

No. 2010-1406

United States Court of Appeals
For The Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD, ARUPA GANGULY, PhD, WENDY CHUNG, MD, PhD, HARRY OSTRER, MD, DAVID LEDBETTER, PhD, STEPHEN WARREN, PhD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, and KATHLEEN RAKER,

Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

and

MYRIAD GENETICS, INC.,

Defendant-Appellant,

(caption continued on inside cover)

Appeal From The United States District Court For The Southern District Of New York In Case No. 09-CV-4515, Senior Judge Robert W. Sweet

**BRIEF OF *AMICUS CURIAE*, KANE BIOTECH INC., IN SUPPORT OF
DEFENDANT-APPELLANT AND REVERSAL**

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October 29, 2010

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MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K.
YOUNG, in their official capacity as Directors of the
University of Utah Research Foundation,

Defendants-Appellants.

CERTIFICATE OF INTEREST

Counsel for *amicus curiae*, Kane Biotech Inc. certifies the following:

1. The full name of every party represented by us is:

Kane Biotech Inc.

2. The name of the real party in interest represented by us is:

Kane Biotech Inc.

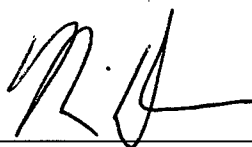
3. All parent corporations and any other publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are:

None.

4. The name of all law firms and the partners or associates that appeared for Kane Biotech Inc. in trial court or are expected to appear in this court are:

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October 29, 2010



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Counsel for *Amicus Curiae*,
Kane Biotech Inc.

**CONCISE STATEMENT OF IDENTITY, INTEREST, AND
SOURCE OF AUTHORITY TO FILE**

The following statement identifies the *amicus curiae*, its interest in the case, and the source of its authority to file.

1. The *amicus curiae* is Kane Biotech Inc., a biotechnology company engaged in the development of products to prevent and disperse bacterial biofilms.

2. The *amicus curiae*'s interest in this case is based on the exceptional legal issues related to patent law raised in the case, namely the patentable subject matter of DNA. As the *amicus curiae* is engaged in the development of products related to the prevention and dispersion of bacterial biofilms, including a growing technology portfolio, the *amicus curiae* has an interest in the development of the patent law concerning the patentable subject matter of DNA.

3. The *amicus curiae*'s source of authority to file is that all parties have consented to filing pursuant to Federal Rule of Appellate Procedure 29(a).

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SUMMARY OF ARGUMENT

1. This Court should reverse the District Court's conclusion that isolated DNA coding for a specific protein is not patentable subject matter.
2. The Supreme Court has clearly stated that the scope of patentable subject matter is quite broad with three limited exceptions—laws of nature, physical phenomenon, and abstract ideas.
3. DNA is a chemical that qualifies as patentable subject matter as a composition of matter or as an article of manufacture and does not fall within the exceptions enunciated by the Supreme Court.
4. The District Court erred by not following the *Chakrabarty* analysis. The District Court also erred by limiting the analysis of isolated DNA to DNA's informational property to the exclusion of all of its other properties.

ARGUMENT

I. THE DISTRICT COURT DID NOT APPLY THE *CHAKRABARTY* ANALYSIS SET FORTH BY THE SUPREME COURT

A. The Scope Of Patentable Subject Matter Is Broad With Limited And Narrow Exceptions

The Supreme Court recently provided a framework for analysis of patentable subject matter in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). The analysis of patentable subject matter starts with 35 U.S.C. § 101.

“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.”

The Supreme Court has found that the boundaries of patentable subject matter are quite broad. *Id.* at 3221; *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130 (2001) (“In choosing such expansive terms . . . modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.” (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980))). Further, the Supreme Court has held that this interpretation of patentable subject matter was clearly dictated by Congress. *Bilski*, 561 S. Ct. at 3225 (“Congress took this permissive approach to patent eligibility to ensure that “‘ingenuity should receive a liberal encouragement.’” (quoting *Diamond*, 447 U.S. at 308-30)).

