor applies for, what examiners examine, and what the PTO ultimately grants to an inventor. Most importantly, claims specify the boundaries of the patented subject matter for which exclusivity is granted, providing notice of those boundaries both to the inventor and to the rest of the world. Moreover, when a court determines the validity or infringement of a patent, the *res* or object of the dispute is the claims, as issued.

Amici suggest that because the word "claim(s)" pervades the patent laws, regulations and examination procedures, the Respondents' Claims, as issued, is the appropriate starting point and ending point for the Court's analysis. *Amici* further suggest that because the "human gene" is not congruent with the isolated DNA in Respondents' Claims, Petitioners have asked the Court to respond to an abstract legal question, which the Court is not empowered to answer.

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[17] Furthermore, the United States, as an assignee of the '282 Patent, expressly recognizes the patentability of isolated DNA.

A. Claims Provide the Metes and Bounds of an Inventor's Exclusivity Rights.

According to the PTO, "The claims define the property rights provided by a patent, and thus require careful scrutiny. The goal of claim analysis is to identify the boundaries of the protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is the invention." MPEP § 2103(I)(C).

One treatise regarding practicing before the Federal Circuit has elaborated on this point.

> A claim in a patent provides the metes and bounds of the right the patent confers on the patentee to exclude others from making, using, or selling the protected invention. The words of a claim describe and point out the invention by a series of limiting words or phrases – "limitations." A court may not disregard claim limitations and effectively rewrite the claims, nor may it read narrow claim limitations into broader claims, whether to avoid invalidity or to escape infringement. Without these fundamental rules, the court fears, the entire statutory and regulatory structure governing the drafting, submission, examination, allowance, and enforceability of claims would crumble.

Robert L. Harmon, Cynthia A. Homan, and Charles M. McMahon, PATENTS AND THE FEDERAL CIRCUIT 18 (10th Ed. 2011) (footnotes omitted, emphasis added).

> After all, the claims, not the specification, provide the measure of the patentee's right to exclude. Indeed, the claims of a patent are the

> sole measure of the patent grant. Once they issue in a particular form, the protected invention is, as a matter of law, that form. The disclosure of a patent is in the public domain, save as the claims forbid. The claims alone delimit the right to exclude; only they may be infringed.

Id. at 10 (footnotes omitted, emphasis added).

B. The Use of the Word "Claims" in Title 35, Patent Regulations, and MPEP Delimit a Patentee's Exclusivity Rights.

1. Claims are a focus, if not the central focus, of Title 35.

Although this case has been presented as a question of whether a "human gene" is patentable subject matter under Section 101, Section 101 explicitly incorporates all the requirements and conditions of Title 35. Section 101 provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or any composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, *subject to the conditions and requirements of this Title*." 35 U.S.C. § 101 (emphasis added). Many of the conditions and requirements expressly refer to a patent's "claims". The word "claim" or "claims" is found either explicitly or implicitly in sections regarding the patent application, § 111, regarding the "specification" and "claims", § 112, regarding the applicant's oath, § 115, and even regarding the fees for submitting an application, § 41.

Section 112 provides that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming what the applicant regards as his invention." 35 U.S.C. § 112 (emphasis added).

The Court may also wish to note that Congress has expressly provided that if some claims within a patent are found to be invalid, the remainder of the claims may still be enforced. Section 288 provides, in part, "[w]henever a claim of a patent is invalid, an action may be maintained for the infringement of a claim of the patent which may be valid...." 35 U.S.C. § 288 (emphasis added).

2. Claims are at the core of the patent examination process and of the rights granted.

Section 2(b)(2)(A) of Title 35 provides: "The [Patent and Trademark] Office ... may establish regulations, not inconsistent with law, which – shall govern conduct of proceedings in the Office." Pursuant to this congressionally delegated authority, the PTO has promulgated numerous regulations regarding or referring to patent "claims". First and foremost is Rule 1.75 entitled "Claims".

