The Uncertain Future of Isolated DNA Patents

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Ever since the U.S. District Court for the Southern District of New York (S.D.N.Y.) issued a decision in the lawsuit brought by the American Civil Liberties Union (ACLU) against Myriad Genetics, the future of isolated DNA patents has been uncertain. Not surprisingly, the S.D.N.Y. decision in Myriad Genetics was appealed to the Federal Circuit. On 29 October 2010, the U.S. Department of Justice (DOJ) filed an amicus brief in support of the S.D.N.Y. position in Myriad Genetics that isolated human genomic DNA is not patentable. The DOJ amicus brief sides with the ACLU on the issue of isolated DNA and with Myriad Genetics on the patentability of scientifically manipulated DNA. Specifically, the DOJ took the position that (a) human-engineered DNA molecules, such as cDNAs, are patent-eligible under 35 U.S.C. § 101, and (b) isolated, but otherwise unmodified, genomic DNA is patent-eligible subject matter under 35 U.S.C. § 101.

In the Myriad Genetics case, the patents in suit encompass breast cancer genes BRCA1 and BRCA2. The composition claims relate to “isolated DNA” containing human BRCA1/2 gene sequences. The method claims refer to diagnostic methods for identifying mutations in the BRCA1/2 genes by analyzing the sequences of the genes. The S.D.N.Y. ruled that DNA’s existence in an “isolated” form does not transform it into something “distinctly different in character” from the nonisolated DNA contained in the human gene sequences. The S.D.N.Y. was of the belief that purifying DNA did not change the underlying characteristic of the DNA, which was to convey information to express a protein. With respect to the method claims, the
S.D.N.Y. held that the claimed comparisons are abstract mental processes and thereby constitute unpatentable subject matter.

The S.D.N.Y. decision in Myriad Genetics on the isolated DNA claims runs counter to established Federal Circuit precedent including Amgen v. Chugai and Fiers v. Revel, neither of which are mentioned by the S.D.N.Y. in the Myriad Genetics decision or in the DOJ amicus brief. In issuing its decision in Myriad Genetics, the S.D.N.Y. appears to have also cast aside many cases from the Federal Circuit and Supreme Court regarding isolated biological or chemical substances, with the explanation that those cases did not relate to Section 101 of the Patent Act, which sets forth what is patentable subject matter, but does not discuss or attempt to distinguish the Amgen and Fiers cases.

The Amgen and Fiers cases both relate to interfering subject matter under 35 U.S.C. § 102(g). The Amgen case relates to isolated DNA-encoding erythropoietin (EPO) and the Fiers case relates to isolated DNA-encoding human fibroblast beta-interferon. In both Amgen and Fiers, the Federal Circuit, in the context of interference proceedings, recognized that an isolated and purified DNA is invented when a complete and correct DNA sequence is provided. The Federal Circuit explicitly stated in Amgen that “[a] gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it.”

However, as under Amgen and Fiers, isolated DNA can be conceived and reduced to practice, and can be the subject of interference proceedings under, inter alia, 35 U.S.C. § 102(g), since it follows a fortiori that it is patentable subject matter under Section 101 of the Patent Act, which is contrary to the holding by the S.D.N.Y. in Myriad Genetics. Likewise, in casting aside many cases from the Federal Circuit and Supreme Court regarding isolated or biological or chemical substances with the explanation that those cases did not relate to Section 101 of the Patent Act, the S.D.N.Y. may have acted erroneously. In other words, it follows from the courts’ decisions in those other cast-aside cases that the subject matter at issue therein had to be patentable subject matter under 35 U.S.C. § 101; otherwise the courts’ decisions in those other cases would arguably be invalid, as those courts would lack jurisdiction to have decided those issues if the subject matter claimed was not itself patentable under Section 101 of the Patent Act.

