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 INTELLECTUAL PROPERTY OWNERS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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TABLE OF CONTENTS

Table of Contents

TABLE OF CITED AUTHORITIES

Page

CASES

Cited Authorities

Page

STATUTES

OTHER AUTHORITIES

Page

Page

Page

Page

Page

Page

Page

INTEREST OF THE *AMICUS CURIAE*[1]

The Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO's membership includes more than 200 companies and over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the USPTO and has filed amicus curiae briefs in this Court and other courts on significant issues of intellectual property law. The filing of this brief was approved by the IPO Board of Directors. A list of the IPO board members can be found in the Appendix.[2]

SUMMARY OF THE ARGUMENT

Isolated human genes[3], particularly genetically-engineered embodiments thereof, are patent-eligible

1. No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person other than *amicus*, its members, or counsel contributed money intended to fund preparing or submitting the brief. Counsel for all parties have consented to the filing of this brief.

2. IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

3. While Petitioners and their *amici* provocatively refer to the subject matter at issue in this case as "human gene patenting," this term inaccurately characterizes the claims in Myriad's patent. Instead, what is claimed is a specific sequence of isolated human DNA.

subject matter under the Patent Act (35 U.S.C. § 101) and controlling Supreme Court precedent. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Claims directed to isolated human DNA show "the hand of man" and are "not nature's handiwork, but [the inventors'] own," the fundamental requirement of patent-eligibility for composition claims. While derived from nature, the processes involved in isolating human DNA alter the chemical structure of these molecules in profound and fundamental ways, converting them into forms that never existed prior to their isolation.

Patenting isolated human DNA is consistent with constitutional provisions defining the powers of Congress, as patenting isolated human DNA "promotes the progress of . . . the Useful Arts" by incentivizing disclosure of genetic information, which is not patentable subject matter *per se*. Such patenting does not inhibit scientific research, as evidenced by the thousands of scientific journal articles published and research grants obtained after patenting of the two breast cancer-related genes (BRCA1 and BRCA2) that are the subject of this lawsuit. Patents and the assertion of patents are related to commercial not basic research activities, and the overwhelming evidence of several studies is that patents on isolated human DNA have had no effect on basic scientific research.

Petitioners fatally overreach in asking this court to hold that isolated human DNA falls outside the scope of patent-eligible subject matter. The patents at issue, directed to isolated human DNA encoding BRCA1 and BRCA2, represent only the beginning of an era of personalized medicine that will be characterized by understanding, and utilizing, genetic differences that impact both an individual's propensity for succumbing to

diseases and disorders as well as making a determination of the best therapeutic interventions and treatments for addressing them. Patents in this area are needed to promote expeditious disclosure of the genetic bases for such diagnostic and therapeutic approaches to human disease; without them, alternative means of protecting such discoveries, *for example* by holding them as trade secrets, will become more attractive. Patent-eligibility of isolated human DNA promotes not only disclosure of the DNA itself (and the proteins encoded thereby) but also the best mode for making and using the isolated human DNA and related methods. Even should the basic genetic information be available elsewhere, failure to patent also means failure to require full disclosure, and the attendant suppression of information would affect the development of reliable drugs and diagnostic methods (or worse, permit private companies to hold such information indefinitely). Such an outcome would be adverse to the public interest and contrary to the sound public policy underlying the Patent Act.

Petitioners wrongly equate patenting of isolated human DNA with patenting genetic information. This equation is false: genetic information is not patentable subject matter *per se*. It is available on public databases, both governmental (patent) and private, throughout the world, and is freely available for genetic research. Patenting isolated human DNA not only does not impact an individual's genetic information, it promotes progress in genetic research by requiring applicants to disclose what they know about the best mode of making and using said isolated human DNA. Moreover, patenting isolated human DNA promotes the elucidation of the identities and functions of the thousands of heretofore unrecognized genes found by researchers involved in the

Human Genome Project. Patents provide the incentive to invest the time, money, and manpower to understand what these genes encode and what the encoded proteins do, both being requirements imposed under 35 U.S.C. § 101 as interpreted by the U.S. Patent and Trademark Office.

All these benefits fall squarely within the ambit of the basis for Congress's power to grant patents, to "Promote the Progress . . . of the Useful Arts." For that reason alone this Court should affirm the Court of Appeals decision below.

ARGUMENT

I. Isolated Human DNA is Patent-Eligible Subject Matter

This Court has recognized that patent eligibility should be given an expansive scope, as mandated by Congress under 35 U.S.C. § 101. In *Diamond v. Chakrabarty*, this Court noted that Congress' intent was for statutory subject matter to "include anything under the sun that is made by man," (447 U.S. 303, 309 (1980) (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952))), consistent with Thomas Jefferson's vision that "ingenuity should receive a liberal encouragement," *Id.* at 308 (quoting 5 Writings of Thomas Jefferson 75–76 (Washington ed. 1871)).

The Patent Act defines four classes of inventions that are eligible for patenting: machines, processes, manufactures, and compositions of matter. 35 U.S.C. § 101. This Court has spoken with great clarity on the scope of the "manufacture" and "composition of matter" classes in *Diamond v. Chakrabarty*:

> [T]his Court has read the term "manufacture" in § 101 in accordance with its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery."

447 U.S. 303, 308 (1980) (quoting *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)). This Court gave an equally expansive reading to the class "composition of matter":

> "[C]omposition of matter" has been construed consistent with its common usage to include "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."

Id. (quoting *Shell Development Co. v. Watson*, 149 F.Supp. 279, 280 (D.D.C. 1957)).

