AN AMERICAN FEDERAL COURT HAS HELD THAT IN PRINCIPLE, GENES CANNOT BE PATENTED: COULD THIS CAST DOUBT ON THE DEVELOPMENT MODEL OF THE BIOTECHNOLOGIES INDUSTRY?

Paris, 31 March 2010 – The US District Court for the Southern District of New York has just held that in principle, genes cannot be patented, since such patents would be contrary to the provisions of Section 101 of the United States Patent Act (35 USC 101).

According to Jacques Warcoin, European and French Patent Attorney, Partner at Cabinet Regimbeau, who, in 2004, secured part revocation by the European Patent Office of the Myriad Genetics patents in respect of the genes BRCA1 and BRCA2, *"this decision could have major consequences for the biotechnologies industry: if it is upheld on appeal, the decision would make it difficult to protect genetic tests based on the comparison of DNA sequences. Diagnostic companies in the United States could be affected by this decision, which will result in a depreciation of the market and put some of them at risk, particularly those raising funds. The US decision also casts doubt on the social advantages of patents, particularly in the area of genetic tests".*

The case was between several organisations representing civil society, including the Association for Molecular Pathology, the American Civil Liberties Union Foundation and the Public Patent Foundation, and the United States Patent and Trademark Office, Myriad Genetics and the University of Utah, and concerned the genes BRCA1 and BRCA2.

In his decision, having considered the technical issues, the social impact of the patents and the substantial case-law of US Appeal Courts and the US Supreme Court, Judge Robert Sweet held, in substance, that:

- By reason of its function as a physical information medium, DNA cannot be regarded as any traditional chemical product,
- DNA in isolation is the same as that found in the living organism from which it is isolated.

DNA sequences are not patentable objects within the meaning of Section 101 of the Patents Act, which, in the absence of substantial modification resulting in the creation of a fundamentally different product, excludes natural products from the field of patents on the basis of precedents established by the Supreme Court.

With regard to the claims relating to the comparison of DNA sequences to identify the presence or absence of a mutation, Judge Robert Sweet took the view that this is also not something that is patentable according to Section 101 of the United States Patent Act, on the grounds that the comparison of DNA sequences is an intellectual exercise excluded from the field of patents.

This belated application for revocation in the United States casts doubt on the rules established in Europe for 25 years, which have formed the basis of registration of thousands of patents in the United States and in Europe. As the European provisions currently stand, it should not be possible to transpose this decision in Europe.

"The period of uncertainty that will follow Myriad's appeal - potentially as far as the United States Supreme Court, may perhaps cause US investors to turn their backs on the North American market", concludes Jacques Warcoin.

Paris – 31 March 2010

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