No. 12-398

In The
Supreme Court of the United States

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 JUHASZ LAW FIRM, P.C. AS AMICUS CURIAE SUPPORTING NEITHER PARTY

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QUESTION PRESENTED

Are human genes patentable?

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INTEREST OF AMICUS CURIAE[1]

The author of this brief is a registered patent practitioner with law and science degrees and is a member of the patent firm The Juhasz Law Firm, P.C. Paul R. Juhasz has been practicing for 29 years and holds a B.S.Chem.E., a B.S.E.E., a J.D., and a P.E. Paul R. Juhasz deals with the issue of subject matter patentability for clients of the Firm on a regular basis. Mr. Juhasz has written extensively and is extensively published on the Supreme Court's *Bilski* and *Mayo* decisions and subject matter patentability under 35 U.S.C. § 101. This brief is filed solely on behalf of the Firm and not on behalf of clients of the Firm. Amicus represent neither party in this action, and offer the following views based on extensive experience on this matter.

[1] Pursuant to Sup. Ct. R. 37.6, amicus note that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus curiae made a monetary contribution to its preparation or submission. Petitioners and Respondents have provided written consent pursuant to Rule 37, Sect. 3(a) of the Rules of the Supreme Court of the United States to the filing of this amicus brief in this case. A courtesy notice of this filing was provided to both Petitioners and Respondents.

SUMMARY OF ARGUMENT

The Federal Circuit incorrectly held that respondent's patent claims are directed to patent-eligible subject matter.

I. The Federal Circuit failed to properly consider whether isolated DNA is an invention or discovery under this Court's *Mayo* and *Funk Bros.* decisions.

II. Isolated DNA is "new" and "useful" under *Chakrabarty*; but more is required under § 101 for the isolated DNA to be patent eligible and it is there that isolated DNA fails.

III. Preemption is the touchstone of an "invention" or "discovery" under this Court's *Mayo* and *Funk Bros.* decisions.

IV. The "engineering at the edges of DNA" for "packaging" of natural DNA does not create the quality in the recited isolated DNA useful for diagnostic targeting which is the work of nature. Those qualities of DNA are not an "invention" or "discovery" under this Court's *Mayo* and *Funk Bros.* decisions for patents cannot issue for the discovery of this phenomenon of nature.

V. The claims which are directed to isolated sequences that are identical to naturally occurring gene sequences fall squarely within the discussion of Section IV above and are not human invention. However, the judgment of the Federal Circuit as to isolated cDNA product claims should be vacated and the case should be remanded to the United States

Court of Appeals for the Federal Circuit for further consideration of whether the packaging of the DNA SEQ into cDNA molecules is an insignificant extra-solution activity or "human invention" deserving of a patent.

VI. The Court should clarify that preemption in isolated DNA arises not from isolated DNA being not "new"; rather that the isolated DNA is not an "invention" or "discovery" entitled to a patent under § 101.

ARGUMENT

I. The Federal Circuit failed to properly consider whether isolated DNA is an invention or discovery under this Court's *Mayo* and *Funk Bros.* decisions

On Friday, November 30, 2012, the Supreme Court granted the petition of Association for Molecular Pathology, et al. for a writ of certiorari.

This is the second time that this case is before this Court. The first time, this Court remanded the case to the Federal Circuit for reconsideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). This time, the certiorari has been limited to the following question "Are human genes patentable?"

On remand, the Federal Circuit once again decided the subject matter patentability of the isolated DNA claims under *Diamond v. Chakrabarty*,

447 U.S. 303 (1980), effectively "cleaving" out the analytical backbone of this Court's *Mayo* case from its decision upholding the subject matter patentability of isolated DNA. *Ass'n for Molecular Pathology v. U.S. P.T.O.*, 689 F.3d 1303, 1325 (Fed. Cir. 2012). This despite this Court's decision in *Mayo* being the reason for the remand. The District Court had invalidated the isolated DNA claims.

