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Myriad Discoveries: Patent Questions Raised by the Myriad Genetics Case

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A fundamental question of patent law is soon to be decided in the *Myriad Genetics* case: whether or not a DNA molecule, isolated from a cell, is patentable subject matter.[1] The district court held: "Because the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C. § 101."[2] Over three thousand U.S. patents have issued with claims to "isolated DNA" or "purified DNA," and thousands more claiming isolated, or purified, proteins, antibodies, or other biomolecules. If this decision is upheld by the U.S. Court of Appeals for the Federal Circuit, the validity of thousands of patents claiming natural biomolecules will be called into question.

This decision has the potential to severely reduce investment in medical research and drug development, and to undermine a significant sector of the U.S. economy. Major portions of the business of the biotechnology, pharmaceutical, and diagnostic industries are based on purified DNA and molecules tied to it, and to comparisons between sample and control or test gene sequences. These industries have been able to rely, for many years, on patents claiming isolated and purified DNA molecules. This is true not only in the U.S., but in most foreign jurisdictions as well. For example, Article 5(2) of the European Union Directive on biotechnological inventions states that "the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element." The *Myriad Genetics* decision, if upheld, would overturn many years of settled precedent and affect a technology that is of critical importance not only to the U.S. economy and its competitive position in the world, but also to the continued development of new drugs and medical treatments.

Thus, this fundamental legal question—whether DNA sequences discovered by isolating DNA from cells constitute patentable subject matter[3]—is of extreme interest and import, and the case is expected to reach the U.S. Supreme Court, where the Constitution, statutes, and case law governing this issue will be evaluated and decided upon. The U.S. Constitution and U.S. patent laws explicitly allow the issuance of a patent to one who ***discovers*** a new and useful composition of matter; such ***discoveries*** could well be interpreted to include isolated DNA sequences found in nature. If so, considerations of what the founders "original intent" may have been regarding such discoveries may become significant. Case law, including Supreme Court precedent, will no doubt be marshaled in arguments in support of both sides of this case. However, the following discussion focuses on how the critical word "discoveries" should be interpreted in view of the "original intent" of the

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Founders who wrote and ratified the U.S. Constitution.

Precedent Supporting the Patentability of Isolated or Purified Natural Products

There is significant precedent in the case law for the patentability of purified natural products. For example purified adrenaline[4]; vitamin B-12[5]; prostaglandins[6] ; and even strawberry flavor (2-methyl-2-pentenoic acid)[7] have been claimed and protected by issued U.S. patents.

Moreover, there is strong and long-standing precedent for the patentability of isolated DNA molecules, as claimed in the *Myriad Genetics* patents. Unlike most eukaryotic genes, the sequences of such isolated and purified DNA molecules are not broken up by intervening nucleic acid residues (termed "introns"), are not bound to proteins, and are not linked to other genes in a chromosome, as is the case with naturally-occurring gene sequences, and so these DNA sequences are structurally different from such sequences found in nature. In view of these differences, the U.S. Patent and Trademark Office ("USPTO") has consistently recognized isolated DNA molecules as patentable subject matter, and has issued thousands of patents claiming newly discovered and useful gene sequences. This is also reflected in the USPTO Utility Guidelines, which deal with the question of whether or not an invention is "useful," and implicitly recognize that the subject matter of gene patents is patentable subject matter. These guidelines state that "where the application discloses a specific, substantial and credible utility for the claimed isolated and purified gene, **the isolated and purified gene composition may be patentable**."[8]

The Myriad Genetics Case

The district court dealt with several U.S. patents, which issued with claims to isolated DNA molecules.[9] For example, claim 1 of U.S. Patent No. 5,747,282 is directed to "[a]n isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2" and claim 6 of U.S. Patent No. 5,837,492 is directed to "[a]n isolated DNA molecule coding for a mutated form of the BRCA2 polypeptide set forth in SEQ ID NO:2, wherein said mutated form of the BRCA2 polypeptide is associated with susceptibility to cancer."

