Our expertise covers inventions involving antibodies against a new target, as well as new antibodies against known targets; and extends further to inventions relating to antibody stabilization and modification; engineered antibodies and fragments; antibody purification; new therapeutic uses of known antibodies, and antibody-drug conjugates.

During prosecution and opposition, issues frequently encountered relate to inventive step and sufficiency. A detailed knowledge of case law in this area, as well as forensic analysis of the facts and creative thinking, enable us to successfully overcome such objections during prosecution and defensive opposition, as well as to successfully construct objections in offensive opposition. This is particularly true when claiming an antibody per se and much thought needs to be given to the best way to define the antibody in the prosecution and defence of such claims.

**Functional definition of an antibody**

Almost all claims to an antibody per se will have some element of a functional definition since, even where an antibody is defined structurally, it is usually a minimum requirement for the claim to specify the antigen target to which it binds. All functional features must be clear and testable.

A claim that defines an antibody solely in terms of its function, for example by reference to the antigen target to which it binds (“an antibody binding to protein X”), is generally well-received by EPO Examiners if the target is new. At the EPO, if an Applicant is in possession of a particular new protein then they are considered also to be in possession of antibodies to that protein. The protein activity must however be known in order for industrial applicability of the antibody to be acknowledged.

If the target is previously known in the art, then it is generally considered by the EPO to be routine to generate antibodies against that target, such that no inventive step can be acknowledged unless the antibody was obtained by a non-obvious method or unless an unexpected, advantageous property of the antibody exists. In the case of a functionally defined antibody having an unexpected, advantageous property, depending on the extent of structural definition in the claim, that property might then need to be recited in the claim.

Although Applicants are typically reluctant to introduce a functional definition into the claim when a structural definition is already recited, a functional definition can have the benefit of excluding non-functioning embodiments.

A functional definition can also put the Applicant in a strong position for arguing in favour of reciting fewer or no structural features in the claim. In the context of an assessment of inventive step, the question then to be asked is whether the skilled person would have had a reasonable expectation of success in isolating an antibody having the recited functional feature.

We have been successful in basing inventive step at the EPO on functional features (recited in the claim or not), for example, binding to a new region of the antigen target with resulting unexpected physiological properties of the antigen target, having a particular cross-reactivity pattern or having high affinity for the antigen target. Reciting a therapeutic effect as functional limitation (whether by using a medical use claim format or as a “suitable for” limitation in a product per se claim) can also be a successful strategy for achieving favourable reconsideration of an objected to claim if there is supporting data to show the
therapeutic effect, for example in a cell line. In many cases, informal discussions with the EPO Examiner have been key to agreeing which functional features are to be recited in the claim in order to achieve allowance. For the attorney, this involves a balance between ensuring commercial protection for the client and alleviating the Examiner’s concerns over scope and often clarity.

**Definition of an antibody by the epitope to which it binds**

Definition of an antibody by reference to the epitope to which it binds is a particular form of functional definition. The epitope itself might be defined structurally or functionally (i.e. the epitope on antigen target X to which mAb Y binds). In order to succeed with such a claim, it will typically be necessary to demonstrate that the antibody binding to the defined epitope was arrived at by a non-obvious method or that some unexpected, advantageous property is associated with the epitope.

Insufficiency is an objection often raised against a claim defining an antibody by reference to the epitope to which it binds. Examiners may take the position that it represents an undue burden to find additional antibodies which bind to the same epitope as the exemplified antibody. If at least one antibody which binds to the epitope is disclosed and the epitope has been characterised then the Applicant should be in a strong position to rebut such an objection. It is embedded in EPO Board of Appeal case law that the concept of sufficiency of disclosure over the whole scope of the claim does not mean that, for a disclosure to be considered as sufficient, it has to be demonstrated that each and every conceivable embodiment of a claim can be obtained. We have been successful in having Examiners withdraw an objective based on lack of sufficient disclosure where there is an absence of serious doubts, substantiated by verifiable facts.

**Structural definition of an antibody**

As the case law stands, there is no acknowledgement of inventive step for an antibody at the EPO on the basis of structural non-obviousness. If however, an unexpected, advantageous property of the antibody is established, then it is an option to define that antibody by its structure, without having to also recite the unexpected, advantageous property in the claim. EPO Examiners however will generally object if the claim recites only one chain of the antibody or recites fewer than all 6 CDRs.

In some circumstances it also possible to obtain a broader scope of protection through use of % homology (e.g. to full variable chain sequences) language.

Increasingly during prosecution, even when we have established an unexpected, advantageous property of an exemplified antibody, we are experiencing lack of inventive step objections from EPO Examiners even for claims that recite all 6 CDRs, on the basis that the properly relied on allegedly requires full heavy and light chain variable sequences. By working with the Examiner and carefully applying the law to the facts of the case, we have been able to overcome such objections either without any amendment to the claim or by inserting a functional feature into the claim.

Paying careful attention to and exercising control over the choice of closest prior art document on the basis of structure as well as functional features has also enabled us to construct the strongest arguments either for or against inventive step.

**The method by which an antibody was obtained**

The decisive question in examining inventive step for an antibody claim (or indeed any other claim) is whether it would have been obvious for the skilled person to arrive at something falling under the terms of a claim. According to the case law, an improvement is not a prerequisite for inventive step. All that is necessary is to ascertain that the respective subject-matter could not be derived by the skilled person in an obvious manner from the available prior art.

Numerous cases discuss the inventive step of an antibody claim in the context of whether the screening protocol and antibody production methods were routine; inventive step being refused only if it was clearly established that the patentee had followed a prescribed route to the antibody, from choice of immunogen to the selection procedure.

This line of argument is often not exploited to its full potential in prosecution or defensive opposition and we have found that a meticulous analysis of the method used to generate the closest prior art antibody as compared with the method used in a patent or patent application can lead to a new line of argument opening up in favour of inventive step.

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