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TIP SHEET™
INTELLECTUAL PROPERTY ALERT APRIL 1, 2010

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Federal judge says no to patents on cancer genes

BY MATT GIBSON
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On March 29, a federal district court in New York ruled that DNA sequences are not eligible for patent protection under the U.S. patent laws. The ruling stems from an action filed by the Association for Molecular Pathology along with other organizations and individuals, challenging the validity and constitutionality of patents directed to DNA sequences for the BRCA1 and 2 genes as well as methods for using such sequences for diagnostic tests. The BRCA1 and 2 genes are important in identifying a predisposition to breast and ovarian cancers. Myriad Genetics, a co-defendant in the lawsuit and the exclusive licensee of the patents, uses the patented sequences to provide a genetic test for mutations in the BRCA genes.

Although laws of nature, physical phenomena and abstract ideas have long been held to be unpatentable subject matter, the United States Patent and Trademark Office (USPTO) has traditionally not considered isolated, purified DNA to fall within these categories based on the distinct differences between it and DNA as it exists naturally in the body. The defendants in this case argued that DNA should be treated the same as other naturally-occurring substances that do not exist naturally in the purified form, subject matter which courts have acknowledged as patentable. However, the court added that products of nature are only patentable in the purified form if they possess "markedly different characteristics" than they do in nature. In the end, the court rejected the defendants' argument that DNA in the isolated, purified form is "markedly different" than naturally occurring DNA. In doing so, the court reasoned that DNA performs the same function, namely encoding information, regardless of whether it is

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inside or outside the body and that the structural differences are not relevant to this particular function. Based on this reasoning, the court held that isolated, purified DNA is not patentable subject matter.

It is likely that the defendants in this case will appeal this decision to the U.S. Court of Appeals for the Federal Circuit. This will be a question of first impression for the Federal Circuit and as such, it will be very hard to predict which way the court will rule on this issue. If the decision is upheld by the Federal Circuit, it could have an enormous impact on the realm of biotechnology. In addition, there could be instant ramifications to owners of patents directed to genetic sequences as other parties may now be more inclined to seek similar judgments from other federal district courts. The case discussed herein is *Association for Molecular Pathology et al. v. United States Patent and Trademark Office, et al.*, Case No. 1:09-cv-04515-RWS (S.D.N.Y. 2010).

Matt Gibson is a registered patent attorney and holds a bachelor's degree in biology as well as a Ph.D. in cell biology. His practice focuses on all aspects of intellectual property issues, with an emphasis in biotechnical, medical and pharmaceutical related matters. Matt has a broad range of biomedical knowledge and experience and has co-authored several scientific articles as well as presented at numerous local, national and international symposiums in the areas of physiology, neurobiology, molecular biology and cell biology.

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