Patent Rule 1.75(a) basically reiterates 35 U.S.C. §112. Rule 1.75(a) provides: "The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery." 37 C.F.R. §1.75(a) (emphasis added).

Rules regarding the "application", *id.* at §1.51(b), the "oath", *id.* at §1.63(b)(2), and the "fees", *id.* at §1.16, also emphasize patent "claims".

Rule 1.104 is directed to the patent examination process. Subsection (a)(1) provides: "On taking up an application for examination …, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention." 37 C.F.R. §1.104(a)(1) (emphasis added). Subsection (c)(1) provides: "If the invention is not considered patentable, or not considered patentable as claimed, the claims, or those considered unpatentable will be rejected." 37 C.F.R. §1.104(c)(1) (emphasis added).

3. Sections 2103 *et seq.* of the MPEP confirm that claims are at the core of the patent examination process and delimit the inventor's rights.

Sections 2103 *et seq.* are directed towards the patent examination process. In conducting an examination, great emphasis is placed on the claims. "[E]ach claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of an application, even if one or more of the claims is found to be deficient with respect to some statutory requirement." MPEP §2103(I).

Subsection 2103(I)(C) discusses how examiners are to review claims. It begins:

> The claims define the property rights provided by a patent, and thus require careful scrutiny. The goal of claim analysis is to identify the

> boundaries of the protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is the invention. USPTO personnel must first determine the scope of a claim by thoroughly analyzing the language of the claim before determining if the claim complies with each statutory requirement for patentability. See *In re Hiniker Co.*, 150 F.3d 1362, 1369 … (Fed. Cir. 1998) ("[T]he name of the game is the claim.").

MPEP §2103(I)(C) (emphasis added).

Section 2105 of the MPEP is particularly relevant. It is entitled "Patentable Subject Matter – Living Subject Matter." It provides:

> The decision of the Supreme Court in *Diamond v. Chakrabaty*, 447 U.S. 303 … (1980), held that microorganisms produced by genetic engineering are not excluded from protection by 35 U.S.C. §101. It is clear from the Supreme Court decision and opinion that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention.

MPEP §2105 (emphasis added). This section sets forth the PTO's interpretation of the *Chakrabaty* decision and guidelines to be used in interpreting Section 101 of Title 35. Quoting *Chakrabaty*, MPEP §2105(2), says:

> In choosing such expansive terms as … "composition of matter," modified by the comprehensive "any", Congress plainly contemplated that the patent laws would be given wide scope.

MPEP §2105 (emphasis added).

Two years ago, Congress prohibited the patenting of human organisms. Section 33 of the Leahy-Smith America Invents Act ("AIA"), Pub. L. 112-29, 125 Stat. 264, §33 (2011) ("Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."). This prohibition is, however, not directed to isolated DNA, DNA, or even genes. The prohibition covers entire human organisms including embryos and fetuses. MPEP §2105 explains:

> The legislative history of the AIA includes the following statement, which sheds light on its meaning of this provision:
>
> [T]he U.S. Patent Office has already issued patents on genes, stem cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter.

MPEP § 2105 (quoting 157 Cong. Rec. E1179 (June 23, 2011) (Statement of Christopher H. Smith (NJ) incorporating Speech of Representative Dave Weldon on November 22, 2003)). Representative Smith expanded upon how this amendment should be construed. He said:

> This amendment should not be construed to affect claims directed to or encompassing subject matter other than human organisms, including but not limited to claims directed to or encompassing the following: cells, tissues, organs, or other bodily components that are not themselves human organisms (including, but not limited to, stem cells, stem cell lines, genes, and living or synthetic organs); hormones, proteins, or other substances produced by human organisms ...

157 Cong. Rec. at E1180 (emphasis added).

Representative Lamar Smith (TX), the lead sponsor of the AIA in the House of Representatives, explicitly recognized the patentability of nucleic acids. He said.

