

# SUMMARIES OF AMICUS BRIEFS FILED IN THE *MYRIAD* APPEAL<sup>1</sup>

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## I. Briefs in Support of Reversal

### A. *American Intellectual Property Law Association (AIPLA)*

The brief characterizes Myriad's invention as to "allow health care practitioners to identify individuals at significant risk of breast and ovarian cancer, tailor existing treatment options to ensure the highest likelihood of therapeutic success, and develop new anti-cancer treatments specifically designed to combat these devastating diseases." Because of such medical advances, it is deemed to be "the type of inventions that the Patent Laws and the policy behind them are designed to incentivize and protect." AIPLA argues separately that both Myriad's product and method claims are patentable as a matter of policy and law.

Firstly, AIPLA elaborates the policy rationales underlying the patent-eligibility of purified/isolated DNA molecules and methods of using them. AIPLA argues broadly that a company "takes the risk of discovering, testing, and bringing to market a novel lifesaving product at the cost of hundreds of millions of dollars *should* be permitted to seek exclusive rights to the invention for a limited period to recoup its enormous investment, fund additional research, and expand its business." AIPLA also emphasizes that once the patent term expires, "all are free to enjoy, commercialize, and improve the claimed inventions." In substantiating the negative impact it suggests, AIPLA cites the incident in 2000, where the stocks of relevant companies dropped 25%-30% after a White House spokesman suggested that the United States and Great Britain would redistrict gene patents. In addition, AIPLA suggests the hostility towards gene patents derives from the perception that one's personal genetic makeup ought not to be the intellectual property of for-profit enterprises. AIPLA clarifies that patents at issue do not confer Myriad "ownership" interests of anyone's genetic heritage. Indeed, the patents only cover "the molecules that have been significantly altered relative to native genomic DNA" by the inventors.

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<sup>1</sup> This summary is prepared for the 19th Annual Intellectual Property Law & Policy Conference, Fordham Intellectual Property Law Institute.

Secondly, AIPLA addresses the patent-eligibility of purified/isolated DNA molecules. Specifically, AIPLA argues that “the so-called ‘products of nature’ exception ... should be narrowly drawn and should not apply ... to exclude Myriad’s inventions.” In explaining the profound chemical difference between a full-length chromosome and the claimed DNA molecules, the brief states that the latter are “much smaller and do not have the same three-dimensional structural and chemical complexity.” Moreover, according to AILPA, the claimed DNA molecules can “no longer perform as nature intended.”

AIPLA then attacks the district court’s “shared essential characteristic” test. Specifically, the district court erred by identifying the DNA’s ability to store biological information as “essential,” and then determining that the claimed subject matter retained that “essential characteristics.” AIPLA argues that the proper test should focus on differences, not similarities. Moreover, the district court’s approach violates the basic principle that “the claimed subject matter must be evaluated as a whole.” AIPLA adds that “the fact that this shared characteristics may contribute to the utility of the claimed subject matter is legally irrelevant to the Section 110.”<sup>2</sup> AIPLA further assures that reversing the district court’s ruling will not result in non-meritorious patents on isolated genes because of the safeguards such as novelty and utility.

Thirdly, AIPLA argues that “[t]he method claims disclose patent-eligible subject matter” under *Bilski* and other precedents. AIPLA states Myriad’s methods are not merely abstract ideas or scientific principles. Specifically, AIPLA argues that even if the claimed methods invoke scientific principle of the correlation between certain DNA consequences and susceptibility to disease, the claimed methods “apply such principles in a series of transformative acts.”

Fourthly, AIPLA discusses the business and real world harms caused by the district court’s decision. The brief quotes *Festo* where the Supreme Court pronounced that “courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community.” Citing the USPTO guidelines implemented ten years ago, AILPA stresses that “the patentability of isolated genes and diagnostic methods is well-settled.”

Lastly, AIPLA urges that Congress is the proper venue for plaintiffs to effect changes in the Patent Law, not the courts. Notably, AIPLA states that “[s]ocietal issues such as the costs of testing ... should play no part in the Section 101 analysis.” The brief further asserts that to

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<sup>2</sup> The brief quotes *In re Bergy*, where CCPA held that the fact of being alive does not exclude the bacteria at issue from the scope of patentability. CCPA also recognized that the utility of the invention also stemmed from the fact of its being alive. 596 F.2d 952, 975 (1979) (“[i]t is because it is alive that it is useful”).

consider such issues would undermine the premise that Myriad’s inventions “are what made the diagnostic tests possible in the first place.”

*B. Alnylam Pharmaceuticals, Inc.*

Alnylam Pharmaceuticals, Inc. is a leader in the RNAi field.<sup>3</sup> Alnylam begins its brief by noting that its “sole concern as *amicus* is to support the traditional interpretation of ‘composition of matter’ under Section 101 as embracing all forms of compositions – including compositions which are derived from natural products and which derive their beneficial effect from their interactions with natural phenomena.”

Alnylam focuses on the discussion of the precedents to the *Myriad* appeal, including *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), and *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Alnylam argues that *Bergy* and *Chakrabarty* “kept the door of patent-eligibility wide open for any ‘composition of matter’ under 35 U.S.C. § 101 – without prejudice as to whether an individual patent-eligible composition of matter was patentable based upon considerations of novelty, nonobviousness, formal matters or enforceability issues.”

Alnylam also addresses the irrelevance of decisions such as *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). According to Alnylam, *Funk Brothers* had absolutely nothing to do with patent-eligibility even though the Supreme Court struck down a “composition of matter” claim. The claimed mixture of bacteria in *Funk Brothers* was found lacked “patentable invention,” or nonobviousness under today’s terminology.

From policy perspective, Alnylam argues that “judicial exclusion of certain ‘compositions of matter’ from patent-eligibility would take an unambiguous term and move the United States into an interpretation of law that is inconsistent with its international treaty obligations.” Alnylam states that “[t]here is absolutely zero ambiguity in the meaning of ‘composition of matter’ as encompassing any chemical compound.” Thus, excluding certain chemical compounds would violate Article 27(1) of the TRIPS Agreement, in which the United States promised to grant “patent rights enjoyable without discrimination as to . . . the field of technology.”

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<sup>3</sup> The field of RNAi includes the research and development of synthetic small interfering RNAs (siRNA) molecules. The siRNAs bind to messenger RNAs and silence the disease-causing genes.

C. *Animal Health Institute (AHI) and Merial Ltd.*

AHI's members engage in developing products based on discoveries of isolated DNA molecules. Merial has a particular interest in the Myriad appeal because it was involved in a Federal Circuit decision where Judge Dyk, in an opinion concurring in part and dissenting in part, questioned whether one of the Merial's claims covering an isolated DNA molecule constituted patentable subject matter. *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282 (Fed. Cir. 2010)

*Amici* argue that “[i]f isolated DNA molecules were not patentable, the ability of animal health industry to develop DNA inventions for the treatment and prevention of global diseases that threaten the world’s animal and human populations would be jeopardized.” Moreover, the *amici*’s reliance on patent protection for isolated DNA molecules is well justified because “the PTO has a long history of approving patents involving isolated DNA molecules.” *Amici* emphasized that “when these patents have been challenged, the Federal Circuit has upheld them.”

