

CHALLENGE TO GENE PATENTS

On February 9, 2010, a United Kingdom appeals court, in *Eli Lilly and Co. v. Human Genome Sciences, Inc.*, case number A3/2008/2673, upheld a lower court decision to invalidate a patent claiming an isolated nucleic acid encoding a Neutrokin-alpha protein. The appeals court held the patent invalid for lack of “industrial application,” despite the fact that the patent provided not only the sequence information but also suggested several therapeutic utilities of the sequences. Nonetheless, the court determined that the claimed nucleic acid had undetermined function, thus rendering the patent invalid.

Researchers at Human Genome Sciences (HGS) identified the neutrokin-alpha sequence using bioinformatics. Subsequent to filing their patent application on the nucleic acid sequence, HGS co-developed a neutrokin-alpha antibody for treatment of lupus. Lilly initially challenged HGS’ gene patent in the European Patent Office (EPO), which upheld the patent there after HGS made amendments to the claims. In reaching its decision on February 9th, the UK appeals court refused to give deference to the EPO, but instead concluded that if the HGS patent were upheld, “valuable research and development work” would be “rendered futile.”

This case highlights the rigor of English Court proceedings with its intensive investigation and testing of evidence over the less intensive opposition procedure at the EPO. It remains to be seen whether the UK courts will become a more regular battleground for parties who wish to overturn finding of facts by the EPO in opposition proceedings.

Lilly v. HGS is the latest in a series of cases challenging patents covering genes and proteins. In the United States, focus is now on a case in the New York District Court, *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, challenging the validity of a patent covering the breast cancer susceptibility genes, BRCA1 and BRCA2. At issue in both cases is the broad question of whether the discovery of new genes, gene variants, and proteins should be patentable when isolated from human cells and used as the basis of a diagnostic or therapeutic.



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