

Patenting Antibodies

Antibody technology has advanced a long way since the early days of Kohler & Milstein's antibody-secreting murine hybridomas. Whilst Kohler & Milstein's invention was not patented, patent protection for the new generation of murine, chimeric, humanized and human antibody-based drugs is essential to safeguard the future development of these drugs.

The claims of a patent application must concisely define the matter for which patent protection is sought. For inventions that relate to antibodies, the claims generally define the antibodies by reference to one or more of the following: (a) the antigen to which the antibody binds; (b) a novel epitope; or (c) the sequence of the antibody polypeptide.

Antibodies defined by antigens

Traditionally, the European Patent Office (EPO) has readily granted claims of the following format, particularly if the protein antigen itself satisfies the criteria for patentability: "An antibody which binds specifically to protein X". In such claims, the antibody is being defined indirectly, that is, by reference to the antigen to which it binds. Care needs to be taken, however, to ensure that such claims do not inherently cover known antibodies, particularly if the protein is part of a family of well-known proteins and antibodies against such proteins are already known. In such circumstances, a claim of the following format should be considered: "An antibody which binds to protein X, but not to protein Y", where protein X is the novel protein and protein Y is a known one having epitopes in common with the novel protein.

In the US, claims of the above formats are allowable, but the US courts have recently imposed a requirement that the claims must refer to a "fully characterized antigen".

Antibodies defined by epitopes

In cases where the antigen to which the antibody binds is already known and some antibodies to that antigen have already been publicly disclosed, a general claim to antibodies to that antigen will lack novelty. However, broad claims to antibodies that are directed to specific epitopes on that antigen might still be possible (assuming that the known antibodies are not directed to those epitopes).

Epitopes may be defined by reference to a specific monoclonal antibody which binds to that epitope or by reference to the amino acid sequence of the epitope in the antigen.

Antibodies defined by sequence

With the advent of phage-display libraries and readily-available DNA sequencing methods, antibodies are now often defined by reference to specific amino-acid or nucleic acid sequences of one or more of the CDRs which form part of the antigen-binding site of the antibody.

It should be noted, however, that if an antibody is known (for example, an antibody that is produced by a known hybridoma), the determining of the sequence of that antibody does not render that antibody novel – it is still the same chemical entity. However, specific fragments of that known antibody might still be patentable.



Further advice

If you would like any further advice please contact us at Dehns using the details below.

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