Notably, *amici* argue that even if isolated DNA molecules somehow did not fit within the definition of “compositions of matter,” they nonetheless qualify as “manufactures” under § 101. *Amici* explain that, firstly, an isolated DNA molecule involves human intervention because “the patents-in-suit make clear to one of skill in the art that isolated DNA molecules must be either (i) chemically synthesized or (ii) excised from the other sequences in the genome and from any proteins or other cellular components, that naturally accompany the particular DNA sequence of interest.” Secondly, creating isolated DNA molecules, whether via chemical synthesis or excision, requires highly technical steps. Thirdly, these technical steps used to create isolated DNA molecules “all result in chemical and structural changes to any starting materials.” Therefore, *amici* state that “any assertion that the creation of isolated DNA molecules is akin to mining a mineral in the earth or plucking a leaf from a tree relies on misunderstandings of the level of human intervention necessary to create isolated DNA molecules.”

*Amici* further argue that isolated DNA molecules are patentable “without limitation to a particular use or application.” This argument is directed to Judge Dyk’s opinion in *Intervet Inc. v. Merial Ltd.* *Amici* suggest that Judge Dyk implied that “claims to isolated DNA molecules

could constitute patentable subject matter if they are limited to the use of a particular isolated DNA molecule in a particular application, such as a vaccine.” *Amici* rebut that “an inventor of a new composition is entitled to the benefit of a patent for all the uses to which its composition can be put, whether or not the patentee envisioned such uses.”

*D. Biotechnology Industry Organization (BIO)*

The BIO brief states three grounds for the proposition that isolated DNA are patentable subject matter under 35 U.S.C. § 101. First, isolated DNA molecules are not the “purification” of naturally-occurring DNA. Rather, they are “man-made compositions of matter” that have different chemical structures from naturally-occurring DNA in a chromosome.

Second, even if isolated molecules are purified products of nature, they are chemical compounds with “new and distinctive properties and uses compared to naturally-occurring DNA.” According to BIO, “native DNA serves its natural purpose within a cell, but it cannot be used in virtually any practical diagnostic, therapeutic, or industrial application.” The isolation of a DNA molecule “imparts new utilities and functions unavailable from native DNA.” Thus, BIO contends that the gene patent does not involve a situation in which natural substances “serve the ends nature originally provided and act quite independently of any effort of the patentee.” *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127, 131 (1948). BIO adds that it is such new utilities and functions that “distinguish[] isolated DNA molecules from native DNA for purposes of patentability.”

Third, BIO argues that the district court erred when it treated DNA as “mere information” rather than as a chemical compound. BIO stresses that “DNA itself is a chemical, and proteins are produced through chemical reactions.” The information metaphor does not change the fundamental nature of DNA molecules as “composition of matter” that are patentable under Section 101.

From policy perspective, BIO argues that invalidating patents on isolated DNA molecules would discourage innovation. According to BIO, patent protection is essential to the ability of biotechnology firms to attract investment of both time and capital. In fact, patents are “typically the only assets [biotechnology] firms possess that are sufficiently stable and valuable to attract the large amounts of capital they need to exploit promising research toward new drugs and diagnostics.” BIO contends “[t]he U.S. biotechnology industry was launched largely because of the possibility of using isolated DNA for medical applications such as gene therapy, genetic

testing and manufacture of therapeutic proteins.” Therefore, BIO states the district court’s ruling would shake investor confidence and interfere with the research and development of biotechnology firms.

*E. Boston Patent Law Association (BPLA)*

BPLA argues that the Myriad inventions are patent eligible. Firstly, eligibility for patent protection under Section 101 is broad. BPLA quotes the Supreme Court’s recent teaching in *Bilski* that “Section 101 is a ‘dynamic provision designed to encompass new and unforeseen inventions.’” Secondly, for purpose of patent eligibility, the claimed isolated DNA can be considered at least as a “manufacture.” BPLA emphasizes that the correct construction of “isolated” DNAs is “chemical structures that have been isolated and then modified or refined through human ingenuity.” Isolated DNA is chemically and functionally distinct from the naturally occurring DNA. According to BPLA, by virtue of their isolation, the molecule has been transformed into “new and useful manufactures with practical applications previously unavailable to humankind.” In fact, such isolating genes can be accomplished only through a series of complicated steps requiring human intervention. Notably, BPLA contends that “[t]hose of ordinary skill in the art view DNA as a chemical composition.” BPLA also notes that “other chemicals convey information and would not be subject to the same scrutiny as in this case.”

In its policy arguments, BPLA questions this case as “an attack on the patent system itself.” BPLA contends that “[t]he criticism of gene-related patents is overstated.” Given the disclosure and design around incentives, Myriad’s patents do not unfairly limit research in and access to technologies for diagnosing and treating breast cancers. In addition, BPLA notes that biotechnology inventions are costly to develop, with an average cost of discovering, developing and commercializing a new product up to \$1.2 billion. BPLA warns that “without Myriad’s patent ... no entity would have taken the financial risk necessary to commercialize [the diagnostic tests].”

F. *Christopher Holman and Robert Cook-Deegan*

Chris Holman has a Ph.D. in molecular biology and is currently a law professor at the University of Missouri – Kansas City School of Law. Robert Cook-Deegan is a Research Professor and Director of the Center for Public Genomics at Duke University.

*Amici* firstly argue that “[g]ene patents have for years played an important role in incentivizing innovation in applied genetics and biotechnology.” Citing two reports by the Federal Trade Commission (FTC), *amici* assert that gene patents serve the same function as drug patents in the traditional pharmaceutical industry. *Amici* also employ biologic drug Epogen as an example. Epogen was first brought to the market by Amgen in the 1980s. It derives from the erythropoietin gene, which is also a naturally occurring compound. *Amici* note that, notwithstanding that Amgen’s core patent claims is “almost identical” to some claims invalidated in the district court, the validity of Amgen’s patent claim was upheld by the Federal Circuit.<sup>4</sup>

*Amici* secondly assert that gene patents have not been shown to create public policy concerns to the extent that “they would warrant innovation of the doctrinal sledgehammer of patent ineligibility.” Identifying anticommons as the initial fear towards gene patents, *amici* quote several studies in support of the proposition that “patents have had little if any limiting effect on research.” Moreover, according to *amici*, patents are not always enforced. *Amici* also cite studies stating that “there is currently no conclusive evidence establishing that gene patents had had a net negative impact on the availability of genetic testing.” Specifically, *amici* point out that “restriction on the ability of competing laboratories to provide the test without licensing patents does not necessarily imply that patients are unable to obtain the testing they desire.” *Amici* explain that no evidence of higher costs for the testing has been recorded.

*Amici* thirdly contend that “[c]oncerns raised with respect to Myriad’s patents, and gene patents in general, could be better addressed using other doctrines of patentability and appropriate claim interpretation.” According to *amici*, both Plaintiffs and the district court expressed concerns that Myriad was not the first to sequence the gene at issue. *Amici* note that if

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<sup>4</sup> *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212-14. (Fed. Cir. 1991).

others had succeeded in isolating the gene prior to Myriad, the novelty requirement should be implicated. Likewise, given the concerns that the claims on “isolated” DNA are overly broad, *amici* suggest a narrower claim interpretation regarding “isolated” can be adopted. In addition, enablement and written description are the doctrinal tools for policing broad patent claims, not patent eligibility. *Amici* state that, *Ariad Pharmaceuticals v. Eli Lilly*, 598 F.3d. 1336 (Fed. Cir. 2010), is an example of using limiting claim interpretation and claim invalidation under section 112 as alternatives to patent ineligibility. *Amici* stress that “[a] careful claim-by-claim review of ... patents could restrict their patent exclusivity to the scope of their actual invention.”