Although the range of patentable subject matter may be wide, it is not unlimited. The analysis is focused on whether the claimed subject matter falls within one of the identified classes of subject matter in the statute: “process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”, or whether the claimed subject matter falls within one of the identified exceptions. Those exceptions are: laws of nature, physical phenomena, and abstract ideas. *Diamond*, 447 U.S. at 309; *Bilski*, 561 S. Ct. at 3225; *Parker v. Flook*, 437 U.S. 584, 589 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). In *Bilski*, the Court further indicated that the existence of these exceptions

does not give the Judiciary the freedom to impose other limitations that are inconsistent with the statute. *Bilski*, 561 S. Ct. at 3226. The exceptions have been crafted with the intent of limiting the use of abstract ideas and laws of nature to a specifically claimed application and to prevent preemption of all uses of the abstract idea or law of nature. *Id.* at 3225.

B. The *Chakrabarty* Analysis Provides That A Non-naturally Occurring Manufacture Has A Distinctive Name, Character, Or Use

Diamond v. Chakrabarty is generally viewed as the case that ushered in the age of commercial biotechnology. 447 U.S. 303, 308 (1980). Both Appellees and Appellants in the instant matter agree with the decision in *Chakrabarty*.

(Plaintiffs' Motion for Summary Judgment, District Court Dkt. No. 62 at 21; Defendants' Motion for Summary Judgment, District Court Dkt. No. 151 at 3.) However, they disagree upon its application to the instant matter.

Chakrabarty affirmed previous decisions with regard to wide patent scope and with regard to the aforementioned limited exceptions. In *Chakrabarty*, the Supreme Court looked to Congressional committee reports accompanying the 1952 Patent Act which stated that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Diamond*, 447 U.S. at 309 (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); and H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)). The Supreme Court also recognized the previously

identified exceptions and provided examples of these exceptions, e.g., a newly discovered mineral, a newly discovered plant, and $E=mc^2$. *Id.* These “discoveries are ‘manifestations of...nature, free to all men and reserved exclusively to none.’” *Id.* (quoting *Funk Bros.*, 333 U.S. at 130).

The question decided in *Chakrabarty* was whether a live recombinant *Pseudomonas* bacterium was a “manufacture” or “composition of matter” and therefore, patent eligible subject matter. The Supreme Court held that the recombinant *Pseudomonas* was “a nonnaturally occurring manufacture or composition of matter...” *Id.* The Supreme Court determined that *Chakrabarty*’s recombinant *Pseudomonas* was “new” and not nature’s handiwork but rather made by the hand of man. *Id.* at 309-10. The Supreme Court characterized the recombinant *Pseudomonas* as nonnaturally occurring because it was “a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Id.* (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). The Supreme Court in *Chakrabarty* adopted *Hartranft*’s requirements for a manufacture; a manufactured article is “a new and different article, having a distinctive name, character, *or* use . . .” *Hartranft*, 121 U.S. at 614 (emphasis added). Although the Supreme Court in *Chakrabarty* characterized the recombinant *Pseudomonas* as having all three characteristics (distinctive name, character, and use), *Hartranft* only requires one of the three characteristics in order for an article to qualify as a manufacture. *Id.*

C. The District Court Did Not Apply The *Chakrabarty* Analysis

The District Court did not analyze the question of patentability of the claims to isolated DNA coding for *BRCA1/2* according to the framework provided by *Charkrabarty. Assoc. for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010). The District Court applied a “markedly different” standard to determine whether the claimed isolated *BRCA1/2* DNA was “markedly different” from naturally occurring DNA and therefore, qualified to be patentable subject matter. However, in *Chakrabarty*, “markedly different” was not a test put forth by the Supreme Court to determine patentability, but rather was a conclusion to characterize the subject matter only after the Supreme Court analyzed the bacterium under the *Hartranft* requirements for a manufacture. The standard used by the District Court represents a departure from the analysis in *Chakrabarty* and adds limitations that are inconsistent with the statute and precedent.

The *Chakrabarty* analysis involves analyzing whether the claimed subject matter falls within one of the broadly defined categories of patentable subject matter enumerated in the statute or whether it falls within one of the narrow exceptions. The *Chakrabarty* analysis found that a genetically engineered bacterium qualified as patentable subject matter as a composition of matter and a manufacture because it was a product having a distinctive name, character, or use. The Supreme Court distinguished the claimed subject matter from natural

phenomena finding that it was a nonnaturally occurring organism made by the handiwork of man and therefore, was a new composition or manufacture.

