PATENT PRIMER

Inventive step and genomics

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As technology develops, experimental boundaries are being pushed further and further. Discoveries that were considered ground-breaking as little as five years ago are today considered routine. In this article, we examine the ever-more stringent inventive step/obviousness requirements of the European and US patent offices.

In Europe, the inventive step is generally assessed by applying the 'problem/solution' approach, which consists of three main stages: first, determining the 'closest prior art'; second, establishing the 'objective technical problem to be solved'; and third, considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to a person skilled in the art. The third step is subjective and constantly changing.

In the US, by contrast, obviousness is determined by following the four factual inquiries — namely, a determination of the scope and contents of the prior art; ascertaining the differences between the prior art and the claims in issue; resolving the level of ordinary skill in the art; and evaluating evidence of secondary considerations. The difference between 'obviousness' in the US and 'inventive step' in Europe might lead to different determinations of the inventive step of a patent application.

Genomic sequences

It has long been established by European Patent Office (EPO) Boards of Appeal that the disclosure of a protein renders obvious the nucleic-acid sequence encoding that protein, irrespective of whether the actual nucleic-acid sequence has been disclosed. The same argument extends to the inventive step of nucleic-acid molecules encoding the same protein in different species.

Exceptions to this general rule do exist — for example, when it can be shown that the nucleic-acid sequence was particularly difficult to obtain and 'inventive skill' was required in obtaining the sequence. Moreover, if it can be shown that the nucleic acid has a 'surprising' feature that could not be predicted from the disclosure of the protein, and that the feature is in some way advantageous, then such a nucleic-acid sequence could be deemed 'inventive', despite the disclosure of the protein sequence.

More recent decisions from the EPO Boards of Appeal have made it apparent that the threshold for an invention to be deemed 'inventive' in Europe is becoming increasingly more stringent. In 'AgrEvo' (see BOX) a new class of compounds was described, along with their alleged effects. In this case, it was considered that the inventive step of the invention lay in the identification of a function for the new class of compounds. That is, it was considered that, for an invention that relates to a new compound to be considered inventive, a 'credible function' for the claimed compound must be demonstrated in the application.

This way of thinking also extends to genomic sequences. That is, for a new genomic sequence to be considered inventive by the EPO, a "specific credible function" for that genomic sequence must be disclosed in the application.

European examiners are increasingly relying on a decision of the opposition division that also considers that "a DNA sequence encoding a protein without a credible function is not a patentable invention". To be inventive, it is clear that a patent must disclose a function that is more than 'speculative'.

In the US, by contrast, a claimed DNA molecule is generally considered to be non-obvious in view of prior art disclosing the full amino-acid sequence of the polypeptide encoded by the claimed DNA molecule, and methods for cloning DNA. However, in the absence of a credible function such a sequence would probably fail the US requirement of utility.

Therefore, in the US and Europe different reasoning still seems to produce very similar results.

Criteria for genetic homologues

In most cases in which the invention is either a new protein and/or the nucleic acid from which it derives, it is generally of commercial importance to obtain protection for homologues of the defined protein or nucleic-acid sequence.

Following from the AgrEvo decision, in the EPO such sequences and/or homologues can, in theory, be considered inventive if it can be demonstrated that the protein homologues of the invention possess a specific and credible function.

However, recent decisions from the EPO Boards of Appeal have indicated that the inventive step of homologues might be difficult to prove. For example, in a recent EPO decision, a human homologue that was 78% identical to a mouse sequence was held to be obvious. In the US, by contrast, it is unlikely that such a sequence would be held to be obvious unless there was some motivation in the prior art to modify the known sequence.

What conclusions can be drawn from recent cases, both in Europe and the US? It is clear that isolated or technically produced genes or proteins are patentable both in Europe and the US, provided that they are structurally sufficiently defined; are neither known nor obvious; the application discloses how they can be obtained; and, additionally, discloses the function of the protein/nucleic acid and what the invention might be used for. Although the approach adopted by Europe and the US in assessing the patentability of inventions relating to nucleic acid is different, the end result is similar.

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DECISION OF THE TECHNICAL BOARDS OF APPEAL-T0939/92: AGREVO

The AgrEvo case relates to a new class of chemical compounds (triazole sulphonamides). It was claimed that these compounds were useful as herbicides. The Applicant argued that because the herbicidal effect of these compounds was not a feature of the claim in question, they were not relevant in considering the inventive step of that claim. What was important, they argued, was whether a person skilled in the art would prepare the claimed compounds on the basis of the prior art. The Board disagreed and considered that for a claim to a new class of compounds to be deemed inventive, those compounds must possess a technical, useful and credible property. Moreover, they considered that all the members of the new class of compounds claimed must possess that (credible) property. In this case, not all of the compounds were considered to possess herbicidal activity, and consequently the claims were deemed to be not inventive.