*Amici* further note that most of the angst against Myriad “centers around the potential negative effect on diagnostic testing.” Rather than interpreting patent eligibility, advocated by *amici*, such concerns could be better addressed by other means. *Amici* propose alternative measures including limitation on infringement liability for those using patented genetic technology in research or genetic testing, compulsory licensing, invocation of march-in rights, and assertion of state sovereign immunity. *Amici* also recognize that the antitrust laws may be invoked against the anticompetitive business practice by Myriad.

*Amici* next assert that the lower court’s invalidation of a method claim of Myriad’s patent “illustrates the problem with using patent eligibility to address a perceived problem with gene patents.” This claimed method is used to identify potential drugs for the treatment of cancer,” and “involves substantial human intervention.” *Amici* contend that “[i]f this claim is patent ineligible, it is hard to imagine a biotechnology claim that is eligible for patent protection.”

*Amici* last argue that “[a]ffirmance of the decision below could result in substantial unintended consequences impeding the development of future genetic diagnostic tests, personalized medicine and biotechnology.” *Amici* rebut the argument that gene patents will be discovered with or without the incentive of a patent. Conceding this argument “might be valid” with respect to single genes highly correlated with disease, *amici* assert that publicly funded research will not suffice to develop the next generation of generic testing technologies. *Amici* assert that such development requires “identifying more complex patterns of genetic variation involving a large number of genes dispersed throughout the genome,” and thus “might require a substantial private investment.” Given the likelihood that the FDA’s future regulation would further increase the investment necessary to commercialize new genetic diagnostic tests, *amici* argue that “patent might be necessary to induce adequate private investment.”

### G. Genetic Alliance

In the first part of the brief, Genetic Alliance argues that the district court's opinion "suffers from several legal errors." In particular, the brief states that the opinion "errs in stating that any compound from a natural source that is isolated and purified without chemical change cannot be patented."

According to *amicus*, the district court committed the first legal error in applying the "markedly different" test for assessing the patent-eligibility of the claimed DNA molecules. The brief argues that the determination of whether a claimed composition is "markedly different" from a related, naturally occurring composition is "highly subjective." The brief contends that "to meet the *Chakrabarty* test a composition or manufacture related to a natural product must be (1) non-naturally occurring, (2) a product of human activity, and (3) ha[ve] a distinctive name, character, and use."

Applying the three-prong test it derives from *Chakrabarty*, *amicus* concludes that the claimed DNA molecules: (1) are not found in nature (which, according to the brief, the district court recognized), (2) "are all made by scientists and require substantial human intervention to prepare them," and (3) have properties and uses that differ in kind from genes in the body. On this last point, the brief summarizes those properties and uses as follows:

Isolated DNA molecules can be used in research as targets for discovering new drugs and as tools for manufacturing protein drugs. Isolated human DNA molecules can be used to produce human proteins in entirely different species, such as yeast or bacteria. Isolated copies of DNA molecules can be sequenced for diagnosis. The small, claimed DNA molecules (primers and probes), which do not exist in nature and do not code for any protein (only a small string of amino acids), are useful as chemical reagents, research tools, and as diagnostic and biological probes. Isolated DNA molecules can be used in gene therapy. DNA in genes inside the body cannot directly be used in any of these ways.

*Amicus* next rebuts district court's conclusion that isolated DNA molecules are "products of nature." *Amicus* states that "the Opinion decides that for patent eligibility under § 101, the

presence of information-carrying nucleotide sequences overrides all other considerations.” The brief contends that:

Apparently agreeing that all chemical compounds carry “information,” the Opinion distinguishes patentable compounds as those in which the information is about their “own molecular structure,” whereas information in DNA is directed to other molecules (proteins). But other kinds of patentable macromolecules contain “Information” directed to other molecules. For example, antibodies, which are patentable subject matter, inherently contain “information” about the structure of other molecules (antigens), which reflects antibodies' primary function (binding to antigens) and makes them able to interact with antigens.

*Amicus* further contends that if modified bacteria of *Chakrabarty* was found to be patent-eligible, then the isolated DNA molecules of the instant case are most certainly patent-eligible. *Amicus* notes that “the genetic manipulation, purification, and change in structure required to engineer isolated cDNA molecules (as in the BRCA patents) result in molecules that differ far more in structure and function from native DNA than did *Chakrabarty*'s patentable bacterium compared to bacteria found in nature.”

In the second part of the brief, *amicus* argues that if isolated DNA molecules are to be deemed patent-ineligible, such determination is for Congress and not the courts. Noting that “[t]he PTO has granted thousands of patents claiming isolated DNA sequences and their use, and the courts have adjudicated disputes regarding DNA patents, without questioning their patent eligibility,” the brief advises the Federal Circuit “not [to] change this almost universally accepted interpretation of the patent statute without a clear and certain signal from Congress.” The brief then discusses how a holding of patent-ineligibility for isolated DNA molecules “would render portions of 35 U.S.C. § 103(b), § 271(e)(1), and § 271(g) meaningless, violating the statutory canon against interpreting a statutory provision in a manner that would render another provision superfluous.”

*Amicus* then concludes with a discussion of why the diagnostic method claims at issue are patent-eligible under § 101, arguing that the method claims require a transformation of matter into a different state or thing and that the method claims do not preempt the idea that mutations in the BRCA genes may increase cancer risk.

*H. Genomic Health Inc., Celera Corp., XDX Inc., Target Discovery Inc., the Coalition for 21st Century Medicine, and Burrill & Co.*

*Amici* in this brief share the interests in ensuring the patent system remains open to personalized medicine inventions. The brief opens with a description of personalized medicine and its benefits to patients, payers and health care systems. In this specific case, *amici* emphasize that “once the utility of diagnostic genes . . . are identified, diagnostic tests are easily copied.” *Amici* thus state that patent exclusivity is required to capture the investment needed to commercialize personalized medicine. In defending strong patent protection, *amici* also acknowledge that high R&D spending fostered by the robust patent system has substantially reduced health care costs. Accordingly, *amici* warn that the district court’s opinion, “if applied broadly, will fundamentally undermine the incentives needed to advance personalized medicine.”

Addressing the substantive merits of the Myriad patents, *amici* state three grounds supporting the patentability of the methods claims at issue. First, *amici* contend that Section 101 encompasses a broad scope of patentable subject matter to liberally encourage any new and useful process. Patents to processes utilizing natural phenomena are distinguishable from the phenomena themselves.

Second, *amici* argue that the district court erred by adopting an overbroad “markedly different characteristics” standard for patent eligibility. The district court derived this standard from *Chakrabarty* where the Supreme Court observed the claimed bacterium exhibited “markedly different characteristics from any found in nature.” Nevertheless, according to *amici*, the *Chakrabarty* Court did not tie the patent eligibility standard to the facts of that particular case. *Amici* insist that *Chakrabarty* and *Funk Brothers* together demarcate the proposition that “human ingenuity must inherently alter or apply a natural phenomenon so that the patented article takes on new and useful characteristics distinct from any found in nature.”

Third, *amici* argue that the method claims at issue “reflect the hand of man and do not pre-empt all uses of the generic correlation.” *Amici* specifically identify a number of claim

limitations, which prevent the claims from covering “the mutations occurring in nature,” or “the effect of sequence changes on human physiology.” *Amici* conclude that Myriad’s method “are not mere natural correlations,” but rather “represent an application of a law of nature”

Lastly, *amici* opine that Congress is the proper entity to determine whether DNA sequence claims and methods for using DNA sequences are patentable.

#### *I. Gilead Sciences, Inc. and BioGenerator*

*Amici* argue that the district court erred in two respects. First, the district court failed to recognize “made by man” as fundamental standard in patentable subject matter inquiry. *Amici* note that “[u]p to the present decision, in every case which a court has explicitly or implicitly evaluated §101-includability of a synthetic DNA molecule, the court has ruled for inclusion.”

