No. 12-398

In The Supreme Court of the United States

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

Petitioners,

v.

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

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF FOR THE INTELLECTUAL PROPERTY AMICUS BRIEF CLINIC OF THE FRANKLIN PIERCE CENTER FOR INTELLECTUAL PROPERTY AT THE UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae is The Intellectual Property Amicus Brief Clinic of the Franklin Pierce Center for Intellectual Property. The Center is a part of University of New Hampshire School of Law (formerly Franklin Pierce Law Center). The Clinic was established to submit briefs for selected cases with the hopes of contributing important perspectives that might not otherwise be adequately represented. The Clinic seeks to file *amicus* briefs that will lead to the development and predictable application of intellectual property law to promote innovation and competition. This brief represents only the views of the participants in the Amicus Brief Clinic and the advisors to the clinic, and does not represent the views of the University of New Hampshire School of Law, the Franklin Pierce Center for Intellectual Property, or their faculty.

SUMMARY OF ARGUMENT

The Court granted certiorari on the question "Are human genes patentable." However this is the wrong

[1] The petitioners have filed a letter of blanket consent to *amici* on January 2, 2013. Respondents granted consent to *amicus* on March 6, 2013, via electronic mail, a copy of which is being submitted herewith. No counsel for any party authored this brief in whole or in part, and no person or entity, other than *amici* and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

question for two reasons. First, the claims in the patents at issue are not directed to human genes in the human body. Instead, the claims are directed to isolated DNA. Second, whether the claims are "patentable" is not the issue in this case. Instead, the issue is limited to whether the claims are "patent eligible." As a result, the proper question is not whether human genes are patentable, but rather "Is Isolated DNA Patent Eligible?"

The standard for patent eligibility is set forth in 35 U.S.C. § 101, which establishes that compositions of matter are patent eligible. The claims at issue in this case are directed to isolated DNA, which is a composition of matter. In addition, isolated DNA is not a law of nature, a natural phenomenon, or an abstract idea. Therefore, the answer to the specific question of whether isolated DNA is patent eligible subject matter is clearly yes.

The next question of whether isolated DNA is patentable is a separate question which includes the requirements of §§ 102, 103, and 112 in addition to the patent eligibility issue of § 101. This question of patentability is not before this Court on appeal.

ARGUMENT

I. Introduction: The Court has Granted Certiorari on the Wrong Question

The Court granted certiorari on the question "Are human genes patentable." This question was presented by the petitioner, but the question is misleading with respect to the claims in this case.[2] As skilled advocates, the way the petitioner presented the question suggests the answer petitioner seeks, but the actual issue in this case does not so easily lead to the same answer. Answering the question presented by the petitioner, human genes in the human body occur in nature and are therefore not patentable. However, this is the wrong question, because this is not at issue in this case. The claims in the patents at issue are not directed to human genes in the human body, but to isolated DNA which codes for a protein. Further, the proper question is not whether such isolated DNA is patentable, but whether it is patent eligible.

II. Patentability is Different from Patent Eligibility, and Patent Eligibility is at Issue in the Present Case

In order for an invention to be patentable, the subject matter must first be deemed patent eligible. Patent eligibility is not the same as patentability.

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[2] The Court has ability to deny the formulation of the issues presented by the petitioner. *See U.S. v. Katz*, 389 U.S. 347, 350 (1967).

Rather, patent eligibility is the gateway to patentability. Patentability considers questions not only of patent eligibility but additionally considers novelty, obviousness, and adequacy of the written description. 35 U.S.C. §§ 101, 102, 103 and 112 (2012). As stated in *Application of Bergy*:

> "Achieving the ultimate goal of a patent . . . involves, to use an analogy, having the separate keys to open in succession the three doors of sections 101, 102, and 103, the last two guarding the public interest by assuring that patents are not granted which would take from the public that which it already enjoys (matters already within its knowledge whether in actual use or not) or Potentially [sic] enjoys by reason of obviousness from knowledge which it already has."

596 F.2d 952, 960 (C.C.P.A. 1979). The present case involves only patent eligibility. *See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1324 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012).

Congress established the patent eligibility standard in 35 U.S.C. § 101: "Whoever invents or discovers any new and useful . . . composition of matter . . . may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. This Court has repeatedly confirmed the broad scope of patent eligible subject matter in § 101: "[i]n choosing such expansive terms modified by the comprehensive 'any,' Congress plainly contemplated that the

patent laws would be given wide scope." *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)). Congress has left to other parts of the Patent Act the task of guarding the public interest by "assuring that patents are not granted which would take from the public that which it already enjoys" and assuring that inventions are adequately disclosed in return for the exclusive right granted by the patent. *Bergy*, 596 F.2d at 960; *see* 35 U.S.C. § 112 (2012).

