Legal and Regulatory Update

Commentary regarding decision in *Myriad Genetics* on 'isolated' DNA claims

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On 29 March 2010, the US District Court for the Southern District of New York (SDNY) issued a decision in the lawsuit brought by the American Civil Liberties Union against Myriad Genetics[1] holding that 'isolated DNA' containing sequences found in nature are unpatentable subject matter. The SDNY further held that claimed comparisons of DNA sequences are abstract mental processes and also constitute unpatentable subject matter. This decision is controversial because it appears to be contrary to established Federal Circuit precedent, and if upheld may have significant ramifications not only for gene patents, but also for other biotechnology and chemical patents relating to any 'isolated' compound.

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 SDNY believed that DNA's existence in an 'isolated' form does not transform it into something 'distinctly different in character' from the non-isolated DNA contained in the human gene sequences. The SDNY 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 SDNY held that the claimed comparisons are abstract mental processes and thereby constitute unpatentable subject matter.

The SDNY decision in *Myriad Genetics* on the isolated DNA claims appears to run counter to such established Federal Circuit precedent as *Amgen* v. *Chugai*[2] and *Fiers* v. *Revel*[3] – which are not mentioned by the SDNY in the *Myriad Genetics* decision. More specifically, in issuing its decision in *Myriad Genetics*, the SDNY appears to have also cast aside many cases from 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,[4] 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 USC §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,[5] with the Federal Circuit explicitly stating 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'.[6]

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 USC §102(g), it follows *a fortiori* that it is patentable subject matter under Section 101 of the Patent Act, contrary to the holding by the SDNY in *Myriad Genetics*. Likewise, in casting 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, the *Myriad Genetics* Court may have acted erroneously. In other words, it follows from the Courts' decisions in those other cast aside cases that the subject matter in issue therein had to be a patentable subject matter under 35 USC §101 – otherwise arguably the Courts' decisions in those other cases would 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 with the explanation that those cases did not relate to Section 101 of the Patent Act, the *Myriad Genetics* Court may have issued a decision with unintended consequences. Some may attempt to argue that the *Myriad Genetics* case stands for the proposition that any 'isolated' biological or chemical substance is not patentable under 35 USC §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.

The SDNY also held that patent claims involving comparisons of DNA sequences are abstract mental processes and hence unpatentable. The invalidation of the diagnostic method claims is through the SDNY endeavoring to follow the Federal Circuit opinion in *In re Bilski*.[7] In *Bilski* the Federal Circuit rejects the previous 'useful, concrete and tangible result' standard for method claims in favor of a 'machine-or-transformation' standard to determine patent eligibility of a method claim. In the *Myriad Genetics* case, the SDNY applies the controversial 'machine-or-transformation' test of *Bilski* to diagnostic claims. The diagnostic claims involve detecting the presence or absence of the BRCA1/2 genes in a sample. The SDNY held that these claims are unpatentable under 35 USC §101 because, as the patients' samples used to detect the presence (or absence) of BRCA1/2 genes are unchanged by the diagnostic method, the *Bilski* 'transformation' standard is not met. The SDNY decision in *Myriad Genetics* is premature because the appeal from the Federal Circuit's decision in *Bilski* is still pending before the US Supreme Court.

Accordingly, the SDNY decision in *Myriad Genetics* appears to be an anomaly that will likely be appealed to the Federal Circuit. The Biotechnology Industry Organization has indicated that it is erroneous by announcing its view that the *Myriad Genetics* decision 'is only a preliminary step in the legal process that does not affect how the US Patent and Trademark Office evaluates patent applications relating to DNA-based inventions'.[8]

REFERENCES AND NOTES

1. *Association for Molecular Pathology et al* v. *United States Patent and Trademark et al*, 09 Civ. 4515.
2. *Amgen* v. *Chugai*, 927 F.2d 1200 (Fed. Cir. 1991).
3. *Fiers* v. *Revel,* 984 F.2d 1164 (Fed. Cir. 1993).
4. 35 USC §101.
5. *Amgen*, 927 F.2d at 1206 and *Fiers*, 984 F.2d at 1169.
6. *Amgen*, 927 F.2d at 1206.
7. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).
8. *BIO Statement on Initial Decision in Myriad Genetics Lawsuit*, 30 March 2010, available at http://www.bio.org/news/pressreleases/newsitem.asp?id=2010_0330_02.

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