II. ISOLATED DNA FULFILLS THE REQUIREMENTS OF A NONNATURALLY OCCURRING COMPOSITION OF MATTER OR MANUFACTURE ACCORDING TO THE *CHAKRABARTY* ANALYSIS

Applying the *Chakrabarty* framework for analyzing patentable subject matter requires a determination of whether the claimed subject matter falls within one of the identified categories of patentable subject matter or falls within one of the exceptions. The crux of the question in the instant matter is whether “isolated” *BRCA1/2* DNA is a nonnaturally occurring manufacture or composition of matter.

A. Isolated DNA Is A Composition Of Matter And A Manufacture

1. DNA is a chemical

DNA is a well known abbreviation for deoxyribonucleic acid. It is undisputed that DNA is a chemical. It is a polymer of deoxyribonucleotides, where each deoxyribonucleotide is comprised of a base (adenine, cytosine, guanine, or thymine), a sugar, and a phosphate group. Although DNA contains biological information, the information is represented by its structural components.

2. Isolated DNA is a composition of matter

A composition of matter is defined as “all compositions of two or more substances and includes all composite articles, whether they be the result of chemical union or of mechanical mixture, or whether they be gases, fluids,

powders, or solids.” *Diamond*, 447 U.S. at 308 (quoting *Shell Development Co. v. Watson*, 149 F. Supp 279, 280 (D.C. 1957)). The term “composition” includes mixtures of chemical components that are joined by chemical bonding, such as compounds. R. Carl Moy, *Moy’s Walker on Patents* § 5.9 at 5-37 (4th ed., 2009). DNA is a composition of matter because it is the chemical union of two or more substances to form a composition, like other chemical compounds.

3. Isolated DNA is also an article of manufacture

A manufacture is defined as the production of articles for use from raw or prepared materials by giving them new forms, qualities, properties or combinations, whether by hand labor or machinery. *Diamond*, 447 U.S. at 308. The Supreme Court in *Chakrabarty* further specified that an altered bacterium containing a foreign gene qualified as a manufacture under the patent laws because it was a product having a distinctive name, character, and use. *Id.* Isolated DNA meets the requirement of an article of manufacture as set forth in *Chakrabarty*.

a. By definition, “isolated DNA” is not found in nature

It is quite clear that, as defined, “isolated” DNA does not occur in nature. In the instant matter, U.S. Patent Nos. 5,693,473 (“473 Patent”); 5,747,282 (“282 Patent”); and 5,837,492 (“492 Patent”) contain the following definition of “isolated.”

An “isolated” or “substantially pure” nucleic acid (e.g., an RNA, DNA or a mixed polymer) is one which is substantially separated from other

cellular components which naturally accompany a native human sequence or protein, e.g., ribosomes, polymerases, many other human genome sequences and proteins. The term embraces a nucleic acid sequence or protein which has been removed from its naturally occurring environment, and includes recombinant or cloned DNA isolates and chemically synthesized analogs or analogs biologically synthesized by heterologous systems.

(‘473 Patent, col. 19:12-15; ‘282 Patent, col. 19:14-18; and ‘492 Patent, col. 18:1-5.) The term “isolated” requires that the DNA as claimed is different than DNA as found in nature. Isolated DNA undergoes separation from cellular components. The process of isolating DNA coding for *BRCA1/2* from at least 25,000 other genes in the human genome requires that the genes be identified and separated from other genetic material as found in nature.

b. Isolated DNA is distinct in name from naturally occurring DNA

The terms associated with the identification and designation of the isolated nucleic acids as claimed are not arbitrary and denote specific characteristics. For example, complementary DNA (cDNA) is DNA that is reverse transcribed from mRNA, which has been spliced to remove intronic DNA. As discussed above, the term “isolated” provides a distinct meaning and is not the same as naturally occurring DNA as defined by the specification of the patents at issue. In contrast, other terms are applied to refer to naturally occurring DNA such as chromosomal DNA, chromatin, etc.