Expert testimony was submitted for the undisputed propositions: i) in its natural state in a cell, DNA is found in chromosomes, which form part of chromatin (a combination of DNA and histones and other proteins); ii) multiple genes are linked together in each human chromosome; iii) the protein-encoding sequences of DNA are often broken up by non-coding elements (introns); and iv) the chromosomes also include other non-protein encoding elements as well (e.g., exons and promoters).[10]

The district court framed the question presented as whether or not isolated human genes and the comparison of their sequences are patentable. The court answered that they were not. The court held that DNA was the physical embodiment of biological information, and that DNA's existence in an "isolated" form alters neither its fundamental quality as it exists in the body nor the information it encodes. Therefore, claims to "isolated DNA" sequences found in nature were held to be unpatentable under 35 U.S.C. § 101. The district court decision noted that courts have also specifically held that "purification" of a natural compound, without more, is insufficient to render a product of nature patentable, citing: "A process to obtain it [refined cellulose] 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."[11].

The district court also cited *Diamond v. Chakrabarty*[12]: "[T]he patentee had produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility" to suggest that, to be patentable, an invention must be markedly different from subject matter found in nature. The

district court further cited *Funk Brothers* (regarding a mixture of naturally-occurring bacteria useful in agriculture) in which the U.S. Supreme Court, discussing the properties of the bacteria held that "Their qualities are the work of nature. Those qualities are of course not patentable."[13]

Despite the fact that the district court had been made aware that multiple genes are linked together in each human chromosome, and that chromosomes include non-coding elements such as introns, exons, and promoters, and to which proteins and other non-coding elements are bound, the district court decision found that "because the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C. § 101."[14]

U.S. Patent Law

Patent law finds its basis in the United States Constitution. Under Article 1, Section 8, Clause 8, Congress has the power:

> To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.

Thus, the U.S. Constitution authorizes Congress to make laws giving inventors exclusive rights to their discoveries.

Congress has acted under this power, and our present patent law provides that:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.[15]

From the words used in the U.S. Constitution, and the words of 35 U.S.C. § 101, it is explicitly clear that a "discovery" may be patentable subject matter.

A court may consider, and may find persuasive, that the USPTO Utility Guidelines (which did not explicitly discuss patentable subject matter, but were instead directed to criteria for deciding whether or not an invention was useful) note that the Constitution uses the word "discoveries" and that 35 U.S.C. § 101 refers to one who "invents or discovers." These Guidelines provide that "an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it."[16]

Since U.S. patent law is based on the U.S. Constitution, and since some Supreme Court justices argue that Constitutional questions involve divining the original "intent" of the Founders, we examine what the word "discoveries" meant at the time the Constitution was ratified.

As defined in *Perry's Royal Standard English Dictionary, First American Edition* (printed in Worcester, January 1, 1788, by Isaiah Thomas) the definition of "discovery" is "detection, a disclosing," the word discover means "to disclose, espy, find out." That which is "discoverable" is defined as "may be found out, apparent, easy to be discovered." Similarly, *A Complete Dictionary of the English Language* by Thomas Sheridan, printed in London in 1789, defines "discover" as "To disclose, to bring to light; to make known; to find out; to espy" and "discovery" is "The act of finding any thing hidden; the act of revealing or disclosing a secret." A little later on, Webster's dictionary of 1833 defined the word "discovery" as meaning "bringing to light, a finding, disclosure."

Thus, the word "discoveries" as used in Article 1, Section 8, Clause 8, was likely understood by the Founders at the time the Constitution was ratified to refer to the detection, disclosure, or revelation to others of something that was previously hidden or secret. This is consistent with the understanding of

patents at the time, with the definition of the word "patent" (meaning "open") and with the modern "quid pro quo" rationale for patents.[17]

Thus, it is likely that, when the people who ratified the U.S. Constitution agreed to grant Congress the power to give rights[18] to inventors to their discoveries, they intended that such "discoveries" would include the discovery of "things hidden" or "secret"—which in no way excludes discovering details about the natural world such as the sequence of nucleotides in a DNA molecule found in a cell.