This Court fashioned a straightforward test of whether a manufacture or composition of matter was patent-eligible: it must demonstrate the "hand of man," something that is "a product of human ingenuity 'having a distinctive name, character [and] use.'" *Id.* at 309–10 (citing *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). The Court distinguished the holding in *Funk Brothers Seed Co.* in this regard, where the patentee had discovered only "some handiwork of nature" and thus had discovered something that was not patent-eligible. *Id.* at 10. The Court's *Chakrabarty* test is the proper standard

for patent-eligibility, not the imposition of bright line, categorical rules applying broad, categorical prohibitions such as that advanced by Plaintiffs and their *amici*. *Anything* that evinces the "hand of man" is patent-eligible.

A. Isolated Human DNA is Patent-Eligible Because it Satisfies These Requirements Set Forth in *Chakrabarty*

Myriad's claims are narrowly focused on isolated human DNA molecules that encode a protein having a particular amino acid sequence. For example, claim 1 of Myriad's U.S. Patent No. 5,837,492 states:

> An *isolated* DNA molecule *coding for* a BRCA2 polypeptide, said DNA molecule comprising a *nucleic acid sequence* encoding the amino acid sequence set forth in *SEQ ID NO:2*.

Since the claimed inventions at issue here are directed to chemical molecules that do not occur in nature, they qualify as both "manufactures" and "compositions of matter." Therefore, *Chakrabarty* is the controlling precedent for determining whether Myriad's claims are drawn to patentable subject matter.

Isolated human DNA is patent-eligible because it satisfies the requirement in *Chakrabarty* that claimed subject matter show "the hand of man." The claimed isolated human DNA does this in several ways.

The claimed human DNA encoding BRCA1 and BRCA2 is isolated human DNA – the claims do not encompass the genes present in any cell. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan.

5, 2001). Thus, a patent on isolated human DNA does not implicate any individual's right to her own genes, since an individual's genes fall outside the scope of the patent claim. Indeed, these claims would not even encompass a recombinant cell containing a copy of either of the isolated human DNAs as claimed, since in that case the human DNA would not be "isolated."

It is important to recognize what "isolating" human DNA and encoding a protein entails. Genes are present in cellular DNA, which in humans is organized into 46 chromosomes; the entire genetic complement (or genome) in the cell comprises about six billion nucleotides of DNA.[4] An individual gene typically comprises about 1,000 of these nucleotides. Thus, to isolate a gene requires these specific 1,000 nucleotides to be separated from the remaining (approximately) 5,999,999,000 nucleotides in the cellular genome. Isolated human DNAs for each species (BRCA1 and BCRA2) have distinct nucleotide sequences and particular physical and chemical properties that distinguish them from all other DNA sequences.[5]

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4. A useful primer on the basics of molecular biology can be found in *In re O'Farrell*, 853 F.2d 894, 895-900 (Fed. Cir. 1988).

5. Genes in human chromosomal DNA, including the BRCA1 and BRCA2 genes at issue here, are not neatly arrayed in the chromosome, but are separated by unrelated DNA. The nucleotide sequence of a gene encodes a protein, and the gene is used by the cell as a "chemical blueprint" for making the protein. In this process, the portions of the gene that encode a protein (called "exons") are separated by unrelated portions of DNA (called "introns"). The cell produces a messenger RNA (mRNA) copy of the gene that removes the introns from the copy; it is this mRNA that is used to produce the protein by a cellular process called "translation." It is also the mRNA copy that can be used to isolate human DNA encoding specific proteins having specific amino acid

Claims to isolated human DNA, including isolated human DNA encoding BRCA1 and BRCA2, encompass in some embodiments DNA copies of mRNA.[6] These copies are termed "complementary DNA" or "cDNA" copies, and are the product of an enzymatic conversion of the mRNA to cDNA by a viral enzyme called reverse transcriptase. This enzyme is not present in cells that have not been infected by a virus that produces the enzyme, and cDNA copies of mRNAs encoding isolated human DNA, including isolated human DNA corresponding to BRCA1 and BRCA2, do not exist without human intervention, *i.e.*, prior to their synthesis by a researcher.

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sequences. Thus, in certain embodiments, claims to isolated human DNA, including the isolated human DNA encoding BRCA1 and BRCA2 at issue here, are copies not of the chromosomal DNA but of the mRNA.

6. RNA (including mRNA) and DNA are distinct molecules that differ structurally and functionally. As the names imply, the molecules are different chemically, DNA comprising *deoxyribose* and RNA comprising *ribose*; these chemical differences are reflected in differences in stability and resistance to degradation. Also, DNA (generally) exists as a "double helix," wherein each molecule comprises two strands wound about each other. The nucleotide sequence on each strand is complementary to the other strand, as found by Watson and Crick as the basis for DNA being the genetic material. RNA, on the other hand, is single-stranded, and contains the nucleotide sequence from only one of the strands of the DNA double helix. The two types of molecules also exhibit a variety of other physical and chemical differences. While every human cell contains two copies of the BRCA1 and BRCA2 genes (and almost every other gene), not all cells express these genes, *i.e.*, make the mRNA that is the starting point for isolating the gene. Thus, the inventor must identify such a cell before human DNA corresponding to the gene can be isolated.

It is not merely that these cDNAs are new (which is a question of patentability rather than patent-eligibility), but that they are a "nonnaturally occurring manufacture or composition of matter - a product of human ingenuity." *Chakrabarty*, 447 U.S. at 309. Like Chakrabarty's bacterium, isolated human DNA, and specifically the isolated human DNA encoding BRCA1 and BRCA2 claimed in the patents-in-suit, are "not nature's handiwork, but [the inventors'] own," and thus are eligible for patenting under Supreme Court precedent. *Id.*

The above characteristics of claimed isolated human DNA, including the isolated human BRCA1 and BRCA2 DNA, demonstrate that claimed isolated human DNA satisfies the requirements of *Chakrabarty* that patent-eligible subject matter show "the hand of man."