35 U.S.C. § 101 provides that:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

To be patent eligible subject matter, § 101 thus requires not only that the invention or discovery be "new" and "useful." § 101 also requires that the composition of matter be an "invention" or a "discovery." *Mayo*, *supra* at 1294 and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948). In *Chakrabarty*, the claimed bacterium was so "new" because of markedly different characteristics from any found in nature that the Court held the claimed bacterium to be "human invention" deserving of a patent. "His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101." *Chakrabarty*, *supra* at 310. Not so with *Mayo* and *Funk Bros.* where the recited claims that albeit being "new" and "useful" were found to be

"nature's handiwork" and so not invention deserving of a patent. *Mayo* and *Funk Bros.*

Mayo, and its predecessor decisions, stand for the proposition that a claim taken as a whole and excluding extra-solution activity must be tailored narrowly enough to encompass only a particular application of a fundamental principle (*i.e.*, a law of nature, natural phenomena, or an abstract idea) rather than to preempt the principle itself. *Id.*; *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010); *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972); *Parker v. Flook*, 437 U.S. 584 (1978); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). Hence, in deciding the question of patentable invention it is not enough to point to marked differences between the claimed product and products existing in nature. The question is whether those marked differences taken as a whole and excluding extra-solution activity amount to human ingenuity. *Mayo*, *supra* at 1294; and *Funk Bros.*, *supra* at 131.

On remand, the Federal Circuit once again decided the patent eligibility of isolated DNA under *Chakrabarty* explaining that "the Supreme Court's decisions in *Chakrabarty* and *Funk Bros.* set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules." *Ass'n for Molecular Pathology*, *supra* at 1326. According to the Federal Circuit, *Mayo* does not control the question of patent eligibility of isolated DNA molecules. *Id.*, at 1325 ("[t]he principal claims of the patents before us on remand relate to isolated

DNA molecules. *Mayo* does not control the question of patent-eligibility of such claims. They are claims to compositions of matter, expressly authorized as suitable patent-eligible subject matter in § 101." *Id.* See also, "[w]hile the *Mayo* decision does not control the outcome in this case, it is nonetheless instructive regarding the scope of the law of nature exception." *Id.*, concurring at 1339, 1340. "The Supreme Court's recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1293 (2012) does not decide this case, but the Court's analysis is nonetheless instructive." *Id.*, dissenting at 1354.

In so deciding *Ass'n for Molecular Pathology*, the Federal Circuit has failed to properly apply the teachings of *Mayo* – and the teachings of *Funk Bros.* on "invention" as viewed through the "preemption" lens provided by *Mayo* – to the question of the patent eligibility of isolated DNA. As § 101 and this Court's *Mayo* and *Funk Bros.* decisions make clear, the patent eligibility of isolated DNA depends as much upon the isolated DNA satisfying the requirements of an "invention" or a "discovery," as it does upon the isolated DNA satisfying the requirements of being "new" and "useful." The Federal Circuit's failure to properly apply these teachings in *Mayo* and *Funk Bros.* has left it to this Court to decide whether isolated DNA is an "invention" or "discovery" under § 101.

II. Isolated DNA is "new" and "useful" under *Chakrabarty*; but more is required under § 101 for the isolated DNA to be patent eligible and it is there that isolated DNA fails

The Federal Circuit decided the subject matter patentability of the isolated DNA claims largely under *Chakrabarty*. *Ass'n for Molecular Pathology*, *supra* at 1325.

The Court in *Chakrabarty* held that a man-made, living microorganism is a patent-eligible manufacture or composition of matter within the meaning of § 101. 447 U.S. at 305, 307. The microorganisms were bacteria genetically engineered with four naturally occurring DNA plasmids, each of which enabled the breakdown of a different component of crude oil. *Id.*, at 305, 305 n.1. The bacteria, as a result, could break down multiple components of crude oil, a trait possessed by no single naturally occurring bacterium and of significant use in more efficiently treating oil spills. *Id.*, at 305, 305 n.2. The Court held that the bacteria was patentable since there was human ingenuity in creating a nonnaturally occurring manufacture or composition. The claim was "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity 'having a distinctive name, character [and] use.'" 447 U.S. at 309-10, quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887).