There is nothing in the Constitution, and nothing in 35 U.S.C. § 101 that requires that a patentable composition of matter be "markedly different" from things found in nature; instead such a requirement is "judge-made" law. Moreover, this requirement ignores the fact that 35 U.S.C. § 101 uses the words "invents **or** discovers" in defining who has an exclusive right to the "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."

Thus, not only is there nothing in the Constitution that excludes discoveries about natural DNA from the power of Congress to grant patents, but the Constitution explicitly refers to discoveries as being the subject matter to which Congress may grant rights to inventors. 35 U.S.C. § 101 is in accordance with the power granted to Congress by the Constitution: it explicitly refers to "whoever invents or discovers" any new and useful invention, and provides that a patent may be obtained therefor. Thus, the district court's reasoning is not grounded in the Constitution nor in statute.

Discoveries Are Explicitly Patentable Subject Matter

The U.S. Constitution, and 35 U.S.C. § 101 (enacted by Congress pursuant to the power granted to it by the Constitution) state that a patent may be granted for a discovery. The discovery of a new gene, such as a gene that plays an important role in a devastating disease, is new and useful. Thus, since the Constitution and the present statutes explicitly allow the issuance of a patent to one who ***discovers*** a new and useful composition of matter, under 35 U.S.C. § 101 the discovery of a novel gene is indeed patentable subject matter. Those members of the U.S. Supreme Court who place great weight on the Founders' original intent may well conclude that it is a matter for Congress, not the courts, to restrict the scope of "patentable subject matter" to exclude isolated DNA molecules.

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The views expressed in this article are those of the author alone, and not of Arnold & Porter LLP or its clients.

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[1] *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 09-CV-04515, 2010 BL 112357 (S.D.N.Y. Apr. 2, 2010); now on appeal to the Federal Circuit (the "*Myriad Genetics"* decision).

[2] *Id*. at 136.

[3] *Id*. at 103 ("whether or not claims directed to isolated DNA containing naturally-occurring sequences fall within the products of nature exception to § 101").

[4] *Parke-Davis & Co. v. H. K. Mulford & Co.*, 196 F. 496 (2d Cir. 1912).

[5] *Merck v. Olin Mathieson Chemical*, 253 F.2d 156 (4th Cir. 1958).

[6] *In re Bergstrom*, 427 F.2d 1394 (CCPA 1970).

[7] *In re Kratz*, 592 F.2d 1169 (CCPA 1979).

[8] Federal Register, Vol. 66, No. 4, (Jan. 5, 2001) pages 1092-1099, at page 1093, column 1, lines 41-46; emphasis added.

[9] The patents and asserted claims: 5,747,282 – claims 1, 2, 5, 6, 7, and 20; 5,837,492 – claims 1, 6, and 7; 5,693,473 – claim 1; 5,709,999 – claim 1; 5,710,001 – claim 1; 5,753,441 – claim 1; 6,033,857 – claims 1 and 2.

[10] *Association for Molecular Pathology v. U. S. Patent and Trademark Office,* 2010 BL 112357 at 29-34.

[11] *American Wood Paper*, 90 U.S. 566 (1874).

[12] 447 U.S. 303, 310 (1980).

[13] *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 330 U.S. 127, 130 (1948). However, in contrast to the inventors of *Funk Brothers*, who combined populations of unaltered bacteria, the inventors of *Myriad Genetics* identified and isolated, separate from all the other elements of the chromosome found in nature, a particular portion of a natural DNA molecule, to provide a DNA molecule not identically found in nature.

[14] *Association for Molecular Pathology v. U. S. Patent and Trademark Office,* 2010 BL 112357 at 135.

[15] 35 U.S.C. § 101.

[16] Federal Register, Vol. 66, No. 4, (Jan. 5, 2001) pages 1092-1099, at page 1093, column 1, lines 25-31.

[17] *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689 (1966).

[18] The only instance of the word "right" in the U.S. Constitution is in this clause, Art. 1, § 8, Cl. 8.