B. There is no Precedent that Controverts *Chakrabarty*

While the Court has recognized that the scope of patent-eligible subject matter is not infinite, it has been parsimonious in setting forth what was not patent-eligible. "[L]aws of nature, physical phenomena, and abstract ideas" fall into this category, which the Court exemplified as "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter." *Chakrabarty*, 447 U.S. at 309. Similarly, this Court has said that "[l]ikewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." *Id.*

These proscriptions against patent eligibility have been most recently revisited by this Court in *Mayo*

Collaborative Services v. Prometheus Labs., Inc.. 132 S. Ct. 1289, 1294 (2012). In *Mayo*, the claims were directed to a natural law relating to the proper therapeutic dosage of a drug for treating Crohn's disease. In finding the claim ineligible for patenting, this Court said that

> [t]he claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. We must determine whether the claimed processes have transformed these unpatentable natural laws into patent eligible applications of those laws. We conclude that they have not done so and that therefore the processes are not patentable.

Id. The deficiency in the claim was that it did no more than "inform a relevant audience about certain laws of nature," and "any additional steps [recited in the claim] consist of well understood, routine, conventional activity already engaged in by the scientific community." *Id.* at 1298. Accordingly, "those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately" and thus the claimed method was unpatentable. *Id.*

As expressed by the *Mayo* Court, these concerns arise when the claims produce no more than information (inform a relevant audience about certain laws of nature). *Id.* Indeed, *Mayo* is simply the latest in a series of such decisions dating back 160 years. This Court has addressed this type of deficiency in *O'Reilly v. Morse*, 56 U.S. 62,

62 (1853), claiming a method of transmitting information using electromagnetism; *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972), claiming methods for converting binary-coded decimal (BCD) numerals into pure binary numerals on a general purpose digital computer using a particular algorithm; *Parker v. Flook*, 437 U.S. 584, 585 (1978), claiming methods for determining an alarm limit; and *Bilski v. Kappos*, 130 S. Ct. 3218, 3224 (2010), claiming methods for hedging commodity trading outcomes. In each of these decisions, the Court found a lack of patentable subject matter because the claimed method provided little (or nothing) more than abstract information as opposed to concrete inventions that "promote the Progress of … the useful Arts." U.S. Const. art. I, § 8, cl. 8.

This Court has been wary of claims that preempt all uses of a law of nature, as it deemed them to be in *Mayo*, *Benson*, *Flook* and *Bilski*. In *Mayo*, the Court warned that "upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries" and would "threaten to inhibit the development of more refined treatment recommendations (like that embodied in Mayo's test), that combine Prometheus' correlations with later discovered features of metabolites, human physiology or individual patient characteristics." *Mayo,* 132 S. Ct. at 1294, 1302. These statements illustrate this Court's continuing concern that laws of nature are "'manifestations of . . . nature, free to all men and reserved exclusively to none'"; *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

The Court's decision in *Diehr* illuminates the boundaries of the Court's concern with preemption. In

Diehr, a method for curing rubber using an application of the Arrhenius equation was deemed patent-eligible. 450 U.S. 175, 177 (1981). There, the production of a tangible outcome -- using the claimed method to make cured rubber -- distinguishes the patent-eligible claims from the information produced in the claimed methods deemed patent-ineligible by this Court. And because the claims in *Diehr* were drawn to a specific method of making cured rubber,this Court found that the claim did not preempt all uses of the Arrhenius equation.

Unlike the method claims in *Mayo*, *Benson*, *Flook* and *Bilski*, Myriad's composition of matter claims at issue here are not broadly preemptive. They are both specific and concrete and as such do not implicate the policy concerns enunciated by this Court in those cases where preemption rendered claims patient-ineligible. Rather than being directed to mere information, the claims at issue are drawn to a useful and concrete composition of matter that falls within the statutory classes of patentable subject matter defined by Congress in Section 101 of the patent statute. Since Myriad's claimed inventions "evince the hand of man," they are directed to patentable subject matter per *Chakrabarty*.

Particularly relevant to the question of preemption is the narrow scope of Myriad's claim. The only isolated (human) DNA molecules that fall within the literal scope of this claim are those that encode the precise amino acid sequence called out in the claim. An isolated human DNA that is changed in any way from the specifically claimed amino acid sequence can be performed freely without

literal infringement liability by anyone.[7] Indeed, such claims to isolated human DNA are the antithesis of the type of broadly preemptive claims that have concerned this Court in the past, because by their nature these narrow claims do not "impede the flow of information that might permit, indeed spur, invention." *Mayo*, 132 S. Ct. at 1305.

Moreover, disclosure as required by the Patent Act is "the *quid pro quo* of the right to exclude." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974). The Federal Circuit has interpreted 35 U.S.C. § 112 to require that claims to isolated human DNA must disclose the specific sequence claimed (or provide a biological deposit thereof). *See Board of Trustees of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *Ariad Pharma. Inc. v. Eli Lilly & Co.,* 598 F.3d 1336 (2010) (*en banc*). In addition, the U.S. Patent and Trademark Office has implemented these requirements. *See* USPTO Written Description Examination Guidelines, 66 Fed. Reg. 1092 (2001). By requiring such a detailed disclosure for isolated DNA claims, the public is provided with a fair and balanced *quid pro quo* for the narrow patent grant given the inventors. And in this case, Myriad's disclosure of the

7. The significance of this limitation in scope of Myriad's claims can be understood by the following: if the single change in the amino acid sequence of the BRCA2 protein encoded by the claimed isolated human DNA is from a valine (Val) residue to an isoleucine (Ile) residue, the number of atoms in the protein is increased by a mere 3 atoms (the difference in structure between these two amino acids is a methylene group,-CH_2-) out a total of more than *60,000* atoms in the protein. Yet, even such a small change means that the altered molecule does *not* literally infringe claim 1 of Myriad's '492 patent.