c. Isolated DNA is distinct in character from naturally occurring DNA

Isolated DNA has distinct characteristics that differ from naturally occurring DNA, especially genomic DNA. In the instant matter, genomic *BRCA1* can be found at chromosome 17q21, and *BRCA2* is located at chromosome 13q12.3. The chromosomes, which contain the *BRCA1/2* genes, are highly condensed DNA. Bruce Alberts et al., *Molecular Biology of the Cell* 207 (4th ed. 2002). The condensed nature of genomic DNA is necessary for that amount of DNA (about 3.2×10^9 nucleotides) to fit in an individual cell. To achieve this degree of compaction in eukaryotes, genomic DNA is coiled around histone proteins that are responsible for forming the nucleosome structure of chromosomes. *Id.* at 204-207. Depending on the phase of the cell cycle, the end-to-end compaction ratio of DNA is 1000 to 10,000-fold. *Id.* In contrast, isolated DNA is relaxed, or at least much less condensed. This difference in structure allows for the utility that makes modern diagnostics possible. There are many other examples of differences between isolated DNA and naturally occurring DNA (e.g., reduced melting point (T_m) of isolated DNA) that are too numerous to note due to the space limitations of this brief.

d. Isolated DNA has distinct uses

As discussed above, the distinct structural characteristics of isolated DNA provide for uses that are impossible if using naturally occurring DNA. For

example, the recombinant bacteria at issue in *Chakrabarty* would not have been possible without isolated DNA. The recombinant *Pseudomonas* was stably transformed with plasmids containing genes for hydrocarbon degradative pathways to provide bioremediation of oil spills. U.S. Patent No. 4,259,444. The genes for octane, salicylate, naphthalene, camphor, salicylate, and naphthalene degradative pathways were isolated nucleic acid sequences that were ligated into plasmids, which were then transformed into the bacteria. This procedure would not be possible if using naturally occurring DNA because just mixing in naturally occurring DNA without isolating the genes of interest would have an extremely low probability of getting the genes of interest into the cell. The distinct characteristics of isolated DNA provide for the ability to perform recombinant DNA techniques that would otherwise be unattainable. Thus, isolated DNA has uses distinct from that of naturally occurring DNA.

B. Isolated DNA Does Not Fall Within Any Of The Identified Narrow Exceptions

The isolated DNA as claimed does not fall within the narrow exceptions of laws of nature, physical phenomenon, or abstract ideas. As discussed above, the isolated DNA meets the requirements of a composition of matter or an article of manufacture without falling into one of the categories of exceptions, and therefore is patentable subject matter.

Laws of nature have been described as universal or statistical factual truths that generally describe concepts such as mass, momentum, and gravity. Such laws may be described by a formula describing the relationship of different elements or forces to one another. An example is the equation that sets forth the relationship of mass and energy, $E=mc^2$ (c represents the speed of light). Isolated DNA as a chemical compound does not fit into the category of law of nature.

An abstract idea as defined in *Bilski* is a “principle, in the abstract, is a fundamental truth; an original cause; a motive; ...”. *Bilski*, 561 S. Ct. at 3230 (quoting *Gottschalk*, 409 U.S. at 67). Most of the cases regarding an abstract idea have centered on the use of algorithms or mathematical formulas in a process. One way to determine whether the claim is so broad as to be just an abstract idea is to determine whether the claim would exclude use of the subject matter in all fields or whether the claim is narrow enough to limit the use of the mathematical relationship or algorithm in a specific application. *Bilski*, 561 S. Ct. at 3225-26.

The claimed subject matter is directed to an isolated specific polynucleotide as identified by the names of each of its components (e.g., specific sequence) and not to the entire genome or the process of construction of the human body. As such, 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 that codes for a specific protein and would not preempt use of all isolated DNA or even

isolated DNA that codes for a different protein. Therefore the claimed subject matter does not fall within an “abstract idea”.

The last category is physical phenomenon. Based on *Chakrabarty* and *Funk Brothers*, this category may include discoveries that are ‘manifestations of...nature, free to all men and reserved exclusively to none.’ *Diamond*, 447 U.S. at 309. Examples given in *Chakrabarty* include a mineral or a plant as it exists in nature. As described above, the isolated DNA coding for *BRCA1/2* as claimed differs from DNA coding for *BRCA1/2* as found in nature in the human body. It differs in name, character, and use. It has been separated from cellular components including other genetic material, and it has specific and substantial uses distinct from naturally occurring DNA. Like the bacteria in *Chakrabarty*, the instantly claimed subject matter does not fall within the narrow exception of physical phenomenon.