The second error *amici* assert is that the district court substituted the “made by man” test by the “marked different” test. According to *amici*, the 1952 Patent Act is a re-codification of prior case law extending patent eligibility to “anything under the sun that is made by man.” The “marked different” test is a narrower interpretation of the statutory language and may not be applied without violating the legislative intent as well as the broad statutory interpretation set forth in *Chakrabarty*.

Notably, in arguing that Myriad synthetic DNA molecule is a “made-by-man substance,” *amici* highlight that “the naturally-occurring DNA of Chromosome 17 has fragments of the BRCA-gene coding sequence *scattered across an 81 million base-pair DNA sequence.*” In contrast, Myriad synthetic DNA molecule “contains *the entire coding sequence*” of BRCA1/2 in “an uninterrupted sequence.” *Amici* also note that there are “at least 11 major steps in the identification and synthesis of the entire DNA coding sequence from the chromosomal gene.” *Amici* thus concludes that but for Myriad’s synthetic activity, the subject matter at issue “would not have come into existence as a chemical entity.”

Lastly, *amici* point to the factual errors committed by the district court in applying the “marked different” test. *Amici* state that Myriad synthetic DNA is both structurally and functionally distinct from natural product. The three structural differences lie in (1) reduction of molecular size from natural-gene 84,000 base-pair length to 5,914 base-pair sequence, (2) excision of non-coding intron-segments from natural gene, and (3) elimination of chromosomal packing directed by chromatin and other cellular components. According to *amici*, Myriad synthetic DNA’s purity (free of other cellular content) and structure (complete uninterrupted

coding sequence) results its distinctive functional feature as a molecular probe for the diagnosis of ovarian or breast cancer in women.

*J. Intellectual Property Association (IPO)*

The IPO argues that isolated DNA is patentable as a “composition of matter” and “manufacture” in light of *Diamond v. Chakrabarty*.

The IPO argues that Chakabarty enunciated a broad § 101 standard. “Anything that evinces the hand of man is patent-eligible.” The IPO contends that isolated DNA satisfies the Chakabarty standard substantially because “claims to isolated DNA do not encompass genes as they exist naturally in any cell.” According the IPO, “[i]n isolating the claimed DNA, an inventor typically identifies a cell that expresses a gene, obtains the mRNA from the cell and enzymatically converts it into DNA before it can be isolated.”

The IPO rigorously argues that “[a] ban on patenting isolated human DNA would negatively impact research, technology and innovation.” The IPO first opines that the Supreme Court has never carved the “products of nature” exception. Adopting the “products of nature” exception would exclude broad categories of important inventions from patent protection, including “most biologic drugs, antibodies, antibiotics, hormones, metabolites, proteins, and genetically-modified organisms and food. “IPO believes such a broad ban is not justified, since there is no other source for these materials but nature.”

The IPO emphasizes the dire consequence that would have resulted to the biotechnology and pharmaceutical industries in the coming era of personalized medicine. The IPO warns that if the district court’s decision that patents on isolated human DNA are directed to patent-ineligible “natural products,” then “the vast majority of human therapeutics” would be patent-ineligible as well. In addition, the IPO questions the effectiveness and soundness of trade secret protection in the absence of human DNA patenting.

*K. Kane Biotech, Inc.*

*Amicus* Kane Biotech is a biotechnology company engaged in the developments of products to prevent and disperse bacterial biofilms.

*Amicus* argues that isolated DNA is a chemical that qualifies as patentable subject matter as a composition of matter or as an article of manufacture. The term “composition” includes mixtures of chemical compounds that are joined by chemical bonding, such as DNA molecules. *Amicus* contends that like the altered bacterium in *Chakrabarty*, isolated DNA is also distinct in “name, character, and use” from naturally occurring DNA.

Moreover, according to *amicus*, isolated DNA does not fall within any of the identified narrow exceptions. Firstly, isolated DNA does not fit into the category of law of nature. Secondly, the claimed subject matter is “not directed to the general concept that DNA encodes a protein but rather it is directed to an isolated chemical compound.” Because claiming the isolated DNA at issue would not preempt use of all isolated DNA, the claim is not so broad as to be just an abstract idea. Lastly, the isolated DNA differs from DNA coding as found in nature in the human body, and thus does not only involve unpatentable physical phenomena.

*Amicus* also argues that the district court erred by limiting the analysis of isolated DNA to DNA’s informational property. The fact that DNA also encodes information does not make DNA any different from other chemical compounds. Moreover, the claims do not prevent some from analyzing the biological information that the DNA represents. Accordingly, *amicus* states that “[w]hen the invention ... is evaluated as a whole, claims to an isolated DNA consequence coding for *BRCAl/2* are patentable subject matter.”

*L. Novartis Corp.*

*Amicus* Novartis Corporation offers innovative medicines, generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products.

*Amicus* begins the brief by introducing the nature of biotechnology research. According to Novartis, the underpinnings of biotechnology research lie in “the identification, production, amplification and use of isolated DNA sequences.” Although the DNA “codes for” the multitude of proteins that the body manufactures, native DNA contains inoperative non-coding sequences as well. *Amicus* stresses that “*in situ*, DNA is unknown, unavailable and unusable.” Thus, biotechnology research is directed to identifying operative DNA sequences and recreating them in a purified form in the laboratory where they can be put to a host of diagnostic and therapeutic uses.

*Amicus* urges the court of appeals to reverse the decision, focusing on two legal errors committed by the district court. First, the district court erred in treating DNA as uniquely unpatentable. This argument is directed to the district court’s statement that “the informational quality” of DNA “is unique among the chemical compounds in our bodies, and it would be erroneous to view DNA as ‘no different[.]’ than other chemicals previously subject of patents.” *Amicus* argues that this treatment for DNA stems from the district court’s exclusion of DNA’s material composition. *Amicus* notes that the district court “cites no basis for treating DNA differently from any other composition of matter under the patent laws.”

Second, the district court erred in invoking a broad exclusion from § 101 for “products of nature.” *Amicus* argues that the district court’s position is again at odds with longstanding precedent which recognizes the patentability of pure forms of naturally-occurring products which do not exist in pure form in nature. *Amicus* urges that “the patentability of such purified products” is “a cornerstone of the biotechnology industry.”

Regarding the “marked different” test, *amicus* opines that the district court “confuses the concepts of patentable subject matter and novelty.” *Amicus* further states that even if DNA is

viewed as information, the information contained in isolated DNA is markedly different from that in DNA found in nature.

*Amicus* lastly discusses the negative impact the district court's ruling would have on the biotechnology industry. *Amicus* states that the Novartis companies alone would face "losses totaling hundreds of dollars in lost sales of products ... and lost royalties."

*M. Pharmaceutical Research and Manufacturers of America (PhRMA)*

*Amicus* PhRMA is a nonprofit association representing leading research-based pharmaceutical and biotechnology companies. Urging a reversal, *amicus* states that the district court's decision undermines "the degree of certainty and predictability in patent law that innovators and investors have depended upon."

*Amicus* first argues that Myriad's patents are directed to patentable subject matter. The brief attacks the district court's decision as "a dramatic departure" from a long-recognized and widely-accepted biotechnology patent practice. *Amicus* particularly quotes Justice Stevens' statement in *Bilski v. Kappos* that "[i]n the area of patents, it is especially important that the law remain stable and clear."

Notably, *amicus* argues that the Federal Circuit has "impliedly confirmed" the patent eligibility of isolated DNA sequences by addressing issues of novelty, obviousness, enablement, and written description with respect to numerous patents claiming purified or isolated biological substances.