The *Chakrabarty* Court distinguished engineered bacteria from the mixed bacterial cultures found unpatentable in *Funk Bros.* In *Funk Bros.*, the patentee

discovered that certain bacterial strains associated with leguminous plants do not mutually inhibit each other. *Funk Bros.*, *supra* at 129-30. Based on that discovery, the patentee obtained a patent on a mixed culture of those non-inhibitive strains. *Id.* The *Funk Bros.* Court held that the bacteria's cooperative qualities were, "like the heat of the sun, electricity, or the qualities of metals," the "work of nature," and thus not patentable. *Id.*, at 130. The Court held the product unpatentable because the bacteria remained structurally and functionally the same as in their natural state. *Funk Bros.*, 333 U.S. at 131. By contrast, because Chakrabarty had produced "a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility," the Court held Chakrabarty's invention to be patentable. *Chakrabarty*, 447 U.S. at 310.

Hence, the Supreme Court has drawn a line between compositions that, even if aggregated in useful combinations or harnessed to exploit newly discovered properties, have similar characteristics as in nature, and compositions that human intervention has given "markedly different," or "distinctive," characteristics. *Id.* (citing *Hartranft*, 121 U.S. at 615; see also *Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1, 11 (1931)). Applying this test to the isolated DNAs in this case, the Federal Circuit held that the challenged claims are drawn to patent eligible subject matter largely because the claims cover molecules that are markedly different – have a distinctive chemical

structure and identity – from those found in nature. *Ass'n for Molecular Pathology*, *supra* at 1328.

As the Federal Circuit noted based upon the evidence submitted by technical experts, isolated DNA is a free-standing portion of a larger, natural DNA molecule. *Id*. Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule. *Id.* For example, the *BRCA1* gene in its native state resides on chromosome 17, a DNA molecule of around eighty million nucleotides. Similarly, *BRCA2* in its native state is located on chromosome 13, a DNA of approximately 114 million nucleotides. *Id.* In contrast, isolated *BRCA1* and *BRCA2*, with introns, each consists of just 80,000 or so nucleotides; and without introns, *BRCA2* shrinks to approximately 10,200 nucleotides and *BRCA1* to just around 5,500 nucleotides. *Id.* Furthermore, claims 5 and 6 of the '282 patent cover isolated DNAs, *e.g.*, primers or probes, having as few as fifteen nucleotides of a *BRCA* sequence. *Id.*

Based on this record, the Federal Circuit held that *BRCA1* and *BRCA2* in their isolated states are different molecules from DNA that exists in the body. *Id.* As the court explained "isolated DNA results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA." *Id.*

Where, as here, a composition is markedly different from naturally occurring compositions, it is hard to refute the Federal Circuit's finding that the isolated DNA composition satisfies the "new" prong of the "new" and "useful" prongs of § 101. To deny patent eligibility to isolated DNA on the grounds that it is not "new" would be to deny patent eligibility to many chemical compositions which are conventionally recited in the claims of chemical patents; including arguably the living microorganisms that the Court in *Chakrabarty* held to be patent eligible subject matter.

But the Federal Circuit's finding begs the question of whether the "new" and "useful" isolated DNA is "human ingenuity" as even the *Chakrabarty* Court makes clear is required and the Court's decisions in *Mayo* and *Funk Bros.* mandate. *Mayo*, *supra* at 1294; and *Funk Bros.*, *supra* at 130. As discussed in detail below, more is required for a composition to be § 101 patent eligible than for the composition to be "new" and "useful." The isolated DNA fails § 101 in these other aspects and hence isolated DNA is not patent eligible subject matter as detailed below.

III. Preemption is the touchstone of an "invention" or "discovery" under this Court's *Mayo* and *Funk Bros.* decisions

A composition which is "new" and "useful" must still satisfy the § 101 requirements of "invention" or "discovery." As explained in *Funk Bros.*, "[b]ut a product must be more than new and useful to be patented;

it must also satisfy the requirements of invention or discovery." 333 U.S. at 131. Apposite is *Mayo* ("They [our precedent decisions] insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.) *Mayo*, *supra* at 1294. See also, *Parker v. Flook*, *supra* at 594 (1978); *Bilski*, *supra* at 3231. In other words, a natural law without more is not an invention that is eligible for patent under § 101.