C. DNA’s Informational Component Does Not Negate The Patentability Of Isolated DNA

The District Court held that the unique qualities of DNA require that it be treated differently than other chemical compounds. “DNA and in particular the ordering of its nucleotides, therefore serves as a physical embodiment of laws of nature-those that define the construction of the human body.” *Assoc. for Molecular Pathology*, 702 F. Supp. 2d at 225. According to the District Court, the preservation of the quality of DNA as an embodiment of information in both native

and isolated forms renders any differences in structure and function of DNA in isolated form as insufficient to satisfy the requirements of patentable subject matter.

Claimed subject matter must be evaluated for patentable subject matter as a whole, and limiting analysis to a single property is not in accord with case law. *Bilski*, 561 S. Ct. at 3226. In this case, a specific chemical compound is claimed and not a law of nature. This chemical compound has many features including a sequence of chemical constituents; it is purified from one or more cellular components; it is useful to identify the risk of breast and/or ovarian cancer; and it has a sequence of nucleotides that provides biological information. Analysis should not be limited to any one of these properties to the exclusion of all others. When the invention or claimed subject matter is evaluated as a whole, claims to an isolated DNA sequence coding for *BRCA1/2* are patentable subject matter.

The dual nature of DNA does not change the analysis of whether isolated DNA is patentable subject matter under § 101. The fact that DNA also encodes information does not make DNA any different from other chemical compounds, such as adrenalin or human growth hormone. Moreover, the claims to isolated DNA do not prevent someone from analyzing the sequence or structure of the isolated DNA (i.e., the biological information that the DNA represents) as it is represented on a piece of paper or a computer screen. The claim recites an isolated

DNA molecule and not just the sequence. A computer or mobile device is still patentable subject matter regardless of the information contained therein. The analysis of patentable subject matter in regards to isolated DNA should not be limited to the informational property to the exclusion of all of its other properties.

III. CLAIMS TO ISOLATED DNA ARE NEW AND USEFUL

Being defined as a composition of matter or an article of manufacture is not the only requirement for isolated DNA to be patentable subject matter. An isolated DNA sequence must be “new” and have a specific and substantial utility. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (“the claimed ESTs have not been researched and understood to the point of providing an immediate well defined real world benefit to the public meriting the grant of a patent.”).

Random, isolated DNAs with no known utility are not patentable subject matter. *Id.* at 1371. The isolated DNA sequence encoding *BRCA1* has a distinctive use in diagnosing the risk of breast and ovarian cancer that was not known prior to the work of the inventors. The inventors of the claims at issue did the research to establish the utility of the DNA sequences as predictive of the risk of breast and/or ovarian cancer. The gene that was of interest had to be identified, the structure of the gene had to be characterized, and reagents created to isolate and sequence the gene (e.g., PCR primers, DNA probes). Once isolated, sequences of the DNA needed to be compared in order to determine the presence or absence

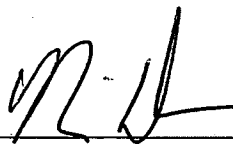
of mutations and the significance of those mutations. Without knowing the sequence of the wild-type gene, the significance of the mutants could not be ascertained.

The isolated DNA as claimed is “new” because it is a product of human ingenuity. As discussed above, isolated DNA has several physical characteristics and uses which distinguish it from naturally occurring DNA. The claimed subject matter was the result of human ingenuity; a DNA coding for *BRCA1* was identified and isolated from all of the other genes in the human genome by the inventors. The isolated DNA was sequenced and mutations in the sequences related to the risk of disease establishing the utility of the claimed subject matter. Thus, the claims to isolated DNA sequence are new and useful compositions of matter or articles of manufacture.

IV. CONCLUSION

Amicus Kane Biotech respectfully requests that the Court reverse the District Court’s decision and find that claimed isolated DNA is patentable subject matter. The District Court has adopted a position that is contrary to Supreme Court decisions and the long held notions of a broad view of patentable subject matter. In view of the foregoing, this Court should reverse the District Court’s judgment that the claims of the patents-in-suit are invalid under 35 U.S.C. § 101.

October 29, 2010



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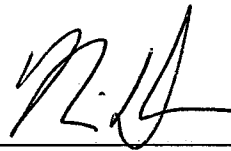
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Dated: October 29, 2010



Brian R. Dorn

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I hereby certify that on October 29, 2010, the Brief of *Amicus Curiae*, Kane Biotech Inc, in Support of Defendant-Appellant and Reversal was served as follows:

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