> The Committee recognizes that the economic viability of the biotechnology industry requires that patents be available for the full spectrum of innovation that may be subject to commercialization. The legislation, accordingly does not limit patent eligibility for any type of biotechnology invention that may be commercialized in the United States. 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 construed to limit the ability of the PTO to issue a patent containing claims directed to or encompassing:

> 1. any chemical compound or composition, whether obtained from animals or human beings or produced synthetically, and whether identical to or distinct from a chemical structure as found in an animal or human being, including but not limited to nucleic acids, polypeptides, proteins, antibodies and hormones ...."

157 Cong. Rec. at E1183 (emphasis added).

MPEP Sections 2171, 2172 and 2173 confirm that patent claims set forth the boundary between an inventor and the public regarding the protected subject matter. These sections also confirm that it is the inventor who specifies, in the patent claims, what is to be patented.

C. According to this Court and the Federal Circuit, Claims Provide the Metes and Bounds of an Inventor's Exclusivity Rights.

In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), this Court provided a historical perspective on the evolution of modern claims practice.

> [A]s early as 1850 "judges were ... beginning to express more frequently the idea that in seeking to ascertain the invention 'claimed' in a patent the inquiry should be limited to interpreting the summary, or 'claim' ....

Id. at 378-379 (emphasis added, citations omitted).

The Federal Circuit, in *Markman*, had even more explicitly made the point that "*[t]he written description part of the specification does not delimit the right to exclude. That is the purpose and function*

of the claims." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) (emphasis added).

Almost two centuries ago, this Court made it abundantly clear that Congress required the specification to include a portion which the inventor "shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery." *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876) (concerning an early version of the patent statute, the Act of July 4, 1836).

More recently, the Court said: "The [patent] monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kabushiki Co.*, 535 U.S. 722, 730-31 (2002).

In 2005, the Federal Circuit held *en banc* that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*), *cert. denied*, 546 U.S. 1170 (2006) (internal quotations and citations omitted). Referring to 35 U.S.C. § 112, ¶ 2, the Chief Judge of the Federal Circuit said: "[b]ecause claims delineate the patentee's right to exclude, the patent statute requires the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent." *Halliburton Energy Services, Inc. v. M-*

1, LLC, 514 F.3d 1244, 1249 (Fed. Cir. 2008) (emphasis added, citations omitted) (Michel, C.J.).

In a number of cases, the Federal Circuit has stated: "An essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." *See e.g., In re Buszard*, 504 F.3d 1364, 1366 (Fed. Cir. 2007) (quoting *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989)).

In short, *Amici* believe that this Court should examine the Respondents' Claims as issued and not examine the "human gene."

D. Having Ignored the Respondents' Claims, Petitioners Have Asked the Court to Issue an Advisory Opinion which Is Beyond the Court's Power.

Although the Petitioners presented three questions to the Court, only their first question is before the Court. That question is: "Are human genes patentable?"

Amici believe that there is no case or controversy. A comparison of a "human gene" to the isolated DNA in the Respondents' Claims reveals that they are not the same and that by examining a human gene, the Court would only be responding to an abstract legal question.

Thus, the first question for this Court, like any court, is whether or not it has jurisdiction to hear the case. As this Court has explained, "'[n]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases

or controversies.'" *Raines v. Byrd*, 521 U.S. 811, 818 (1997) (internal citation omitted). Furthermore, "[t]he Court has recognized that the case-or-controversy limitation is crucial in maintaining the tripartite allocation of power set forth in the Constitution." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341 (2006) (internal quotation marks and citations omitted).

Because "[t]he Supreme Court is not empowered to decide abstract propositions ..." *Webster v. Reproductive Health Services*, 492 U.S. 490, 507 (1989) (quoting *Tyler v. Judges of Court of Registration*, 179 U.S. 405, 409 (1900)), it may not hear this case.

CONCLUSION

For the foregoing reasons, the Court should either affirm the decision below or withdraw certiorari as having been improvidently granted.

Respectfully submitted,

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