

Gene Patents: A Potential Move on Patentability Standards

On March 29, in *Association of Molecular Pathology v. United States Patent and Trademark Office*, Judge Sweet of the U.S. District Court for the Southern District of New York held that seven out of 23 patents related to the genes BRCA1 and BRCA2 linked to breast and ovarian cancer jointly owned by Myriad Genetics and the University of Utah Research Foundation do not qualify as patentable subject matter under 35 U.S.C. 101. This ruling has the potential of overturning more than three decades of case law which holds that “anything under the sun that is made by man is patentable” (*Diamond v. Chakrabarty*, 447 U.S. 303, 309, 1980) and that natural substances are patentable if they are claimed as “isolated” or “purified” because such forms do not exist in nature (*In re Kratz*, 592 F.2d 1169, 1174, CCPA, 1979).

Myriad’s gene patents claim “isolated DNA” encoding the BRCA1 and BRCA2 genes and methods of detecting BRCA mutation and the use of cells transformed with BRCA to screen for potential drugs. Judge Sweet, in ruling that “isolated DNA” does not qualify as patentable subject matter, compared isolated DNA to DNA in nature, stating that the patents were “improperly granted” because they involved a “law of nature,” even though the genes were isolated, which merely “circumvents the prohibition of the direct patenting of DNA in our bodies but which, in practice, reaches the same result.” The court failed to address the constitutional issues involving the patentability of gene sequences.

Expect this decision to be immediately appealed to the Federal Circuit. If the Federal Circuit affirms Judge Sweet’s decision, it could have far-reaching implications, such as stifling innovation in gene research, as companies will have less incentive to invest in new gene developments. About 20 percent of human genes have been patented and multibillion-dollar industries have been built as a result of the intellectual property rights that such patents grant. It also could have a significant future impact on medicine, which has become increasingly more personalized, with genetic tests used to diagnose diseases and determine which medicine is best for which patient.

As the Federal Circuit is in line with innovation and the incentives to make new discoveries, it may reverse or narrow the district court’s decision.



FOR MORE INFORMATION

For more information, please contact:

Gwen R. Acker Wood, Ph.D.	216.566.5751	Gwen.Wood@ThompsonHine.com
Justin C. Ward	404.407.3606	Justin.Ward@ThompsonHine.com
Megan D. Dortenzo	216.566.5636	Megan.Dortenzo@ThompsonHine.com

or any member of our **Intellectual Property** practice group.

If you do not wish to receive future communications by email, please send an email with the word “unsubscribe” as the subject line to Pam.Ray@ThompsonHine.com.

This advisory may be reproduced, in whole or in part, with the prior permission of Thompson Hine LLP and acknowledgement of its source and copyright. This publication is intended to inform clients about legal matters of current interest. It is not intended as legal advice. Readers should not act upon the information contained in it without professional counsel.

This document may be considered attorney advertising in some jurisdictions. Some of the design images and photographs in this document may be of actors depicting fictional scenes.

© 2010 THOMPSON HINE LLP. ALL RIGHTS RESERVED.