BRCA1 and BRCA2 gene sequence has provided current and future researchers with the ability to continue to research and alter and make improvements in the BRCA1 and BRCA2 genes.

None of the cases asserted by Plaintiffs or their *amici* counters this Court's clear precedent in *Chakrabarty*.[8] On the contrary, the correct interpretation of each of these cases is consistent with patent-eligible subject compositions of matter having but one requirement -- that it show "the hand of man."

For example, *American Wood-Paper Co. v. Fibre Disintegrating*, 90 U.S. 566 (1874) ("*The Wood-Paper Patent Cases*"), which involved claims for the product of a method for making paper from wood pulp, held that claims to *prior art* compounds could not be made patentable merely by isolating them. The Court's concern was not to define categories of subject matter that are *per se* patent-ineligible, but rather that a patentee not be permitted to withdraw from the public domain subject matter that had been previously freely available for public use. *Id.* at 594–95 Indeed, the Court expressly declined to decide whether purification could convert a compound present in an impure state into a patent-eligible purified compound as the product of a process. *Id.*

The same infirmities arose in the patents at issue in *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293

8. Plaintiffs or their *amici* cite several cases from lower courts regarding what they allege are "natural products" and that purportedly show the unpatentability thereof. These cases do not represent this Court's precedent; indeed, the only direct authority that speaks to the question before this Court is *Chakrabarty*.

(1884), where the patents disclosed methods for preparing a dye, alizarine, and the product of such methods. The Court found that what the disclosed process produced was "the substance already known as alizarine," and the Court found claims to "artificial alizarine" were not patentable because what was claimed was something that was already known:

> According to the description in [the patents in suit], and the evidence, the article produced by the process described was the alizarine of madder, having the chemical formula $C_{14}H_8O_4$. It was an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction to being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially, for the first time, from anthracine, if it was set forth as alizarine, a well-known substance. *Wood Paper Patent*, 23 Wall. 566, 593. There was therefore no foundation for reissue No. 4,321, for the product, because, on the description given, no patent for the product could have been taken out originally.

Id. at 301–12. It is clear that the Court was not rendering a decision on patentable subject matter, but was instead applying the principle that a patentee cannot remove a known article from the public domain merely by providing a new way of making that old article.

In *Funk Brothers Seed Co.* the Court held unpatentable an article of manufacture comprising a mixture of two types of nitrogen-fixing bacteria, in a context where the bacteria were known in the art, and also known to fall into six well-defined groups that could not be cultivated together (they exhibited growth inhibition when grown in mixed culture).[9] The Court said that it had "long been well known" to produce cultures of these bacteria in the laboratory and provide farmers with such cultures for inoculating leguminous plant seeds, and also that the properties of the different bacterial species, their capacity to infect different plants, and their growth inhibition were known in the art. *Funk Bros. Seed Co.*, 333 U.S. at 129. Under these circumstances, the Court held that claims to the co-cultures were unpatentable. *Id.* at 130. These concerns echo the statements of this Court in *Mayo*, that the steps of the method there disclosed were not more than "well-understood, routine, conventional activity previously engaged in by researchers in the field. " *Mayo*, 132 S. Ct. at 1294. Likewise, in *Funk Bros* this Court concluded that "there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention.

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9. Claim 4 illustrates the claims of the patent-in-suit, U.S. Patent No. 2,200,532:

> 4. An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.

Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 128 n.1 (1948).

But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed." *Funk Bros. Seed Co.,* 333 U.S. at132.

It was the properties of the strains (being non-inhibitory when certain strains were mixed together) that were the "ancient secret of nature now disclosed" and which formed the basis for the invention; mixing of the strains without that knowledge would be insufficient. *Id.* The Court considered mere mixing of the two strains insufficient to make claims to the co-cultures patentable.

Myriad's claims implicate none of the legal or policy concerns that arose in any of these prior cases, and nothing in these cases supports a determination that Myriad's claims to isolated human DNA are not eligible for patenting.

C. Isolated Human DNA as Claimed in the Patents-in-Suit is a Product of the "Hand of Man" and Hence is Patent-Eligible

Plaintiffs contend that claims of the patents-in-suit encompassing isolated human DNA encoding BRCA1 and BRCA2 are patent-ineligible based upon their status as being "products of nature." This contention is incorrect as a matter of law and as a matter of fact.

The claimed isolated human BCRA1 and BCRA2 DNA are not "products of nature" because, as claimed, they are not found in nature. These isolated human DNAs are never found "isolated" in nature. First, they are not merely associated with contaminants (like the "intracellular material" contaminating cellulose in the

Wood Paper Patent Cases); they are intrinsically (and covalently) attached to and are a part of the physical and chemical structure of the chromosomal DNA, and their isolation requires them to be separated from this DNA, *i.e.*, to be present in an entirely new chemical structure. As discussed above, in other (cDNA) embodiments the claimed isolated human DNA is also not merely "isolated" but chemically changed in the process, first by the cell in making mRNA, and again by the inventor in converting the mRNA into cDNA. Thus, the claimed subject matter is different, physically and chemically, from the DNA present in nature. They are also changed functionally, being capable *inter alia* for use as probes or for making recombinant proteins.

These differences are sufficient to distinguish the claimed isolated human DNA in the patents-in-suit from DNA as it occurs in nature. Prior decisions of this Court do not mandate a contrary result. In each of these prior cases, the Court was concerned with one (or both) of the following bars to patent-eligibility: that the claimed product was known in the art prior to the inventor's claim (actually, a bar to patentability), or that the claim was so broad that it encompassed a law or phenomenon of nature. Thus, in both the *Wood-Paper Patent Cases* and *Cochrane*, the claimed subject matter encompassed the prior art (cellulose and alizarine, respectively). In those cases, the products were known and used prior to the patent claim, and thus were unpatentable (rather than being patent-ineligible). And in the *Funk Brothers* case, the Court's concern was patenting the phenomenon of co-culture viability, particularly in view of the scope of the claims (*i.e.*, any combination of bacterial culture mixtures exhibiting the capacity to grow together without inhibition).