In its policy argument, *amicus* estimates that creating a medicine takes an average investment of "ten to fifteen years" with costs "between \$1.2 to \$1.3 billion." *Amicus* also quotes the Congressional Budget Office that "pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm." *Amicus* tries to justify the business model of pharmaceutical industry by stating that a limited period of exclusivity is "paid by this generation" in exchange of the public disclosure as "a gift to future generations." According to *amicus*, "[s]uch benefits include the further progress spurred in the area of biotechnology by existing patents."

N. *Rosetta Genomics, Rosetta Genetics and George Mason University*

The first issue the brief addresses is how the judicial abolition of gene patents will deter and not stimulate innovation. Besides emphasizing the incentive functions of patents for biomedical industries, *amici* contend that the district court “apparently summarily assumes that gene patents negatively impact scientific knowledge and innovation in biotech and biomedical fields.” Focusing on the Murray study and the Cho study offered by Appellees, *Amici* contend that “[t]he district court does not consider nor critique whether the methodology used in the Murray study actually provides relevant information,” and “the Cho study reports the *perceptions* of certain basic researchers regarding the impact of patents on their research, but does not explore the validity of those perceptions.” *Amici* argue that “[o]ne should not dictate patent policy based on perceptions that are not grounded in legal reality,” adding that both studies “fail[] to illuminate whether gene patents actually increase or decrease public knowledge and innovation.”

The second issue addressed by *amici* is the patentability of Myriad’s isolated DNA claims. *Amici* suggest that, like DNA molecules, “[m]any other naturally-occurring molecules manifest a physical embodiment of information.” As but one example, *amici* propose an amino acid sequence of a protein, which determines the protein’s three-dimensional structure and biological properties. *Amici* then contend that “DNA composition is qualitatively different from the product occurring in nature.” In particular, *amici* note that “the human body does not have a mechanism for isolating DNA, and consequently, isolated DNA is not found in the body.” In addition, *amici* assert that isolated DNA molecules have “a vast number of other uses and properties, [which] ... cannot be duplicated with naturally-occurring DNA.”

Lastly, the brief discusses Judge Hand’s determination in *Parke-Davis & Co. v. HK. Mulford & Co.*, that claims directed to purified adrenaline were patentable, stating that:

[The inventor] was the first to make it available for any use by removing it from the other gland-tissue. . . . It became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.

*Amici* suggest that similarly, “it was not until identification and purification of the *BRCA1* and *BRCA2* genes that the isolated nucleotide sequences could be used in a variety of highly important and beneficial methods including disease diagnosis.”

O. *University of New Hampshire School of Law (UNH)*

The brief opens with the argument that the district court has “erroneously established a new limitation on patent-eligible subject matter.” UNH states that “DNA is acknowledged as a result of a ‘chemical union,’ which fits squarely within the *Chakrabarty* definition of a composition of matter.” UNH notes that under the Supreme Court case law, “the only criteria for patent-eligibility for compositions of matter, even those derived from naturally-occurring compositions, are that they be new and useful.” UNH then criticizes the district court for imposing additional exclusion on patent eligibility if the composition of matter “serves as the physical embodiment of the laws of nature.” UNH stresses that no Supreme Court decision or Federal Circuit panel has established this limitation. UNH explains that even in *Funk Bros.*, the closest decision that can be read in such a way, nothing suggests that if a composition of matter has a “unique characteristic” that “serves as the physical embodiment of the laws of nature” that it is disqualified from patent-eligibility under § 101. UNH goes on to presents supporting case law where no “special exception” for living matter was articulated when it was sought.

UNH next argues that there exist genuine issues of material fact and thus a summary judgment ruling was improper. UNH first points to the disputes over the term “isolated.” AMP defined isolated DNA as a “fragment of DNA found on chromosome.” *Amicus* asserts that this definition “impl[ies] that the fragments can simply be removed from the cell with no change in structure or function.” In contrast, Myriad’s definition adds that “extraction of isolated DNA requires ‘excision from the chromosome and extraction from the cell or chemical synthesis.’” Another disputed fact is whether isolated DNA is different in function from DNA in the body. While AMP no such differences exist, Myriad maintains that, unlike native DNA, isolated DNA can be used use as probes or primers, rendering isolated DNA suitable for mutation detection.

UNH also dismisses all policy concerns advanced in the district court’s decision: the funding for the tests; enforcement of the patents; impact of the patents on BRCA testing; and impact of gene patents on the advancement of science and medical treatment. Citing

*Chakrabarty*, UNH contends that policy discussions are irrelevant and inappropriate to the issue of whether isolated DNA is patent-eligible. UNH adds that on a summary judgment motion, facts relating to public policy should also “be resolved in a manner most favorable to Myriad.”

*P. CropLife International*

*Amicus* CropLife International is a global federation representing the place science industry. Its member companies include BASF, Bayer, Dow AgroSciences, DuPont, Monsanto, etc. *Amicus* states that these companies are actively applying DNA-based inventions to produce seeds and plants that are unfound in nature. Thus, as stated by the brief, “it would be untenable, and even absurd, to judge patent eligibility of such inventions by the district court’s ‘markedly different’ test.”

*Amicus* then argues that “failure to reverse the district court will create a conflict with Supreme Court’s *Chakrabarty* and *J.E.M.*, which unquestionably support the patent eligibility of modern-day agricultural inventions.” *Amicus* notes that “the claimed living organisms, when judged on the basis of the totality of their properties, had many in common with their natural counterparts.” In fact, these claimed products are “seldom markedly different” in most respects. Their patentability derives from the fact that they are made by man.

Analyzing the prior case law, *amicus* contends that the Supreme Court has never carved out a “product of nature” exception or a “markedly different test.” Instead, according to the brief, *Chakrabarty*’s basic message was that “[i]f the claimed invention can be fairly characterized as a manufacture or composition of matter that is the product of human ingenuity, and it is not something ‘created wholly by nature unassisted by man’, it is eligible for patenting under 35 U.S.C. § 101.”

## II. Briefs in Support of Affirmance

### A. AARP

AARP is nonprofit organization dedicated to addressing the needs and interests of people age fifty and older. With respect to the § 101 issue, AARP argues that “DNA molecules and human genes are natural phenomena that when discovered are not the kind of 'discovery' that Section 101 was designed to protect.” AARP relies heavily on the *Wood-Paper Patent* case,<sup>5</sup> quoting that “[a] process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.” AARP thus concludes that “isolating a gene from the human body does not then make the gene itself, patentable.”

AARP next lays out public health considerations that “demand that the patents in question be denied.” AARP notes that a “comparison of results obtained on samples shared between different labs” can best assure quality in laboratory testing. According to AARP, through the assignment of exclusive licenses to perform genetic tests, human gene patents not only limit a given genetic test to a single laboratory, but also affect patient access. Thus, AARP argue that many individuals will be harmed if the patent is upheld because patented genetic testing will be denied to them either due to cost or unavailability of a second opinion. Quoting the limited coverage of genetic testing for Medicare and Medicaid patients, AARP states that “many patients must pay for genetic testing out of their own pockets.” Accordingly, AARP opines that “[r]ejecting the patents in this case and allowing more laboratories to do the tests will result in lower prices for the tests and greater patient access.”

B. *American Medical Association, American Society of Human Genetics, American College of Obstetricians and Gynecologists, American College of Embryology, and the Medical Society of the State of New York*

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<sup>5</sup> 90 U.S. 566 (1874). In *American Wood-Paper*, the Supreme Court found merely removing pulp from straw, wood, or other natural sources did not make it a patentable new composition of matter.

