

## **Biotech directive implemented**

On February 28 2005 the German law implementing EU Directive 98/44/EC on the legal protection of biotech inventions entered into force. It included a new sub-section 4 in §1a) of the German Patent Act which represents a departure from the absolute compound protection for naturally occurring human DNA sequences.

In particular, sub-section 4 of §1a) now reads as follows:

If the subject-matter of the invention is a sequence or partial sequence of a gene, the structure of which is identical to the structure of a natural sequence or partial sequence of a human gene, then its use, for which the industrial applicability has been described in concrete terms in accordance with sub-section 3, is to be included in the claim.

However, this new sub-section 4 of §1a) leaves practitioners with lots of unanswered questions. In particular, it will be difficult to determine the scope of protection of a compound claim for naturally occurring human DNA sequences which is limited to a specific use. There appears to be no doubt that the scope of protection for a naturally occurring human DNA sequence should cover at least naturally occurring variants of the actually identified DNA sequence, for example alleles. However, such a claim directed to a human DNA sequence should thus also cover artificial variants which do not fall under sub-section 4 of §1a) and hence should be susceptible of absolute compound protection. Moreover, it is unclear whether human cDNA sequences, which do not occur in nature as such, but are composed of partial sequences as they occur in nature, are excluded from absolute compound protection in view of the reference of sub-section 4 to a "partial" sequence of a gene. Finally, it is unclear which use is actually to be included in a claim directed to naturally occurring DNA sequences. Is it the biological activity of the protein encoded by such a gene, or is it a medical use? In summary, Germany's statutory restriction of patent protection for human DNA sequences contradicts the intent of the EU directive to give full patent protection to the discoverer of the human gene sequence, including new uses discovered later using the same gene sequence, and therefore undermines harmonization. It can only be hoped that the courts will provide useful guidelines on how to interpret sub-section 4 of §1a) of the German Patent Act in view of the EU directive, from which it emanated.

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