Neither situation exists in this case. DNA encoding BRCA1 and BRCA 2 was completely unknown prior to isolation and identification by the patentees. Indeed, the only thing that was known about these genes was that they *might* reside at a particular region of the human genome at each of two specific sites on human chromosomes[10] that were inherited by women who developed breast or ovarian cancer prematurely. What was known in the prior art was merely a phenotype, a predisposition to develop such cancers at a much higher rate than the average, and a correlation of the presence of the phenotype with these chromosomal sites. This was the "phenomenon of nature," the correlation, but while it provides value to these cloned isolated human DNAs, it is not *equivalent* to the genes themselves, which have their own chemical identities. Isolating these human DNAs is not equivalent to patenting the phenomenon, as in *Funk Brothers*, but as required by *Chakrabarty*, the isolated human DNAs are "nonnaturally occurring manufacture[s] or composition[s] of matter – . . . product[s] of human ingenuity [each] 'having a distinctive name, character [and] use.'" *Chakrabarty*, 447 U.S. at 309–10 (quoting *Hartranft v. Wiegmann,* 121 U.S. 609, 615 (1887)).

This conclusion would follow even if the proteins encoded by BRCA1 and BRCA2 had been known in the art, since the protein and the DNAs encoding them are chemically-distinct species; the fact that their sequences are related (by the genetic code) is not necessarily sufficient to put the skilled artisan in possession of the isolated human DNA merely by isolating the corresponding

10. On the long arm of chromosome 17 at position 21 (BRCA1) and on the long arm of chromosome 13 at position 12.3 (BRCA2).

protein. *In re Kubin*, 561 F.3d 1351, 1361 (Fed. Cir. 2009). Here, the very existence of the protein encoded by each of the BRCA1 and BRCA2 genes was unknown.

The other line of reasoning, enunciated by the Court in *Funk Brothers* and recited with approval in *Chakrabarty* and more recently in *Mayo*, is that claims cannot encompass a "natural law" or "phenomenon of nature." Myriad's claims to isolated human DNA do neither. These claims recite man-made manufactures or compositions of matter, not phenomena. They are tangible, physical compounds, having particular and specific structures capable of being elucidated and described. They do not foreclose anything other than making, using, selling, offering to sell, or importing these specific and particular chemical compounds. As such, they are outside the limited range of subject matter proscribed from patent-eligibility by this Court's prior decisions and the Constitution's strictures, and are thus properly the subject of the patents-in-suit.

D. Patents to Isolated Human DNA do not Claim Genetic Information

Plaintiffs wrongly equate patenting of isolated human DNA with patenting genetic information. There is no dispute that genetic information, standing alone, is not patentable subject matter and does not belong to one of the statutory categories required for patent-eligibility. *See Chakrabarty*, 447 U.S. at 314. Indeed, information *per se*, like ideas, does not constitute patentable subject matter, *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498, 507 (1874). Critically, however, patents on isolated human DNA do not claim or preempt genetic information. *See Bayer AG v. Housey Pharma., Inc.*, 340 F.3d 1367, 1377 (Fed. Cir.

2003) (holding "that in order for a produce to have been 'made by a process patented in the United States' [under 35 U.S.C. § 271(g)] it must have been a physical article that was 'manufactured' and that the production of information is not covered.") Patent claims to isolated DNA only cover the isolated DNA itself, and not the genetic information per se.

Indeed, plaintiffs' argument has it backwards. A great many of the known human genes were disclosed for the very first time in patent applications. This disclosure of genetic information was a beneficial byproduct of 35 U.S.C. § 112, which requires the disclosure of the invention "in such full, clear, concise, and exact terms" to permit one of ordinary skill in the art to make and use the invention. Thus, the patenting of isolated human DNA promotes progress in genetic research by requiring applicants to disclose what they know about the best mode of making and using isolated human DNA. This ability to patent isolated genes results in genetic information being freely available on public databases, both governmental (patent) and private, throughout the world.

The dichotomy between patent-eligible isolated human DNA and patent-ineligible genetic information is consistent with precedent. For example, in *O'Reilly v. Morse*, 56 U.S. 62, 63 (1853), the ability to use electricity for communication was found to be patent-ineligible, but the specific telegraph invented by Morse was determined to be patent-eligible. Algorithms *per se* have also been held to be patent-ineligible, *Parker v. Flook*, 437 U.S. 584, 585 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972), while the use of an algorithm (an equation) in a patented process has been found to be patent-eligible, *Diamond*

v. Diehr, 450 U.S. 175, 177 (1981). These principles are consistent with the constitutional restrictions on the exercise of Congress' power to grant patents, *i.e.*, that they "promote the Progress of . . . useful Arts." U.S. Const. art. I, § 8, cl. 8.