As a general rule, patent eligibility extends "to 'include anything under the sun that is made by man.'" *Chakrabarty*, 447 U.S. at 309 (1980) (citing S.Rep.No.1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep.No.1923, 82d Cong., 2d Sess., 6 (1952)). While this seems to establish an extremely low bar for patent eligibility, the Court has carved out some exceptions to this general rule, restricting from patent eligibility "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Diehr*, 250 U.S. 175, 185 (1980). Furthermore, claims which wholly preempt the use of a judicial exception are not patent eligible. *Bilski*, 130 S. Ct. at 3258 (2010) (Breyer, J., concurring). As will be discussed below, isolated DNA is not a law of nature, a natural phenomenon, nor an abstract idea; it is a composition of matter. A composition of matter is a real physical thing with physical limitations that cannot simply be ignored.

Once an invention has passed this minimal bar of patent eligibility, the invention should then be analyzed for the remaining patentability requirements

of 35 U.S.C. §§ 102, 103, and 112. We urge the Court not to infuse the patent eligibility analysis with these other patentability considerations, which are better suited for consideration under these more appropriate provisions of the statute. For example, just because a claim is extremely broad does not mean that it is not directed to patent eligible subject matter.[3] These problems with claim scope are better resolved under, for example, the enablement requirement of 35 U.S.C. § 112. Claims that belong to a category of inventions that some believe are of "suspect validity" does not necessarily mean that the claim is not patent eligible at the threshold. *Bilski*, 130 S. Ct. at 3229. Validity concerns are better resolved, for example, under the standard for nonobviousness of 35 U.S.C. § 103. This is particularly true after the Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). This decision is widely recognized as tightening the obviousness standard. *See generally* Jennifer Nock & Sreekar Gadde, *Raising the Bar for Nonobviousness: An Empirical Study of Federal Circuit Case Law Following KSR*, 20 FED. CIRCUIT B.J. 369 (2011). Just because a claim recites an old element (*e.g.*, hedging in *Bilski* – not patent eligible; the Arrhenius equation in *Diehr* – patent eligible) does not indicate that the claim is directed to

[3] This is analogous to the Court's recognition that: "Broad general language is not necessarily ambiguous when congressional objectives require broad terms." *Chakrabarty*, 447 U.S. at 315.

patent ineligible subject matter. *See Bilski*, 130 S. Ct. at 3229; *Diehr*, 450 U.S. at 178. Questions regarding the novelty of an invention are better analyzed under 35 U.S.C. § 102.

The Court's recent decision in *Mayo v. Prometheus* states that to be patent eligible, a method claim including a law of nature must include "additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012). The Court recognized that in evaluating additional method steps to determine whether they add such additional features, "the §101 patent-eligibility inquiry and, say, the §102 novelty inquiry might sometimes overlap." *Id.* at 1304. The claims that are currently before the court, however, are not method claims, nor (as will be argued below) are they directed to laws of nature or natural phenomena. Thus, the Court's decision in *Mayo v. Prometheus* is inapplicable to the claims at issue. The isolated DNA to which the claims are directed are compositions of matter which have been significantly altered from their naturally occurring forms. The explicit limitations of the claims separate the subject matter of the claims from any natural law or natural phenomenon, and cannot be ignored.

III. The Myriad Claims are Directed to Isolated DNA, a Composition of Matter, and the Specification Specifically Defines "Isolated"

The claims in a patent describe the metes and bounds of an invention. All claims have three principal components: a preamble, a transitional phrase, and a body. One of the basic claim types is a composition of matter claim which corresponds to the composition of matter statutory category in 35 U.S.C. § 101.

The preamble is generally a short introductory phrase to frame the context of the claim. The purpose of the preamble is to "indicate the statutory class of the claim (often by implication from the words in the preamble) and to name or define the thing that is to be claimed." ROBERT C. FABER, LANDIS ON MECHANICS OF PATENT CLAIM DRAFTING § 2.4 (6th ed., release no. 8, 2012). Most patents contain more than one claim. If some of the claims are directed to different statutory classes of invention, the preambles of the claims to each statutory class will be different. JEFFREY G. SHELDON, HOW TO WRITE A PATENT APPLICATION § 7.3.3 (2nd ed., release no. 6, 2012). The transitional phrase separates the preamble from the body of the claim. The term "comprising" is the most frequently used transitional phrase. The body of the claim includes the limitations of the invention.