In this brief, *amici* urge the Court to establish that isolated and purified genes, cDNA, synthetic genetic materials and methods of comparing and analyzing genetic sequences are all drawn to unpatentable subject matter. *Amici* state that the government’s rationales for reversal for claims to cDNA would allow harms to medical care and innovation to continue.

*Amici* start with an analysis as to why gene patents harm medical practice and scientific innovation. *Amici* state that patents on gene sequences have contributed to patients’ deaths. *Amici* also point out that Myriad’s exclusive control over the use of *BRCA* consequences has led to the misdiagnosis of patients and has precluded the deployment of improved genetic tests. Because some women do not have access to an independent confirmatory test, they underwent unnecessary surgery based on erroneous *BRCA* genetic test result. *Amici* go on to illustrate how gene patents interfere with access to health care. Given the cost of the genetic tests,<sup>6</sup> *amici* predict personalized gene analyses would be even if technology will soon allow the sequencing of a person’s entire genome of approximately 30,000 genes.

*Amici* next assert that “[e]xisting non-patent incentives are fully adequate to encourage in genetics.” *Amici* state that “genetic diagnostic tests have been routinely developed by clinical laboratories without the incentive of patents on gene sequences or correlations.” *Amici* also contend that the genetic sequences covered by the Myriad patent “would have been discovered without the patent incentive.” According to *amici*, while a publicly-funded consortium “was completing” the work to identify the *BRCA1* gene, Mark Skolnick found Myriad Genetics and sought a patent on the *BRCA1* gene.

*Amici* then argue that “isolated gene sequences and cDNA are not patentable inventions.” *Amici* assert that “[e]xtracting the gene sequence from the chromosome ... does not make the gene sequence any more patentable than isolating cellulose from wood.” cDNA is single-stranded DNA with the non-coding regions removed. *Amici* state that contrary to Myriad’s assertion, “cDNA molecules can be found existing naturally in the human body.”<sup>7</sup>

*Amici* also address Myriad’s assertion that Congress “thought DNA molecules were patent eligible” in Section 103(b). Section 103(b) “addresses the obviousness of ‘biological process[es] using or resulting in a composition of matter that is novel under Section 102 and nonobvious under subsection (a).” According to *amici*, Congress only recognized that “cells

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<sup>6</sup> Myriad’s test on the BRCA gene costs \$3,000, while the other test on the Long QT gene costs \$5,400.

<sup>7</sup> See International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 Nature 860, 880 (2001).

could contain native or introduced genetic material and that patents could issue for non-obvious methods of affecting their expression.”

*Amici* lastly argue that “methods of comparing and analyzing genetic sequences are ineligible subject matter.” *Amici* concern that to affirm solely on the composition claims will “not adequately protect[s] medical care and innovation.” *Amici* note Myriad’s method claims “on their face are not limited to any steps other than ‘comparing’ or ‘analyzing’ genetic sequence information.” Thus, the method claims “cover the use of any and all techniques to determine the presence of a mutation” from the BRCA genes. Moreover, according to *amici*, Myriad itself did not invent any of these techniques.

Notably, *amici* rebut Myriad’s assertion that someone cannot perform their method by merely analyzing or comparing the sequence data. *Amici* state that “a software program already has done just done that” by allowing users to search the BRCA genes for 68 known cancer-causing mutations.

*Amici* also analogize the instant case to the patent at issue in *Bilski*. According to *amici*, the medical fact claimed by Myriad has already existed. Thus, “Myriad can no more prevent people from using the fact by thinking than *Bilski* could prevent people from employing the abstract idea of hedging risk.” *Amici* also contend that even if Myriad’s method claims were to be construed to require data gathering steps, those steps would constitute only “trivial pre-solution activity” under *Bilski*.

*C. Canavan Foundation, Claire Altman Heine Foundation, March of Dimes Foundation, Massachusetts Breast Cancer Coalition, National Organization for Rare Disorders, National Tay-Sachs, and Allied Diseases Association*

*Amici* begin the brief by opining that the *Myriad* appeal “exemplifies how too much protection can impede ... collective efforts to minimize the pain and suffering caused by fatal diseases.” Describing genes are the same “basic building blocks” as elements from the period table, *amici* warn that “the consequences of affording patent protection to human genes can be lethal.” In the instant case, *amici* assert that Myriad’s monopoly not only controls what types of tests to offer, but also who qualifies for the tests. Thus, the Myriad patents have worsened patient outcomes. Moreover, the Myriad patents disincentive and limit the further research in understanding what is unknown about the BRCA genes, particularly the mutations.

*Amici* next defend the “products of nature” exception applied by the district court. According to *amici*, the Supreme Court has used this phrase interchangeably with “natural

phenomena” and “laws of nature.” Moreover, the terms “physical phenomena” and “laws of nature” are as broad or broader than the term “products of nature.”

*Amici* then assert that “isolated human gene sequences are not patentable subject matter.” *Amici* emphasize that isolated gene sequences, “whether extracted from cells or extracted and further purified into cDNA,” are “structurally and functionally identical” to gene sequences as they naturally occur. *Amici* also opine that patenting an isolated gene is seeking “a monopoly on its natural functions.” Consequently, according to *amici*, Myriad’s patents failed the “markedly different characteristics” test under *Funk Brothers* and *Chakrabarty*.

*Amici* go on to argue that “the mere extraction and purification of human DNA does not render it patentable subject matter.” *Amici* maintain that “an isolated and purified product of nature is not patentable if the product functions in a way that is not significantly different than what occurs in nature.” Based on this premise, *amici* assert that patent-eligibility could not derive from “any labor expended by Myriad” in isolation and purification.

*Amici* finally assert Myriad’s method claims are invalid for only involving abstract steps of analyzing and comparing. *Amici* dismiss the additional claim limitations identified by Myriad, including (1) breaking open cells of a tissue sample, (2) extracting DNA or RNA from those cells, and (3) using a diagnostic probe to hybridize to the target DNA or RNA to initiate a sequencing reaction. Specifically, *amici* state that these alleged limitations are distinguishable from the transformative steps in *Prometheus* since “the sequence information is not altered by the additional steps.” In contrast with the instant case, *amici* note that the required determination of metabolites in *Prometheus* was based upon bodily changes to an administered drug.

#### *D. Cancer Council Australia and Luigi Palombi*

*Amici* are both from Australia. *Amici* acknowledge that how patent law is interpreted and applied in the United States can have a corresponding influence on patent law in other countries.

*Amici* first assert that the bedrock principle of “invention” binds the patent laws of Britain, the United State and Australia. *Amici* cite a report by the Australian Senate Committee rejecting the notion that “genetic information that is ‘isolated’ from its naturally occurring state in the human body may be classed as an invention.”

*Amici* also specifically address the patent-ineligibility of cDNAs. First, cDNAs contains the same genetic information as that in the DNA of the human gene. Second, unlike the claimed bacteria in *Chakrabarty*, cDNAs “cannot be said to perform an unprecedented function from any

found in nature.” *Amici* note that the Patent Act Amendment Bill to preclude the patentability of biological materials was introduced in the Australian Parliament on November 24, 2010. According to *amici*, the preclusion under the Bill was broad as covering such materials “whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.”

#### *E. Professor Andrew Chin*

Professor Chin focuses his brief solely on the patentability of short DNA molecules, as claimed by Myriad in claims 5 and 6 of the '282 patent.<sup>8</sup> He argues that both claims are invalid under printed matter doctrine.