II. A Ban on Patenting Isolated Human DNA Would Negatively Impact Research, Technology and Innovation, and be Contrary to the Constitutional Mandate That the Patent Act "Promote the Progress of . . . the Useful Arts"

Patents provide the incentive to invest the time, money, and manpower to understand what these genes encode and what the encoded proteins do, both being requirements imposed under 35 U.S.C. § 101 as interpreted by the U.S. Patent and Trademark Office. And once these characteristics and properties of genes and their encoded proteins are determined, they can be exploited for their various utilities, as they have for a generation in providing new and heretofore unavailable therapies. These include proteins like human Blood Clotting Factors VIII and IX, insulin, human growth hormone, erythropoietin, tissue plasminogen activator, and all monoclonal antibodies that are the basis for anticancer and other therapies. Any number of such drugs have been developed that, according to a recent Federal Trade Commission report, "have improved medical treatments, reduced suffering, and saved the lives of many Americans."[11] Biologics are predicted to become the most prescribed drugs over the next decade, to be used in the treatment of diseases such

11. Federal Trade Commission Report, Emerging Health Care Issues: Follow-on Biologic Drug Competition, i (2009), *available at* http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

as cancer that have been otherwise incurable throughout human history. Today, such biologics include Enbrel® for treating rheumatoid arthritis; Rituxan® for non-Hodgkin's lymphoma; Remicade® for Crohn's disease, arthritic, ulcerative colitis, and other inflammatory disorders; and Avastin® for colon cancer. In 2008, biologics comprised 39% of drug revenues.[12] Biologic drug products are expected to account for 75% of drug revenues by 2014, and additionally to include Herceptin® for breast cancer, Lantus® for diabetes, and Humira® for arthritis. Biologics thus treat chronic diseases of aging and are particularly important for the U.S. public as well as the U.S. economy.

Biologics, like other drugs, are cost-and investment-intensive to develop and commercialize, and may in fact be more expensive than conventional therapeutic drugs. Development of a single biologic drug product can take up to 12 years and cost over $1 billion to bring to market.[13] Even the manufacturing facilities required to make biologics are more expensive to build than conventional drug manufacturing plants, costing between $400 and $500 million.[14] Patent protection is necessary to support this level of investment, and its absence can be expected

12. Biosimilars 101, Credit Suisse, 6 (2009), *available at* http://www.scribd.com/doc/53368888/20090824-Biosimilar-theme-report.

13. Jim Hollingshead & Rob Jacoby, Avoiding No Man's Land: Potential Unintended Consequences of Follow-On Biologics 9 (2009), *available at* http://www.pharmamanufacturing.com/Media/1001/Deloitte_Biosimilars.pdf.

14. *Squawkbox* (CNBC television broadcast Aug. 9, 2009) (comments of James Greenwood, President of the Biotechnology Industry Organization BIO), *available at* http://www.cnbc.com/id/15840232?video=1213899782&play=1.

to severely inhibit further development of biologic drugs.[15] Patents on isolated human DNA protect the means for making many of these biologic drugs and their absence due to a ban would negatively impact the ability of such drugs to be developed.

A. Genetic Information is the Basis for the Coming Era of Personalized Medicine and Requires Patents to Promote Investment and Development

One of the most promising benefits of the elucidation of human genetic sequence information is the development of personalized medicine, the use of genetic information for diagnosing disease propensity and making improved therapeutic choices.[16] Examples of how this technology can be used include pharmacogenomics, defined as "the application of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, and help determine a person's predisposition to a particular disease or condition."[17] Currently, the technology includes detection

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15. Amicus brief on behalf of the Biotechnology Industry Organization, *Bilski v. Kappos,* No. 08-964 (Aug. 6, 2009).

16. Anil Potti et al., *A Genomic Strategy to Refine Prognosis in Early-Stage Non-Small-Cell Lung Cancer*, 355 New Eng. J. Med.. 570, 578–79 (2006); Wolfgang Sadee & Zunyan Dai, *Pharmacogenetics/Genomics and Personalized Medicine*, 14 Human. Mol. Genet. R207, R207 (2005).

17. Genomics and Personalized Medicine Act of 2007, S. 976, 11th Cong. § 2 (2007), *available at* www.govtrack.us/congress/bill.xpd?bill=s110-976 ("A bill [t]o secure the promise of personalized medicine for all Americans by expanding and accelerating genomics research and initiatives to improve the accuracy of disease diagnosis, increase the safety of drugs, and identify novel treatments.").

of enzyme variants for identifying patients susceptible to adverse reactions to the anticoagulant drug coumarin,[18] and identifying molecular markers for making cancer treatment decisions.[19]

Development of personalized medicine is thus important for diagnosing diseases, the propensity for developing diseases (including chronic diseases like cancer and diabetes), and making informed and effective treatment decisions. Indeed, researchers have developed a "gene chip"[20] that can be interrogated to detect hundreds of mutations in up to 170 genes relating to drug metabolism.[21] Continued development of this technology will depend on patent protection to provide the incentive for investment.

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18. U. I. Schwarz, *Clinical Relevance of Genetic Polymorphisms in the Human CYP2C9 Gene*, 33 Eur. J. Clin. Invest., 23, 33 (2003).

19. John C. Mansour & Roderich E. Schwarz, *Molecular Mechanisms for Individualized Cancer Care,* 207 J. Am. Coll. Surg. 250 (2008); Laura J. van't Veer & René Bernards, *Enabling Personalized Cancer Medicine Through Analysis of Gene-Expression Patterns*, 452 Nature 564 (2008).

20. A gene chip, or microarray, is described *inter alia* in DNA Microarrays: A practical approach, (Mark Schena, ed., 1999).

21. *Personalized Medicine Advancing*, UPI.com (Dec. 31, 2009, 2:10 PM), www.upi.com/Health_News/2009/12/31/Personalized-medicine-advancing/UPI-44821262286609/.

B. A Ban on Patenting Isolated Human DNA Would Promote Suppression of Genetic Information Relevant to Diagnostic and Therapeutic Applications

Banning patents on isolated human DNA and patents on diagnostic uses of genetic information will provide incentives for this technology to be developed in a way that can be protected. And in the absence of patenting, this will most likely involve trade secret protection.