In *Funk Bros.*, the patentee discovered that certain strains of nitrogen-fixing bacteria associated with leguminous plants do not mutually inhibit each other. 333 U.S. at 129-30. Based on that discovery, the patentee produced (and claimed) mixed cultures of nitrogen-fixing species capable of inoculating a broader range of leguminous plants than single-species cultures. *Id.* The Court held that the bacteria's cooperative qualities were, "like the heat of the sun, electricity, or the qualities of metals," the "work of nature," and thus not patentable. *Id.*, at 130. The Court also held that applying the newly discovered bacterial compatibility to create a mixed culture was not a patentable advance because no species acquired a different property or use. *Id.*, at 131.

In *Funk Bros.*, once nature's secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. *Id.*,

at 132. It was not enough that the application of this newly discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance or even the product of skill. *Id.*, at 131. § 101 requires more than the creation of something "new." § 101 requires that the claimed cultures also be the product of invention. *Id.*

As the Court explained, Funk Brothers' packaging of inoculants could not be called an invention unless the discovery that certain strains of the several species of these bacteria are noninhibitive, and may thus be safely mixed, is invention; which the Court held that it was not. *Id.*, at 132. For as the Court explained "we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough." *Id.*

It is for the purpose of ensuring that the "ancient secrets of nature" and the "storehouse of knowledge of all men" are "free to all men and reserved exclusively to none" as explained by the Court in *Funk Bros.* that the Court articulated three judicially created exceptions to § 101's broad patent-eligibility principles: " 'Laws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo*, *supra* at 1293 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)). The Court has also referred to those exceptions as precluding the patenting of mental processes, *Gottschalk v. Benson*, *supra* at 67, and products of

nature, *Chakrabarty*, 447 U.S. at 313 ("[T]he relevant distinction for purposes of § 101 is . . . between products of nature . . . and human-made inventions."). The Court has explained that, although not required by the statutory text, "[t]he concepts covered by these exceptions are 'part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.'" *Bilski*, 130 S. Ct. at 3225 (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

These judicially created exceptions provide the guidelines for use in defining the boundary line within which a product is patent eligible subject matter and outside of which a product is not. When a product falls outside this boundary line, they are "part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none." *Bilski*, 130 S. Ct. at 3225 (quoting *Funk Bros.*, 333 U.S. at 130). But when inside, the product may qualify as patent eligible subject matter.

When the subject matter sought to be patented falls clearly inside or outside of this boundary line, the guidelines provided by the Court are easy to apply. But in some cases, where the subject matter arguably straddles that boundary line, such as may be in the case at bar, the application of these guidelines become more difficult. As Justice Frankfurter noted in his concurring opinion in *Funk Bros.*:

> It only confuses the issue, however, to introduce such terms as "the work of nature" and

> the "laws of nature." For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed "the work of nature," and any patentable composite exemplifies in its properties "the laws of nature." Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.

Funk Bros., *supra*, concurring at 134, 135.

However, the body of law by the Court has and continues to evolve on this point. With this Court's recent decision in *Mayo*, defining where subject matter falls with respect to this boundary line has become clearer. 132 S. Ct. at 1293 (quoting *Diehr*, 450 U.S. at 185) (laws of nature, natural phenomena, and abstract ideas exceptions); *Benson*, 409 U.S. at 67 (mental processes); *Chakrabarty*, 447 U.S. at 313 (products of nature); *Bilski*, 130 S. Ct. at 3231 (abstract ideas).

As this Court explained in *Mayo*:

> Those cases warn us against interpreting patent statutes in ways that make patent eligibility "depend simply on the draftsman's art" without reference to the "principles underlying the prohibition against patents for [natural laws]." *Flook*, *supra* at 593. They warn us against upholding patents that claim processes that *too broadly preempt the use of a natural law*. *Morse*, *supra* at 112-120; *Benson*, *supra* at 71-72. And they insist that a process that focuses upon the use of a natural law also contain other elements or a

> combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself. *Flook*, *supra* at 594; see also *Bilski*, *supra* at 3230 ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant post-solution activity'" (quoting *Diehr*, *supra* at 191-192)).