Citing Judge Linn’s concurrence in *In re Nuijten*, Chin states that the printed matter doctrine “precludes patentability where the differences between the claimed invention and the prior art subsist merely stored information.” Chin further asserts that this doctrine extends to any physical substrate capable of holding information, except that there is a “new and unobvious functional relationship between the printed matter and the substrate.” Chin notes the recent *Bilski* decision does not affect the operation of the printed matter doctrine.

Chin then asserts that short DNA molecules are “analogous in structure and function to other physical substrates that store and manifest information as printed matter.” Chin also notes that claimed short DNA molecules differ from DNA molecules used in prior art hybridization probe procedures only with respect to the nucleotide sequences carried thereon. Although acknowledging that hybridization reaction involving a claimed short DNA molecule has specific and substantial utility, Chin states such utility is by virtue of the semantic properties that scientists have attached to the complementary sequence, not “a new and unobvious functional relationship between the sequence information and the molecular substrate.” Chin thus concludes that Myriad’s claims 5 and 6 should be invalidated under the printed matter doctrine.

#### *F. Professor Eileen M. Kane*

Professor Kane begins her brief in framing the issue of the Myriad case as whether it is possible to patent the genes and the correlations between genes and disease. Kane asserts that two patent law principles are contracted by patenting on genes and genetic correlation.

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<sup>8</sup> Claims 5 and 6, both dependent claims, read: “An isolated DNA having at least 15 nucleotides of the DNA of claim 1” and “An isolated DNA having at least 15 nucleotides of the DNA of claim 2,” respectively.

First, the patenting of genes preempts the genetic code, and is invalid under the Supreme Court's precedents that maintain the essential knowledge tools in the public domain. According to Kane, the genetic code is equivalent in status to the laws of physics. The genes are the natural embodiments of the genetic code. Moreover, according to Kane, the genetic code is an essential component of the public domain in molecular biology. Kane comments that the merger doctrine in copyright law is helpful in understanding genes and genetic code.

Second, the gene has a general patent ineligibility as a product of nature. Kane opines that "[t]he isolated gene of the challenged patent claims is not altered from its natural state, but simply reproduced outside the cell." Kane stresses that "[a]ny deviation from the natural DNA sequence would compromise the use of the isolated DNA" in medically-related applications. Kane specifically notes a determination that genes are ineligible for patenting does not preclude the patent eligibility of the "truly inventive alterations of natural products."

Kane further argues that the claimed methods are also invalid. Kane constructs the method claim as describing "the act of comparing a patient's BRCA1 or BRCA2 DNA sequence to the normal DNA sequences for these genes in order to identify any mutations and identify cancer risk." Kane contends that such patenting effects monopolizing on the knowledge regarding the genetic correlation between the genotype (the DNA consequence) and the phenotype (cancer risk).

From policy perspective, Kane argues that "access to the basic tools of genetic science is critical for the patent system and the scientific enterprises." Kane warns that allowing patents on genes and genetic correlation would enable the patent owner to "set the intellectual agenda for an entire clinical field." Consequently, "decisions regarding access and comparative research can be dictated by commercial objectives." Kane further opines that when "the de facto clinical testing standards are set by a patent holder, rather than the scientific community," the standard then "becomes a function of the marketplace."

*G. International Center of Technology Assessment, the Indigenous Peoples Council on Biocolonialism, Greenpeace, Inc., Friends of the Earth, and the Council for Responsible Genetics*

In supporting the district court's decision, *amici* note that "a mere description using the terms 'isolated,' or cDNA should not create patentable subject matter if there is not a difference in substance." *Amici* further explain that the useful properties of a gene are not scientifically invented, "but rather are the natural properties of genes themselves."

*Amici* next assert four arguments in supporting the proposition that gene patents have significant negative consequences. First, the privatization of genetic heritage through gene patents violates fundamental precepts of common heritage, public domain and the public trust doctrine. “Human genetics are owned by all people and a single firm should not be granted the right to exclude others from using human genetics.” Citing *Graham v. John Deere*, *amici* avail further support from the Supreme Court’s teaching that “Congress may not authorize the issuance of patents whose effects are to remove existing knowledge from the public domain, or to restrict free access to materials already available.” Similarly, gene patents also contradict the policies underlying the common heritage and the public trust doctrines.<sup>9</sup>

Second, gene patents privatize genetic information that scientists still lack a full understanding of. *Amici* emphasize that gene sequences are not akin to conventional chemical compounds because “they are instead fundamentally information.” *Amici* note that the mechanism by which the gene defects contribute to breast cancer risk remains unknown. Thus, patents on genes halt research of this scientific paradigm. Accordingly, gene patents are antithetical to the purpose of U.S. patent law to “promote the Progress of Science and useful Arts.”

Third, patents on indigenous people’s genes facilitate the exploitation of indigenous peoples and violate international law. *Amici* condemn the view that Indigenous peoples are “treasure troves” in genetic research. *Amici* note that although the U.S. government voluntarily elected to drop patents on Hagahai and Guayami genes,<sup>10</sup> Indigenous peoples remain vulnerable to similar attempts to patent their genes. *Amici* opine that excluding gene sequences as impermissible subject matter would serve to protect the rights of Indigenous peoples.

Lastly, *amici* contends that “the granting of gene patents creates a system that violates the basic rights of patients to informed consent.”

*H. National Women's Health Network, the Asian Communities for Reproductive Justice, the Center for Genetics and Society, Generations Ahead, the Pro-Choice Alliance for Responsible Research, and Alliance for Human Biotechnology*

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<sup>9</sup> The underpinning of common heritage is that public resources are available for use by all, without restrictions, for the benefit of humanity. The public trust doctrine hinges on the notion that “certain interests are so intrinsically important to every citizen that their free availability tends to mark the society as one of citizens rather than selfs.”

<sup>10</sup> Sally Lehrman, *U.S. Drops Patent Claim to Hagahai Cell Line*, 384 NATURE 500 (1996); Marina L. Whelan, *What, If Any, Are the Ethical Obligations of the U.S. Patent Office: A Closer Look at the Biological Sampling of Indigenous Groups*, 2006 DUKE L. & TECH. REV. 14, 13-15 (2006).

In the beginning of the brief, citing the *Bilski* decision, *amici* state that “as cases emerge in ‘The Information Age,’ biology is information ... and when considering the question presented in the case at bar ‘it is the information flow that is of interest in biotechnology, and hence of interest in biotechnology patenting.’”

*Amici* distinguish the instant case from *Chakrabarty*. According to *amici*, unlike the oil-eating bacterium in *Chakrabarty*, the minor structural differences between the isolated and native BRCA 1/2 genes “do not result in a distinctive ‘name, character and use’ from DNA as it exists within the human body.” Regarding character, *amici* assert that “native DNA inherently contains the claimed isolated compound.” *Amici* also stress that “the isolated DNA molecule is the same structure of nucleotides, and same sequence as it existed within the chromosome.”

Notably, *amici* rebut the argument that the application of isolated DNA in diagnostics makes their use distinctive from that of native DNA. *Amici* contend that such use “rel[ies] on the non-distinctive natural biological characteristics of DNA sequences.” Moreover, “[i]f isolated DNA had a distinctive character or use from native DNA, these applications would not be possible.”

*Amici* also argue that the method claims are invalid because the claimed “correlations, the comparisons and the analyses” are laws of nature, mental processes and abstract ideas. Specifically, despite isolation and sequencing, the claimed techniques “do not transform the sequences nor are they transformed by the comparisons and analyses.” *Amici* note that “[h]ad those sequences been transformed it is arguable that the utility and efficacy of the diagnostics would be in question.” Citing research results illustrating that the methods of comparison do not necessarily implicate the process of isolation and sequencing, *amici* question the soundness of granting Myriad’s right to exclude the use of such methods.