The isolated human DNA and diagnostic methods claimed in the patents-in-suit represent a rare and possibly unique genetic situation: mutations in one or two genes that increase a woman's propensity to develop breast or ovarian cancer from 5-10% to 95% (recalling that estimates of breast cancer in the general population are about 1 in 8 (12.5%)[22] and, for ovarian cancer, 1 in 100 (1.0%)[23]). While similar "propensity for disease" genes have been identified,[24] most diseases are different: they are the result of several inherited and/or acquired changes in gene structure, expression, or function. Thus, it will be more difficult to determine genetic changes and patterns thereof that reliably indicate an increased likelihood

22. *Breast Cancer Statistics & Survival Rates*, IMAGINIS.COM, www.imaginis.com/breasthealth/statistics.asp (last visited Jan. 14, 2010).

23. *Hereditary Breast and Ovarian Cancer,* CDC, *http://www.cdc.gov/features/hereditarycancer/ (last updated Oct. 18, 2010).*

24. An example is familial adenomatous polyposis. *See Familial Adenomatous Polyposis*, GENETIC HOME REFERENCE (2008),ghr.nlm.nih.gov/condition=familialadenomatouspolyposis.

of developing diseases like diabetes,[25] cardiovascular disease,[26] autism,[27] Parkinson's disease,[28] Alzheimer's disease,[29] immunological disorders,[30] asthma[31], and most forms of cancer.[32] A critical review of the field concluded that "[g]enetic profiling may have the potential to identify

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25. Saxena et al., *Genome-Wide Association Analysis Identifies Loci for Type 2 Diabetes and Triglyceride Levels*, 316 Science 1331 (2007).

26. Matthew Kelly & Christopher Semsarian, *Multiple Mutations in Genetic Cardiovascular Disease: A Marker of Disease Severity?,* 2 Circulation Cardiovascular Genetics 182, 182 (2009).

27. Deborah Halber, *Multiple Genes Implicated in Autism; Discovery Could Lead to Drugs Targeting Gene Interactions*, ScienceDaily (Feb. 10, 2009), www.sciencedaily.com/releases/2009/02/090209205049.htm.

28. William K. Scott et al., *Complete Genomic Screen in Parkinson Disease: Evidence for Multiple Genes*, 286 J. Am. Med. Assoc. 2239, 2239 (2001).

29. Nienwen Chow et al., *Expression Profiles of Multiple Genes in Single Neurons of Alzheimer's Disease*, 95 Proceedings of the Nat. Acad. of Sci. USA 9620, 9620 (1998).

30. Vesela Gateva et al., *A Large-Scale Replication Study Identifies TNIP1, JAZF1, UHRF1BP1 and IL10 as Risk Loci for Systemic Lupus Erythematosus,* 41 Nature Genetics 1228, 1229 (2009).

31. Kate G. Ackerman et al., *Interacting Genetic Loci Cause Airway Hyperresponsiveness,* 21 Physiol. Genomics 105, 105 (2005).

32. Wei Jiang et al., *Constructing Disease-Specific Gene Networks Using Pair-Wise Relevance Metric: Application to Colon Cancer Identifies Interleukin 8, Desmin and Enolase 1 as Central Elements*, 2 BMC Sys. Bio. 72, 73 (2008).

individuals at higher risk of disease depending on the prevalence and heritability of the disease"[33] and a separate study on prostate cancer found that "[t]he genetic basis of many common human diseases is expected to be highly heterogeneous, with multiple causative loci and multiple alleles at some of the causative [genetic] loci."[34]

As a consequence, it can be expected that most human diseases will be multigenic in origin and vary with race, ethnicity, age, and other variables.[35] The studies cited herein are but the beginnings of this technology. Absent patent protection, and under the circumstances of multigenic causation (or at least association) of common diseases, the impetus will be to develop and protect this nascent technology using, *inter alia*, trade secret protection.

Such tests could be developed as follows. A gene chip (as discussed above) could be developed to contain isolated human DNA that is diagnostic for a disease (such as prostate cancer) in a defined population (such as African American men). Multiple genes whose expression or sequence suffers genetic alteration in prostate cancer could be identified from archival normal and prostate

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33. A. Cecile J. W. Janssens et al., *Predictive Testing for Complex Diseases Using Multiple Genes: Fact or Fiction?,* 8 Genetics in Med. 395, 395 (2006).

34. Daniel J. Schaid et al., *Nonparametric Tests of Association of Multiple Genes with Human Disease,* 76 Am. J. Human Genetics 780, 780 (2005).

35. Stephen B. Liggett et al., *A GRK5 Polymorphism That Inhibits ß-Adrenergic Receptor Signaling is Protective in Heart Failure,* 14 Nat Med. 510, 511 (2008).

cancer tissue samples that are available in multiple cancer tissue banks, both public and private. Isolated human DNAs specific for these genes, or alternations or mutations in these genes, could be included in a gene chip containing thousands of unrelated DNAs; indeed, each chip could contain several iterations of isolated human DNAs from the diagnostic genes, at both diagnostic (*i.e.*, mutated) and control (*i.e.*, "normal") sites. Disease or propensity for disease would be determined by identifying diagnostic isolated human DNAs contained on the chip for the genes of interest.

The development of bioinformatics[36] methods makes possible production of a plurality of such chips containing several (up to hundreds) of isolated human DNAs that are diagnostic for the disease of interest, and positive and negative control isolated human DNAs that will be detected *vel non* in all (or almost all) samples. In addition, such chips could contain thousands of unrelated isolated human DNAs. The technology could permit each chip to be encoded in such a way (with a bar code, for example) that would uniquely identify for each chip a pattern indicative of disease presence or propensity. In the absence of patent protection, such information could be kept proprietary, *i.e.*, only the company providing the test would have knowledge of the genes involved in the test or the diagnostic pattern of detected alterations in particular genes or their expression. The encypted bar code could relate each chip uniquely with a pattern that

36. A term used to describe the application of computer analysis to genetic sequences. *See*: *Bioinformatics,* WIKIPEDIA, http://en.wikipedia.org/wiki/Bioinformatics (last modified March 1, 2013).

indicated disease, disease propensity or the absence of either. Such information could be kept as a trade secret because the large number of isolated human DNAs on each chip would be sufficient to effectively preclude reverse engineering of the chips to determine which collections of genes and which alternations in sequence or expression are diagnostic. Under these circumstances, innovation in genetic-based diagnostics would be severely limited, since there would be no incentive (indeed, there would be strong *dis*incentives) to disclose the genetic basis of the diagnostic assay. This information, as a trade secret, could be kept out of the public domain indefinitely.