(*Emphasis added*) *Mayo*, *supra* at 1294.

Mayo, and its predecessor decisions stand for the proposition that a claim taken as a whole and excluding extra-solution activity must be tailored narrowly enough to encompass only a particular application of a fundamental principle (*i.e.*, a law of nature, natural phenomena, or an abstract idea) rather than to preempt the principle itself. *Id.*; *Bilski*, 130 S. Ct. at 3231; *Benson*, 409 U.S. at 72; *Flook*, 437 U.S. at 594; and *Diehr*, 450 U.S. at 185.

In *Ass'n for Molecular Pathology*, the Federal Circuit stopped short of applying this Court's *Mayo* and predecessor precedent in finding largely that the "markedly different" properties of the isolated DNA made the isolated DNA a man-made invention deserving of a patent. The case before this Court is not a *Chakrabarty*-like bacterium involving human engineering at the core of the claim. Rather, the case before this Court is about human engineering the edges

of naturally occurring DNA in a particular way as discussed in greater detail below. The Federal Circuit's decision in *Ass'n for Molecular Pathology* fails to explain how human engineering the edges of naturally occurring DNA amounts to more than extra-solution activity preemptive of a fundamental principle; thereby amounting to an invention deserving of a patent.

As the Court has repeatedly pointed out in *Mayo* and its predecessor cases, even a product decidedly "new" and "useful" may nonetheless fail § 101 if the composition preempts the fundamental principle itself. For as this Court held in *Mayo*, if a new and useful product "too broadly preempt[s] the use of a natural law," it is not an invention created by man and so it is not patent eligible subject matter. As the Court noted in *Funk Bros.* "there is no way in which we could call it such [an invention] unless we borrowed invention from the discovery of the natural principle itself." 333 U.S. 133.

Through the prism of "preemption" that the Court has provided in *Mayo* and predecessor decisions, the question of whether isolated DNA is patent eligible subject matter can be finally answered.

IV. The "engineering at the edges of DNA" for "packaging" of natural DNA does not create the quality in the recited isolated DNA useful for diagnostic targeting which is the work of nature. Those qualities of DNA are not an "invention" or "discovery" under this Court's *Mayo* and *Funk Bros.* decisions for patents cannot issue for the discovery of this phenomenon of nature

Myriad ascertained that two "isolated" human genes, *BRCA1* and *BRCA2* (collectively, "*BRCA1/2*" or "*BRCA*"), and certain alterations, or mutations, in these genes are associated with a predisposition to breast and ovarian cancers. *Ass'n for Molecular Pathology*, *supra* at 1309. Myriad then isolated these genes for use in providing BRCA diagnostic testing services to women. *Id*., at 1314.

Representative composition claims before this Court include claims 1, 2, and 5 of the '282 patent:

> 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
>
> 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
>
> 5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.

Id., at 1309.

The Federal Circuit construed the claims in several places as follows:

> Isolated DNA, in contrast, is a free-standing portion of a larger, natural DNA molecule. Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule. *Id.*, at 1328.

As discussed in detail in the Section V of this brief, to be sure, some of the claims may require more than simply the isolation of natural DNA from its natural habitat and those claims require further analysis. But claims that differ from naturally occurring DNA only because they are isolated falls squarely within the ambit of the sole issue before this Court which is "Are human genes patentable?"

The Federal Circuit relied on the foregoing construction of the claims (*i.e.*, that isolated DNA has a "cleaved" structure) in holding the isolated DNA to be patent eligible subject matter. *Id.*, at 1328, 1329. In short, the difference between isolated DNA and natural DNA resides largely from the "cleaved" structure (*i.e.*, broken covalent bonds in the backbone, removal of genetic material, etc.). *Ass'n for Molecular Pathology*, *supra* at 1328.