Composition of matter claims are used to define "all compositions of two or more substances and . . . all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether

they be gases, fluids, powders or solids." *Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957). As explained below, the claims at issue in this case are composition of matter claims.

IV. Isolated DNA as Defined in the Myriad Patents is a Composition of Matter and is Therefore Patent Eligible

Having established that the issue is patent eligibility, and that compositions of matter, such as isolated DNA, are generally patent eligible, the argument turns to the invention at issue: isolated DNA.

Claim 1 in Myriad's '282 patent [hereinafter Claim 1] claims "An isolated DNA coding for a BRCA1 polypeptide. . . ." U.S. Patent No. 5,747,282 col. 153 l. 56 (filed June 7, 1995). Claim 1 is representative of the claims at issue in this case. This claim and the other claims in the patents at issue are directed to isolated DNA molecules. The preamble of Claim 1 states "[a]n isolated DNA. . . ." *Id.*

In Myriad's patents at issue, "[a]n 'isolated' . . . nucleic acid . . . is one which is substantially separated from other cellular components. . . . The term embraces a nucleic acid sequence of protein which has been removed from its naturally occurring environment. . . ." U.S. Patent No. 6,033,857 (filed Mar. 20, 1998); U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996); U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S.

Patent No. 5,710,001 (filed June 7, 1995); U.S. Patent No. 5,709,999 (filed June 7, 1995); U.S. Patent No. 5,693,473 (filed June 7, 1995). When a term is clearly defined in the specification of a patent, this meaning must be applied when construing the claims using that term. *Phillips v. AWH Corp.*, 415 F.3d 1303 (2005) ("the specification 'acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication"). The isolated DNA, as limited by the preamble in Myriad's claims, therefore, is DNA that has been extracted, purified, and chemically altered. Thus, the isolated DNA "constitute[s] an *a fortiori* situation, where [it is] not only purified; [it is] different from the natural products in 'name, character, and use.'" *Chakrabarty*, 447 U.S. at 309-10; *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1328-29 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012). Unlike in *Funk Bros*, where the nematodes were not changed in any manner other than mixing of different unaltered nematodes, the isolated DNA at issue here is significantly changed from its naturally occurring form. *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

Additionally, the particular claims of Myriad's 5,837,492 patent relate to a subset of isolated DNA, as defined by Myriad's patents, known as complementary DNA, or cDNA. U.S. Patent No. 5,837,492 cols. 167-69 (filed Apr. 29, 1996) (claiming cDNA as a "replicative cloning vector" as defined in the

specification). As explained in the prior Federal Circuit decision:

> cDNA is synthesized from mRNA using complementary base pairing in a manner analogous to RNA transcription. . . . Because it is synthesized from mRNA, cDNA contains only the exon sequences, and thus none of the intron sequences, from a chromosomal gene sequence.

Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d at 1313-14. The claimed cDNA is an invention that is made by man as was the microorganism made by Chakrabarty. *See Chakrabarty*, 447 U.S. 303.

Substances that have been isolated from naturally occurring sources are "new" under 35 U.S.C. § 101 when the resulting substance is substantially different from the naturally existing source. *Id.* at 310. This must be true, for § 101 specifically grants patent eligibility to compositions of matter, and all matter is made completely of known atoms and derived from naturally existing materials. 35 U.S.C. § 101 (2012). What matters for issues of patent eligibility is the specific structure of the compound claimed. In the patents at issue, the specific claimed structures are particular isolated DNA sequences.

At no point during a cell's natural lifecycle are sequences isolated in the manner claimed by Myriad.[4]

As noted in other *amicus* briefs, it is possible for the random process of DNA fragmentation following cell death to result in a DNA fragment with any sequence. *See, e.g.,* Brief for Eric S. Lander as Amicus Curiae in Support of Neither Party, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303 (Fed. Cir. 2012), *appeal docketed*, No. 12-398 (U.S.