C. Patenting Isolated Human DNA does not Impede Basic Research

Patenting isolated human DNA does not impede, or indeed impact to any significant degree, basic genetic research, a conclusion supported by an overwhelming majority of analyses reported over the past ten years on the effects of such patents, from the U.S.,[37] Germany,[38]

37. John P. Walsh, Charlene Cho & Wesley M. Cohen, *Science and Law: View from the Bench: Patents and Material Transfers*, 309 Science 2002, 2002 (2005); John P. Walsh, Ashish Arora & Wesley M. Choehen , *Science and the Law: Working Through the Patent Problem,* 299 Science 1021, 1021 (2003).

38. Organisation for Economic Co-Operation and Development, Genetic Inventions, Intellectual Property Rights and Licensing Practices 47 (2002), *available at* http://www.oecd.org/dataoecd/42/21/2491084.pdf.

Australia,[39] and Japan.[40] A specific (predicted) consequence of patenting isolated human DNA, the creation of patent "thickets" that would impede research (provocatively termed the "tragedy of the anticommons[41]), has had no substantive effect on basic academic research,[42] even when researchers focused their inquiry on precisely those research reports relating to practical applications

39. Dianne Nicol & Jane Nielsen, Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry, Centre for Law & Genetics, Occasional Paper 6 (2003), *available at* http://www.ipria.org/publications/reports/BiotechReportFinal.pdf.

40. Sadao Nagaoka, An Empirical Analysis of Patenting and Licensing Practice of Research Tools from Three Perspectives, presented in OECD Conference in Research Use of Patented Inventions, 22 (May 2006), *available at* http://www.oepm.es/cs/OEPMSite/contenidos/ponen/conferenciantes/archivosPDF/36816178.pdf.

41. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 699 (1998).

42. *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 Innovation Policy and the Economy 119, 120 (Adam B. Jaffe, Josh Lerner and Scott Stern eds., 2001); John Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patenting and Licensing and Biomedical Innovation*, *in* Patents in the Knowledge-Based Economy 285 (Wesley M. Cohen and Stephen A. Merrill, eds. 2003); Zhen Lei, Rakhi Juneja & Brian D. Wright, *Patents Versus Patenting: Implications of Intellectual Property Protection for Biological Research*, 27 Nat. Biotech. 36, 36 (2009); Ronald Bailey, *The Tragedy of the Anticommons: Do Patents Actually Impede Innovation?,* Reason.com (Oct. 2, 2007), www.reason.com/archives/2007/10/02/the-tragedy-of-the-anticommons.

of biotechnology.[43] Indeed, it was reported (in a study done by the American Association for the Advancement of Science on the effects of patenting isolated human DNA on basic research in the U.S., Europe (Germany and the U.K), and Japan) that "all four studies suggest that intellectual property rights had little negative impact on the practice of science."[44] More recently, a study from the Catholic University in Leuven, Belgium showed that legal uncertainty, not patents on isolated human DNA, caused the principal negative effect on genetic diagnostic testing.[45]

The results of these studies are consistent with the experience of the scientific community on the effects of the BRCA1 and BRCA2 patents on research activity on these genes. Perhaps the best measure of such activity is the number of research reports in public databases that reflect ongoing basic scientific research in peer-reviewed scientific journals. While reported estimates differ depending on the search term used, a simple search of "brca1 or brca2" resulted in 10,652 publications, the most

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43. Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-commons Hypothesis,* 63 J. Econ. Behavi. & Org. 648 (2007).

44. Beck Ham, *Research Not Slowed by Intellectual Property Protections, AAAS Surveys Find*, AAAS.org (May 28, 2007), http://www.aaas.org/news/releases/2007/0529sippi.shtml. *See* AAAS, International Intellectual Property Experiences: A Report of Four Countries, 14–15 (Hansen, ed., 2007).

45. Isabelle Huys et al., *Legal Uncertainty in the Area of Genetic Diagnostic Testing*, 27 Nat. Biotech. 903 (2009).

recent of which was published on February 20, 2013.[46] U.S. Patent No. 5,747,282, directed to isolated human DNA encoding BRCA1, issued on May 5, 1998, and U.S. Patent No. 5,837,492, directed to isolated human DNA encoding BRCA2, issued on November 17, 1998. If either of these patents had a chilling effect on basic research, the expectation would be that the number of scientific research reports would have declined in the face of these patents. On the contrary, the number of such publications has steadily increased each year, which is precisely what would be expected if these patents had no significant effect on basic scientific research.

What these patents do, of course, is prevent commercial activity – using the patented isolated human DNA or performing the patented methods for profit. This is a legitimate exercise of the patent grant.

46. L. Bonanno et al., *The Predictive Value of BRCA1 and RAP80 mRNA Expression in Advanced Non-Small-Cell lung Cancer Patients Treated with Platinum-Based Chemotherapy*, Ann. Oncol (February 20, 2013) (Epub ahead of print).

CONCLUSION

For all the reasons set forth herein, *amicus curiae* IPO asks the Court to affirm the Federal Circuit's decision that claims to isolated human DNA are patent-eligible.

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