To determine whether 35 U.S.C. § 101 is satisfied, it is necessary to consider the claim as a whole. *Diehr*, 450 U.S. at 188. The claims as a whole recite a "DNA" component and a "cleaved" component that together

form the recited cleaved composition known as isolated DNA.

DNA is a product of nature regardless of amount. DNA is DNA whether it includes its entire make-up or a fraction thereof as recited in the asserted claims. As a product of nature, DNA alone is not patent eligible subject matter. Hence, if there is to be invention from a discovery involving DNA, it must come from the application of the law of nature to a new and useful end. *Mayo*, *supra* at 1294 and *Funk Bros.*, *supra* at 131. See also *Telephone Cases*, 126 U.S. 1, 532-533 (1888); *De Forest Radio Co. v. General Electric Co.*, 283 U.S. 664, 684-685 (1931); *Mackay Radio & Tel. Co. v. Radio Corp.*, 306 U.S. 86, 94 (1939).

The Federal Circuit noted that the difference between isolated DNA and natural DNA resides largely in the "cleaved" structure (*i.e.*, broken covalent bonds in the backbone, removal of genetic material, etc.). In other words, the application involving DNA recited in the isolated DNA claims largely amounts to a way in which to chemically package certain fractions of DNA. It is human engineering done at the edges of the DNA in order to contain the naturally occurring DNA in a tidy package. More specifically, the broken covalent bond structure in the backbone, the removal of genetic materials, etc., largely provides a "chemical package" in order to contain the piece of naturally occurring DNA for use in diagnostic detection purposes. In other words, natural DNA resides in the genetic mass resulting from the human engineered

detection delivery package. The human engineered package makes the natural DNA which is contained therein useful for diagnostic detection purposes.

While the "cleaved" packaging makes the isolated DNA a composition that is "new" as the Federal Circuit has held, the question of "invention" or "discovery" under § 101 turns on whether that new packaging of DNA can be called an invention deserving of a patent under § 101. Under the Court's *Mayo* and *Funk Bros.* precedent, isolated DNA falls short of invention within the meaning of § 101.

The packaging of DNA into an isolated DNA does not create the quality in the recited DNA useful for diagnostic targeting. The diagnostic targeting quality of the isolated DNA is the work of nature. Those qualities of DNA are not patentable. For patents cannot issue for the discovery of this phenomenon of nature. *Mayo*, *supra* at 1294; see also *Funk Bros.*, 333 U.S. 131.

The qualities of DNA for use in diagnostic targeting, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. *Mayo*, *supra* at 1294. See also *Funk Bros.*, 333 U.S. 131. The qualities of DNA for use in diagnostic targeting are manifestations of laws of nature, free to all men and reserved exclusively to none. *Mayo*, *supra* at 1294. See also *Funk Bros.*, 333 U.S. 131. As the Court decisions in *Mayo* and *Funk Bros.* make clear, he who discovers a before unknown phenomenon of nature has no claim to a monopoly of it

which the law recognizes. *Mayo*, *supra* at 1294 and *Funk Bros.*, *supra* at 131.

The application of the "cleaved" packaging to the problem of packaging natural DNA for diagnostic detection purposes is an important commercial advance. But once nature's secret of the diagnostic detection quality of human genes *BRCA1* and *BRCA2* was discovered, the state of the art made the production of a chemically packaged DNA SEQ of those human genes by "cleaving" for use in diagnostic detection a simple step. However ingenious the discovery of the natural principle of correlating human genes *BRCA1* and *BRCA2* with a predisposition to breast and ovarian cancers may be, the application of that discovery through isolation of the relevant DNA is hardly more than an advance in the "chemical packaging" of the DNA. It is human engineering of the DNA at the edges. The DNA contained in the "cleaved" package targets the same DNA SEQ which the natural DNA SEQ is disposed to target. No isolated DNA acquires a different use. The isolation of DNA produces no new DNA, no change in the DNA, and no enlargement of the range of their utility. The DNA has the same effect in isolated form as it always had. The DNA in isolated DNA performs in its natural way. The isolated DNA does not improve in any way natural functioning of the DNA. The isolated DNA serves the ends nature originally provided, and acts independently of any effort of the patentee.