From policy perspective, *amici* argue that restrictions on the use of the BRCA 1/2 genes limit significant research. Pointing out that “the Myriad database contains more than 95% of the entire BRCA 1/2 testing data in the United States,” *amici* concern that patent monopoly “allows Myriad to control who can perform researching using that data and what types of research can be performed.”

*Amici* also assert that the patenting and licensing of genetic tests affects patient access. *Amici* note that prior to the granting of the Myriad patents, several researchers provided a similar genetic test offered by the British Columbia Cancer Agency (BCCA). But testing was halted in

2001 after Myriad obtained its patent. Serving a cease and desist order, Myriad indicated it would be charging 3,850 USD for the test, more than three times the cost of the Canadian test.

*Amici* further note that the patenting of genetic test can affect the quality of testing. The exclusionary Myriad patents prevent women who have been tested for BRCA 1/2 from securing a recommended second opinion. In fact, according to *amici*, one 2006 study showed that “Myriad’s test for BRCA 1/2 genes missed mutations relating to risk for breast cancer in about 12% of breast cancer patients from families with multiple cases of breast and ovarian cancer.” While genetic testing is least occurs in underserved communities, *amici* conclude gene patents “create disproportionate harms to women of color and lower income women, their families and patients.”

Lastly, *amici* argue that gene patents “restrict the constitutional guarantees of freedom of speech.” Specifically, “the free speech rights of doctors and patients to think about genetic information must be guaranteed.”

#### I. *Richard Gold, James P. Evans, and Tania Bubela*

*Amici* agree that the district court properly invalidated Myriad’s claims, but contend “[t]he effect of the district court’s decision is too wide.” *Amici* instead suggest that DNA, as information embodied in a molecule, is patentable when that embodiment is linked to a specific function beyond its function as storage medium.

In elaborating their position, *amici* state its first premise that “one cannot claim an invention in the abstract but only in specific form.” *Amici* note that in *Diehr, Flook, and Benson*, the Supreme Court did not exercise a “*per se* exclusion,” but a “claim-by-claim analysis” as to whether the inventor “restrict[ed] him or herself to what he or she contributed to art.”

*Amici* next assert that “[p]atent history supports the understanding of “abstract” as being equivalent of overly “broad” and the opposite of “specific.”” Citing the writings of Thomas Jefferson and early Supreme Court case law, *amici* contend that the distinction between the abstract and the specific is “a touchstone for determining the outer boundaries of patentable subject-matter.” *Amici* also draw support from the recent *Bilski* decision where the Supreme Court affirmed that “the unpatentability of abstract ideas provide useful tools” in the Section 101 inquiry.

*Amici* then contend that information is “abstract” and only constitute patentable subject-matter “when linked with a specific function.” According to *amici*, when the restriction of the

information serves some purpose beyond imposing some physical limit on the claim, then the claim is not too abstract.” Thus, “the nature of the medium on which information is stored is not material to the [patentability] determination.” *Amici* state that “the presence of a specific function ... is the key to patentability.”

Applying above observations to the context of gene patents, *amici* conclude that “most DNA-based claims will be found to state patentable subject-matter ... because they will disclose a function for DNA that goes beyond the function of the information stored on the DNA.” In buttressing their position, *amici* note that the distinction drawn between abstract and specific claims to DNA promote important policy goals of the patent law.

#### *J. Southern Baptist Conexistvention*

*Amicus* states that its members adhere to the religious principle that “the human body and its parts should not be owned.” According to *amicus*, this religious principle is “akin to the legal principle that products of nature, laws of nature and natural phenomena are not subject matter eligible for patent protection.” *Amicus* then argues that “because the gene patents at issue cover everyone’s BRCA1 and BRCA2 genes, the patents put [its] members in the untenable position of being personally subject to patents that violate their religious beliefs.”

Arguing Myriad’s method claims are invalid, *amici* invokes the mental process doctrine. *Amici* constructs that Myriad’s claims “cover solely the mental act of recognizing a similarity or a difference” *Amici* also note the steps of isolating and sequence the gene cannot be read into the claim, because to do so would violate the prohibition against incorporating claim limitations from the specification.

#### *K. Universities Allied for Essential Medicines (UAEM)*

*Amicus* begins the brief by identifying the nature of the gene technology. *Amici* states that “[t]he process of isolating a gene requires only the application of well-understood scientific principles.” Research universities and its members implement these principles on a daily basis. *Amicus* thereby expresses concern that the Myriad patents “remove essential facts from the realm of public use, particularly when the discovery of those facts was funded by the public, and took place in a public university.”

*Amicus* contends that the gene patent controlled by Myriad “fail to promote the progress of science embedded in the Constitutional rationale of the Patent Act.” Among the studies cited by *amicus*, one study suggests that Myriad’s gene patents are “essentially impossible to invent

around,” thus completely foreclosing research on any effects of the BRCA genes. Another cited study reports “a thirty-percent drop in subsequent scientific development outcomes for a genetic disease after a patent was granted on the targeted gene.”

*Amicus* also asserts that “[t]he preclusion of additional research by the claims-at-issue detrimentally affects patients.” *Amicus* cites a 2006 research report demonstrating a 12% of error rate in the Myriad tests. In addition, *amicus* points that Myriad’s test has “a higher rate of error for women of non-European ancestry than those of a Caucasian background.”

Lastly, *amicus* notes that other nations have refused to accept the Myriad patents. According to *amicus*, the European Union has prohibited the enforcement of patents that would prevent research.

#### *L. United States*

The United States’s brief notes that the Supreme Court has addressed the patent-eligibility of biotechnology inventions twice. In *Chakrabarty* and *J.E.M.*,<sup>11</sup> the Supreme Court drew the distinction “between products of nature ... and human-made inventions.” Thus, according to the government, “Section 101 embraces only ‘human-made inventions.’”

In applying this distinction, the brief asserts that the district court erred in invalidating the composition claims. Specifically, “molecules that are engineered by humans” do not “occur in nature, but are instead the synthetic results of scientists’ manipulation of the natural laws of genetics.”

The brief next addresses the patent-eligibility of “isolated DNA.” The brief states the term “isolated DNA” as defined by the specification at issue includes “genomic DNA that has merely been separated from other cellular components which naturally accompany a native human sequence and removed from its naturally occurring environment.” The brief thus constructs that “claim 1 of the ‘282 patent encompasses any isolated DNA molecules whose nucleotide sequence codes for the natural BRCA1 protein,” including an ordinary BRCA gene isolated from a tissue sample taken from a woman in a hospital. The brief argues that such “isolated DNA” is “no less a product of nature” than are “cotton fibers that have been separated from cotton seeds or coal that has been extracted from the earth.” “Common sense would suggest that a product of nature is not transformed into a human-made invention merely by isolating it.” Moreover, even conceding that “purification can in some cases transform a natural

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<sup>11</sup> *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124 (2001).

substance into a new compound ... to cross the threshold of section 101,” the brief contends that the “purified” BRCA genes does not involve the requisite “inventive work of humankind.”

As such, the government advocates a change in policy regarding the patent-eligibility of isolated genomic DNA. The brief advances a distinction between isolated DNA that is the subject of “human manipulation” (such as cDNA) that is patent-eligible, and human DNA that has been merely “isolated,” which should not be.

In particular, the government acknowledges that its position is contrary to the practice of the USPTO or the NIH, but states “[t]he district court’s judgment ... prompted the United States to reevaluate” the patent-eligibility of “isolated DNA” under Supreme Court precedent.