[4] While long chain DNA exists in nature, it exists in a highly organized structure, and is generally only dissolved upon cell death. The primary purpose of long chain DNA is the storage of genetic information to serve as a set of instructions for protein generation. An analogy to construction may be helpful. When proteins are built by cells, DNA serves as the architect; its base pairs interact with RNA polymerase to create mRNA, the blueprint. RNA polymerase "unzips" the native DNA's double-helix structure by temporarily breaking the hydrogen bonds connecting the strands, creating the mRNA through breaking the hydrogen bonds connecting the strands, creating the mRNA through use of base-pair association with the strand of DNA it is attached to. As RNA polymerase moves along the DNA strand, the DNA "rezips" back into its original structure. Upon reaching a transcription terminator, the RNA polymerase disengages from the DNA, leaving the DNA fully reassembled, and releasing the completed mRNA into the cell. It is from this mRNA "blueprint" that proteins are created. Through this entire process, the gene region on the DNA strand remains bound to the rest of the DNA. Due to the substitution of uracil in RNA for the thymine bases in DNA, RNA is not interchangeable with DNA, thus, isolated DNA is not found in this process. *See generally Animation: mRNA Synthesis*, MCGRAW-HILL, http://highered.mcgraw-hill.com/sites/0072507470/student_view0/chapter3/animation__mrna_synthesis__transcription___quiz_1_.html (last visited Mar. 9, 2013).

Sept. 25, 2012), 2013 WL 432959. However, the claims must be read in light of the specification. 37 C.F.R. § 1.75(d)(1) (2012). As previously stated, the specifications at issue all define "isolated" as "substantially separated from other cellular components." U.S. Patent No. 5,747,282 col. 19 ll. 8-18 (filed June 7, 1995). Therefore, any DNA fragments that may result from this process are still not "isolated" DNA as defined in the specifications.

Because isolated DNA must be obtained through laboratory techniques, it is not naturally occurring, and therefore fulfills the "new" requirement of 35 U.S.C. § 101. 35 U.S.C. § 101.

While the utility of isolated DNA is not at issue in this case, for a proper patent eligibility determination, it must be considered. 35 U.S.C. § 101; *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012); Brief for Petitioner, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303 (Fed. Cir. 2012), *appeal docketed*, No. 12-398 (U.S. Sept. 25, 2012), 2012 WL 4502947. Isolated DNA has many scientifically-recognized uses, including experimental marking and testing for genetic diseases or predisposition to certain genetic diseases (as in the case of the BRCA1 and BRCA2 genes at issue here). *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303, 1314 (Fed. Cir. 2012). With such identified man-made uses, it is clear that isolated DNA has operable and practical utility. *Juicy Whip v. Orange Bang*, 292 F.3d 728 (Fed. Cir. 2007).

As discussed above, in addition to being new and useful, it is necessary that none of the judicial exceptions to patent eligibility apply. In particular, isolated DNA is not a law of nature, a natural phenomenon, nor an abstract idea; it is a composition of matter and as such, a real, physical thing.

Abstract ideas have been repeatedly held patent-ineligible. *See, e.g., Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *State St. Bank & Trust Co. v. Signature Fin. Grp., Inc.*, 149 F.3d 1368 (Fed. Cir. 1998). Unlike the inventions in any of those cases, isolated DNA is a physical, tangible thing; therefore, it cannot be abstract nor can it wholly preempt an abstract idea. Laws of nature have similarly been held not patent eligible. *See, e.g., Mayo Collaborative Servs v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012). But, unlike, for example, Einstein's famous $E=mc^2$, isolated DNA is a composition of matter, not a law of nature. Finally, although discussed in several cases, the physical phenomena exception to patent-eligibility has not been formally defined. Douglas L. Rogers, *Coding for Life – Should Any Entity Have the Exclusive Right to Use and Sell Isolated DNA?*, 12 PITTSBURGH J. TECH. L. & POL'Y 3 (2011) ("The Supreme Court has not defined 'physical phenomena'"); *see, e.g., Mayo Collaborative Servs.*, 132 S. Ct. 1289; *Bilski*, 130 S. Ct. 3218. Regardless of this lack of definition, as a composition of matter, isolated DNA should not fall into a category supposedly containing such concepts as electromagnetism or the weather. Additionally, the isolated DNA is man-made and cannot wholly preempt a natural

phenomenon because the preamble to the claim is limited specifically to isolated DNA. *See* U.S. Patent No. 5,747,282 col. 19 ll. 8-18 (filed Jun. 7, 1995).

V. The Correct Question to Ask is "Is Isolated DNA Patent Eligible?"

Based on the issues presented in this case, the question the Court should be asking, and is understood to be the question the Court intended to ask, is "Are isolated DNA molecules patent eligible?" As the Federal Circuit stated in its opinion, "the issue is *patent eligibility,* not *patentability*." *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1324 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012) (emphasis added). The principal claims at issue relate to isolated DNA molecules, not to human genes in the human body. *See id.* at 1325.