The identification of the recited SEQ as an effective marker of DNA sites is an important discovery;

allowing the medical community to know which portion of DNA to isolate for use in the diagnostic detection of *BRCA1* and *BRCA2* and mutations thereof. But the correlation that is derived between *BRCA1* and *BRCA2* and predisposition to breast and ovarian cancer is a correlation existing in nature. It is not a correlation created by human ingenuity and hence is not patentable matter. *Mayo*, *supra* at 1294.

The "cleaved" packaging resulting from "engineering the edges" of the natural DNA that is done to create the recited isolated DNA SEQ does bring significant advantages to the DNA SEQ isolated when compared to the form taken by the DNA SEQ as it exists in nature. The packaging provides an effective vehicle for use in diagnostic targeting. The packaging prepares the DNA SEQ for use in diagnostic targeting. But a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery. *Mayo*, *supra* at 1294. See also *Funk Bros.*, 333 U.S. 131.

The "cleaved" packaging in *Ass'n for Molecular Pathology* is not unlike the general purpose computer in *Benson* and *Flook* and the technological field limitation in *Flook*. Neither are central to the claim. Each are insignificant extra-solution activity. In *Benson*, "once that algorithm [wa]s assumed to be within the prior art, the application, considered as a whole, contain[ed] no patentable invention." *Flook*, at 594. In *Ass'n for Molecular Pathology*, once the *BRCA1* and *BRCA2* DNA correlation was assumed to be in the prior art, the "application" of cleaving of the covalent

bonds, that is to say, the engineering of the edges of the naturally occurring DNA SEQ to put the naturally occurring DNA SEQ into the recited isolated packages for diagnostic targeting purposes, considered as a whole, contained no patentable invention.

The biotech community knows that you can place a selected piece of a naturally occurring DNA SEQ that you want to use for diagnostic targeting into a cleaved package. The biotech community knows that you can engineer the edges of the selected DNA SEQ as it exists in the body, by cleaving the covalent bonds, in order to provide a vehicle for use in determining a correlation existing in nature useful in diagnosing a condition. The biotech community knows how to engineer the edges of the DNA to do this. While it may be the case that there may be other ways to test for predisposition without using isolated DNA, that doesn't change the fact that isolating DNA for use in detecting a predisposition is a standard way that the biotech industry uses to do this. See *Ass'n for Molecular Pathology*, *supra* at 1333. ("[I]t is estimated that the PTO has issued 2,645 patents claiming "isolated DNA" over the past twenty-nine years.") Beyond isolating the natural DNA SEQ, the human engineered package does largely no more than to hold that naturally occurring DNA SEQ and make it useful for determining the correlation useful for detecting a biological condition all of which occurs by the handiwork of nature.

Once the correlation of the *BRCA1* and *BRCA2* DNA SEQ to a predisposition to breast and ovarian

cancers was known, the packaging of that DNA SEQ into a cleaved package by engineering the edges of the DNA SEQ was a matter of known practice; an insignificant extra-solution activity. Hence, the application of cleaved packaging to isolate the natural DNA SEQ, considered as a whole, contains no patentable invention. Absent the known packaging, the *BRCA1* and *BRCA2* DNA SEQ is all that remains and that is not patent eligible matter.

There seems to be no way in which the Court could call isolated DNA as being an "invention" or "discovery" under § 101 unless the Court borrowed invention from the discovery of the natural principle itself. In other words, there is no invention in isolated DNA unless the discovery that the correlation of the *BRCA1* and *BRCA2* DNA SEQ to a predisposition to breast and ovarian cancers is invention. But under the preemption doctrine of *Mayo* and *Funk Bros.*, the Court cannot hold the isolated DNA to be patent eligible subject matter without allowing a patent to issue on one of the fundamental principles of nature, DNA itself.

All that remains, therefore, in the isolated DNA as claimed are advantages provided by the "cleaved" package made possible by "engineering the edges" of the naturally occurring DNA SEQ by cleaving of the covalent bonds to form the isolated DNA itself; an insignificant extra-solution activity. That should not be enough.