Furthermore, by casting aside many cases from the Federal Circuit and Supreme Court regarding isolated biological or chemical substances, giving the explanation that those cases did not relate to Section 101 of the Patent Act, the S.D.N.Y. may have issued a decision with unintended consequences. Some have argued that Myriad Genetics stands for the proposition that any “isolated” biological or chemical substance is not patentable under 35 U.S.C. § 101, despite the large body of Federal Circuit and Supreme Court case law that indicates that “isolated” biological or chemical substances are patentable subject matter under Section 101 of the Patent Act.

Examples of these arguments include the DOJ amicus brief and Judge Dyk’s dissent...
in the *Intervet v. Merial* Federal Circuit decision. In *Intervet*, Judge Dyk opined that the claim relating to an isolated DNA molecule raises substantial issues of patentable subject matter under 35 U.S.C. § 101. According to Judge Dyk, the Federal Circuit and the Supreme Court have not yet directly decided the issue of the patentability of isolated DNA. Judge Dyk admits that the Federal Circuit has upheld the validity of several gene patents (including the *Amgen* case), but he believes that none of the cases directly addresses the question of whether such patents encompass patentable subject matter under 35 U.S.C. § 101. In this instance, Judge Dyk employed the same reasoning as the S.D.N.Y. in the *Myriad Genetics* case and failed to recognize that isolated DNA had to be patentable subject matter under 35 U.S.C. § 101. Otherwise, the Federal Circuit decisions regarding gene patents would be invalid, as the Federal Circuit would have lacked jurisdiction to have decided those issues if the subject matter claimed was not itself patentable under Section 101 of the Patent Act.

The DOJ amicus brief adopts Judge Dyk’s position that the mere fact that genes do not naturally occur in isolated form does not provide a basis for patent eligibility. The DOJ amicus brief suggests that the process of isolating DNA from the human genome was patent-eligible when it was first conceived, but the isolated DNA remains what it was in the human body. The DOJ amicus brief further opines that the pure BRCA1 polynucleotide is structurally identical to the DNA that occurs in the human body, absent the isolation. It was the position of the DOJ that isolated DNA is a product of nature.

The arguments, as set forth in the DOJ amicus brief, that isolated DNA is a product of nature, do not make sense from a scientific standpoint. Unlike what is characterized in the DOJ amicus brief, the isolation of a gene is not necessarily a standard and routine process of extracting and amplifying a desired gene. A gene is not merely the necessary sequence to express a protein. Rather, a gene may have several components, including, but not limited to, promoters, enhancers, exons, introns and untranslated regulatory sequences that are not ultimately translated into a protein. In other words, genes are not merely products of nature that can be routinely isolated. Furthermore, an isolated gene does differ from what is naturally occurring. For example, in a naturally occurring state, DNA is often coiled and bound to DNA binding proteins, such as histones. In contrast, isolated DNA is often relaxed and free of DNA binding proteins and exists in a buffered environment. Thus, contrary to the DOJ amicus brief, isolated DNA is not structurally identical to DNA found in the human body.

While the *Myriad Genetics* case remains pending in the Federal Circuit, what options are available to a patent practitioner? Recitation of “isolated” or “substantially pure” may raise issues during the prosecution of a gene patent, wherein the recitation of “non-naturally occurring” may be a better alternative. Furthermore, the inventive aspects of a gene patent should be stressed, especially the difficulties in isolating and characterizing the gene and the inventive characteristics thereof. The use of genes in diagnostic assays should also be emphasized, particularly in view of the *Bilski v. Kappos* decision that suggests that biotech and diagnostic methods will likely pass muster as patentable subject matter.

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Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al., 09 Civ. 4515 (S.D.N.Y., March 29, 2010).

Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al., case number 2010-1406 in the U.S. Court of Appeals for the Federal Circuit.

Brief for the United States as Amicus Curiae in Support for Neither Party for Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al., case number 2010-1406 in the U.S. Court of Appeals for the Federal Circuit.


Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).


Amgen, 927 F.2d at 1206; Fiers, 984 F.2d at 1169.

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