In addition to not answering the issues in this case, there are other consequences of asking the wrong question. Asking the question presented has led to public alarm. Jonathan Stempel, *Supreme Court to Decide if Human Genes Patentable*, REUTERS (Nov. 30, 2012), http://www.reuters.com/article/2012/11/30/us-usa-court-genes-idUSBRE8AT19620121130 (last visited Mar. 10, 2013). The question presented is a "sound bite" question to raise the public interest in this case, but this case is not about patentability of human genes. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1324 (Fed.

Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012). This case is about the patent eligibility of isolated DNA molecules, not the patentability of human genes. *Id.*

Asking the broader question "are human genes patentable" has already had consequences. *Amicus* briefs in this case as well as articles in the popular patent press have already speculated on a "parade of horribles," raising public alarm. Brief for James D. Watson as Amicus Curiae in Support of Neither Party, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303 (Fed. Cir. 2012), *appeal docketed*, No. 12-398 (U.S. Sept. 25, 2012), 2013 WL 432951; Stempel, *supra*. A common horrible is that allowing patents on human genes would "preempt" research. The issue of whether the patents at issue in this case "preempt" or prevent scientific research is not presented by this case. Dr. Ostrer, the only plaintiff found to have standing, has never been prevented from scientific research using the isolated genes. Dr. Ostrer's assertion that: "The claims preempt any use of the genes for any purpose" is not consistent with the long standing experimental use exception to infringement. Brief for Petitioner at 2, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303 (Fed. Cir. 2012), *appeal docketed*, No. 12-398 (U.S. Sept. 25, 2012), 2012 WL 4502947. This exception is found in the jurisprudence of this Court and in many decisions of the Court of Appeals. *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511, 527 (Fed. Cir. 2012); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011);

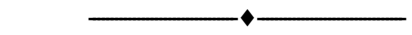
Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

Additionally, finding isolated DNA to be not patent eligible would place the United States in an awkward position with respect to international harmonization of patent law.[5] In many countries, the patent eligibility of isolated DNA is not an issue; it is patent eligible subject matter. For instance, Rule 29(2) of the EPC states that "element[s] isolated from the human body . . . including the sequences or partial sequences of a gene" are patent eligible subject matter "even if the structure of that element is identical to that of a natural element." Eur. Patent Convention Rule 29(2), *available at* http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/r29.html. However, the simple discovery of the sequence of a gene itself is not patent eligible according to Rule 29(1). Eur. Patent Convention Rule 29(1), *available at* http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/r29.html. As a second example, the sister case filed in Australia was recently dismissed on summary judgment because the Myriad claims were distinctly patent eligible. *Cancer Voices Australia v Myriad Genetics, Inc.* [2013] FCA 65 (Austl.).

[5] It is noted that during the oral argument in *Bilski*, there was an inquiry about European patent law. Transcript of Oral Argument at 12-13, *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) (No. 08-964).

VI. The Court Should Find That the Myriad Claims are Directed to Patent Eligible Subject Matter: Isolated DNA

Claim 1 is directed to an isolated DNA molecule. A human gene is not an isolated DNA molecule. A gene is "one of the elements of the germ plasm serving as specific transmitters of hereditary characters and usually regarded as portions of DNA linearly arranged in fixed positions and as functioning through control of the syntheses if specific polypeptide chains." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 944 (Philip B. Gove, et al., eds., 1993). Therefore, even if the Court answers the question "Are human genes patentable?", the result will not address the controversy presented. The claims at issue are not directed to genes and do not reference genes. The claims at issue are directed to isolated DNA molecules, as seen in the language of representative Claim 1: "An isolated DNA molecule. . . ." U.S. Patent No. 5,837,492 col. 167 l. 17 (filed Apr. 29, 1996). However, if the Court asks the question presented here "Is isolated DNA patent eligible?", then the issues presented in this case will be addressed.



CONCLUSION

The Court is currently asking the wrong question. The correct question is "Is isolated DNA patent eligible?" Because isolated DNA is a product of human ingenuity and a composition of matter, we believe it to be patent eligible. Because it is understood

that the Court intended to ask the question of "Is isolated DNA patent eligible?", the Court should find for Myriad. Whether isolated DNA is patentable is a separate question and is not before the court on appeal. The question of patentability includes the requirements of §§ 102, 103, and 112 in addition to the patent eligibility issue of § 101.

Respectfully submitted,

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