Since the isolated DNA product claims do not disclose an invention or discovery within the meaning of § 101 of the patent statutes, the isolated DNA patent claims should be held invalid. The Federal Circuit holding to the contrary should be reversed.

V. The claims which are directed to isolated sequences that are identical to naturally occurring gene sequences fall squarely within the discussion of Section IV above and are not human invention. However, the judgment of the Federal Circuit as to isolated cDNA product claims should be vacated and the case should be remanded to the United States Court of Appeals for the Federal Circuit for further consideration of whether the packaging of the DNA SEQ into cDNA molecules is an insignificant extra-solution activity or "human invention" deserving of a patent

As discussed in detail in Section IV of this brief, to be sure, some of the claims may require more than simply the isolation of natural DNA from its natural habitat and those claims require further analysis.

As Judge Moore noted in her concurring opinion:

> The isolated DNA claims of the patents in suit fall into two categories. The first category of claims is directed to isolated sequences that are identical to naturally occurring gene sequences. These include claims encompassing both the isolated full length gene

> sequence (e.g. claim 1 of '282 patent), which are thousands of nucleotides, and claims to shorter isolated DNA strands, with as few as fifteen nucleotides, whose nucleotide sequence is found on the chromosome (e.g. claim 5 of '282 patent). The second category of claims is directed to isolated DNA sequences that are different from the naturally occurring gene sequences. These include claims to isolated cDNA molecules (e.g. claim 2 of the '282 patent), which differ from the natural gene sequence in that the introns are removed, and are the opposite (complementary) sequence of the naturally occurring RNA.

Ass'n for Molecular Pathology, *supra*, concurring at 1340.

The first category of claims which are directed to isolated sequences that are identical to naturally occurring gene sequences falls squarely within the discussion of Section IV above. All that remains in those isolated DNA as claimed are advantages provided by the "cleaved" package made possible by "engineering the edges" of the naturally occurring DNA SEQ by cleaving of the covalent bonds to form the isolated DNA itself; an insignificant extra-solution activity. That should not be enough. Since those isolated DNA product claims do not disclose an invention or discovery within the meaning of § 101 of the patent statutes, those isolated DNA patent claims should be held invalid. The Federal Circuit holding to the contrary should be reversed.

The second category of claims, which are isolated cDNA molecules (e.g. claim 2 of the '282 patent) (*id*., at 1340, 1341), differ from the natural gene sequence in that the introns are removed, and are the opposite (complementary) sequence of the naturally occurring RNA. *Id*. The judgment of the Federal Circuit as to those isolated DNA product claims should be vacated and the case should be remanded to the United States Court of Appeals for the Federal Circuit for further consideration in light of the decision of this Court in this isolated DNA case now before it. In particular, the Federal Circuit should consider whether the packaging of the DNA SEQ into cDNA molecules is an insignificant extra-solution activity or "human invention" deserving of a patent. It would be improvident to decide this difficult question without fully briefing this question.

VI. The Court should clarify that "preemption" in isolated DNA arises not from isolated DNA being not "new"; rather that the isolated DNA is not an "invention" or "discovery" entitled to a patent under § 101

There seems to be a great deal of confusion in the patent community about preemption and in particular which requirement in § 101 invokes the preemption doctrine. The case law suggests that preemption may be triggered by either or both "new" and "invention" requirements in § 101. For example, claims directed to "pure DNA" would appear to fail because "pure DNA" is not "new." On the other hand, the

"isolated DNA" claims before this Court that fail would appear to do so because albeit "new," those "isolated DNA" claims are not "inventive."

The Court's decision in the isolated DNA case now before it is believed will provide much valuable guidance on this important point.

CONCLUSION

The judgment of the court of appeals directed to isolated sequences that are identical to naturally occurring gene sequences reversing the district court's ruling under 35 U.S.C. § 101 should be reversed. The judgment of the court of appeals directed to isolated cDNA product claims should be vacated and the case should be remanded to the United States Court of Appeals for the Federal Circuit for further consideration of whether the packaging of the DNA SEQ into cDNA molecules is an insignificant extra-solution activity or "human invention" deserving of a patent.

Respectfully submitted,

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