

PATENT PRIMER

Added matter and patentability

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The European Patent Convention (EPC) states that a patent or patent application cannot be amended in such a way that it contains subject matter that extends beyond the content of the application as filed. It seems that the European Patent Office (EPO) is interpreting this provision with ever-increasing severity. This article considers the effects of this and related provisions to inventors in obtaining patent protection for their inventions in Europe and also consider the consequences of 'flouting the rules'

What is 'added matter'?

The EPC stipulates that: "A European patent application or a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed."

The reasoning behind this provision is that an applicant should not be allowed to improve their position by adding subject-matter not disclosed in the application as filed, which could provide an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application in order to assess freedom to operate.

Interpretation of 'added matter'

Case law issued by the European Appeal Boards that is used to interpret the statutory provisions of the EPC has provided guidance on the meaning of "subject-matter, which extends upon the content of the application as filed." Early case law suggested that a strict interpretation of this requirement was appropriate. Moreover, it was suggested that the test for 'added matter' is a disclosure test. This test stipulates that an amendment to an application is not allowable if the overall change in content of the application, either by way of addition, alteration or excision, results in the skilled person being presented with information which is not directly and unambiguously derivable from that previously presented by the application, even when account is taken of matter which is implicit to a person skilled in the art

More recent case law has suggested that a more generous interpretation of the term might be allowed in certain circumstances. For example, in a decision of the Enlarged Board of Appeal of the EPO, it was decided that features could be added to an application after filing so long as

they do not provide a 'technical contribution' to the subject matter of the claimed invention. In effect, this means that certain limiting features that are not in the application as filed can be added to the application after filing.

The penalty for 'flouting the rules'

Most significantly, the requirement for added matter is a ground on which the validity of a patent can be challenged in opposition proceedings before the EPO. If the patent in question is found to contain such matter, then it must be revoked.

In this regard, it is noteworthy that the majority of opposition proceedings cite added matter as a ground of opposition. Moreover, it seems that opposition divisions are becoming ever-more stringent in their interpretation of the presence of such matter in an application. The result? Many biotech patents are revoked or amended during opposition proceedings on the basis of the presence of added matter (BOX).

Claims to priority

A related issue, and one which inventors also need to consider, is priority claiming. The EPC permits those applicants who file a European application to 'claim priority' (that is, use the filing date) of a previous national application for the same invention so long as certain conditions are fulfilled. Significantly, recent case law

dictates that the test for a valid claim to priority for the 'same invention' is similar to that for an allowable amendment; that is, a valid claim to priority requires that those elements which are claimed in the European filing must also be directly and unambiguously derivable from the priority application.

What does this mean for inventors?

In real terms, recent case law dictates that priority applications can no longer be lacking in substance and detail: all elements of an invention claimed in a European patent application must be present in a priority application. Features added at the time of filing of the European application risk losing their claim to priority, whereas features added after filing the European application risk being deemed added matter, resulting in possible revocation of the patent. The effect is that it is increasingly risky to file speculative applications that are lacking in any substance and any detail. Although there is always the temptation to file as early as possible, in order to obtain an early filing date, it might be prudent to wait until you really know what the invention is about before filing.

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TECHNICAL BOARD OF APPEAL DECISION (T500/01)

A patent relating to a method for the humanization of immunoglobulin (Ig) molecules, 'Humanized immunoglobulin molecules and their productions and use', could not be maintained because of added matter. The humanization method comprised the grafting of complementarity determining regions (CDRs) from a mouse Ig molecule into the framework region of a human Ig molecule. Essential in defining the scope of protection conferred by the main claim was the definition of the term 'CDR', which in the application as filed was defined "according to Kabat...". During the prosecution of the case an additional passage was added to the introduction which read, "The hypervariable regions (also called ... CDRs) ... were originally defined by Kabat *et al.* More recently Chothia *et al.* have given an alternative definition of hypervariable regions or CDRs ... for each of the six CDRs the Chothia CDR is a subset of the Kabat CDR with the exception of ... the first heavy chain CDR, where the Chothia CDR contains amino acids 26–30 that are not in the Kabat CDR." This unusual definition of the term 'CDR' was introduced in order to overcome some novelty-destroying prior art. The Appeal Board considered that by introducing the passage above into the application, the definition of the term CDR "underwent a major change" and should be understood to mean "that defined by Kabat together with that defined by Chothia". As such the Board considered that the patent contained added matter and could not be maintained.