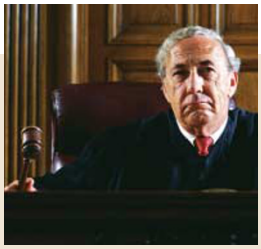
PATENTWATCH



# Written description not good enough

**Possession of the partial amino-acid sequence of a patented protein does not necessarily entitle the inventors to claim the DNA sequence that encodes it, according to the US Patent and Trade Office (PTO). In the case *In re* Wallach, the PTO rejected Wallach's claims to the DNA molecules that encode tumour-necrosis factor (TNF)-binding protein II (TBP-II), on the basis that these claims do not meet the 'written description' requirement, a ruling that was upheld recently by the US Court of Appeals.**

**In the 1980s, Wallach and colleagues discovered two proteins in urine that inhibit the cytotoxic effect of TNF and termed them TBP-I and -II. After obtaining a partial sequence for TBP-II, they filed an application that included claims to proteins with this partial sequence and molecular mass, as well as the DNA that encodes them. The claims to the proteins are not at issue in this case; however, the claims directed to the DNA were rejected because the applicants are only in possession of a partial amino-acid sequence and according to the PTO this does not comprise adequate written description of the claimed subject matter — that is, the DNA sequence.**

**Wallach and colleagues appealed on the basis that the determination of the amino-acid sequence of a protein immediately puts one in possession of all DNA sequences encoding that protein. Furthermore, they argue that the complete amino-acid sequence is an inherent property of an isolated protein and that being in possession of the protein means that they were necessarily in possession of its complete sequence. However, the court ruled that although the written description requirement can in some cases be satisfied by functional description, this is only sufficient if there is a known structure–function relationship. In this case, the Appellants provided no evidence that there is any known or disclosed correlation between the combination of a partial structure of a protein, the protein's biological activity and the protein's molecular mass, on the one hand, and the structure of the DNA encoding the protein on the other.**

***In re* Wallach:** http://www.fedcir.gov/opinions/03-1327.doc

## Poster presentation can be printed publication

The US Court of Appeals has upheld the decision of the US PTO's Board of Patent Appeals and Interferences in denying the October 2000 patent application of Carol Klopfenstein and John Brent for an invention for lowering serum cholesterol levels and raising high-density-lipoprotein-cholesterol levels. The patent was denied, because the invention had already been described in a printed publication more than one year before the date of the patent application, which is one of the bars to issuing a patent.

In October 1998, the inventors, along with another colleague, set up a poster at a meeting of the American Association of Cereal Chemists (AACC), and displayed it continuously for two and a half days. Later that year, the same poster was put on display for less than a day at Kansas State University. On each occasion, the poster disclosed the invention, and there was no disclaimer or notice to the intended audience prohibiting note-taking or copying of the presentation. As there were no factual disputes between the parties, the issue for the Appellate court was to decide whether the poster constituted a 'printed publication' as a matter of law.

The appellants argued that the poster was not a 'printed publication' because no copies were distributed and there was no evidence that it was photographed. In addition, the poster was never catalogued or indexed in any library or database. However, the Federal Circuit determined that the poster was sufficiently publicly accessible to count as a printed publication: it was shown for an extended period of time to members of the public unskilled in the art, but they were not precluded from taking notes or even photographs of the poster. In addition, copying the information on the poster would have been a relatively simple task, particularly given the amount of time available and the lack of any restrictions on their copying of the information.

***In re* Klopfenstein and Brent:**
http://www.fedcir.gov/opinions/03-1583.doc

## Primate stem cell patent denied in Europe

**Examiners at the European Patent Office (EPO) have refused to grant a patent for primate embryonic stem cells to the Wisconsin Alumni Research Foundation, on the grounds that the claims are applicable to human embryonic stem cells, which are specifically excluded from patentability in Europe.**

**Because the methods would require the use of a human embryo as starting material, or as a source for the starting material, the invention is considered contrary to morality. Although the applicant argued that the invention does not concern, or have as its object, the use of a human embryo, this was rejected by the EPO. The applicant also argued that as the morality rule does not apply to methods useful for therapy or diagnosis carried out on a human embryo, the invention could be of benefit to an embryo and therefore was not excluded from patentability. However, the EPO did not accept that the methods serve any useful purpose to a human embryo. Furthermore, it was argued that the interpretation of the morality rule was incorrect, because, taken to the limit, all downstream products that were isolated or derived from embryonic tissues would be excluded from patentability. But as these products can be generated by methods that do not require the direct and unavoidable use of a human embryo, the EPO rejected this argument too.**

**James Thomson, a researcher at the University of Wisconsin at Madison, invented a method to isolate primate embryonic stem cell lines in 1995 and was issued US patent 5,843,780 in 1996. The patent covers claims on purification methods used to prepare stem cells for laboratory growth, as well as methods for obtaining and maintaining them. Geron paid for the university's research and received commercial rights to develop five embryonic stem cell lines owned by the university.**

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