EIP

Patenting Antibodies

Overview of Patenting Antibodies in the EPO and USPTO

Over the past 40 years, antibodies have become a significant class of therapeutics. Big molecule pharmaceuticals, such as antibody drugs, are associated with even greater costs in the drug discovery phase than small molecule pharmaceuticals. Therefore, if you are an SME looking to develop a novel antibody therapy, the stakes are particularly high. A key part of ensuring success involves developing a strong IP strategy to protect your invention.

When patenting an invention relating to an antibody, there are several factors that need to be considered. This is particularly true when seeking protection in several jurisdictions with differing patentability guidelines, including the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO). Despite attempts to harmonise patent law surrounding antibodies, including the efforts of The Standing Committee on the Law of Patents (SCP) set up by the World Intellectual Property Office (WIPO), the requirements for patentability at the EPO and USPTO continue to differ.

In 2021, the EPO first published specific recommendations on features of antibodies which are patentable in its "Guidelines for Examination". Since then the EPO Guidelines have evolved and, as of March 2024, they provide the following non-exhaustive list of ways in which antibodies can be defined:

a. specific structure (amino acid sequences);
b. nucleic acid sequences encoding the antibody;
c. reference to the target antigen;
d. target antigen and further functional features;
e. functional and structural features;
f. the production process;
g. the hybridoma that produces the antibody.

Key Differences in the EPO and USPTO

Some of the key differences in the EPO and USPTO jurisdictions stem from the differing expectations placed on the abilities of the "skilled person" in the technical field. This hypothetical skilled person provides a useful tool to interpret what an patent application fundamentally discloses, and whether that (a) constitutes an invention, and (b) allows the invention to be reproduced.

At the EPO, the skilled person working on antibodies is considered to have a high level of knowledge in the technical field.

- For 'first in class' patent filings, which disclose the first antibody which binds a particular receptor, broad claims defining the antibody functionally are typically seen. Data for a limited number of antibodies can support a broad claim in view of the notional skilled person's expertise.
- However, once an antibody targeting a particular antigen is known, the EPO considers it obvious and within the skilled person's uninventive remit to identify alternative antibodies binding the same antigen. This means that patent applications which are not 'first in class' typically need comparative data to show that the claimed antibody has improved properties (e.g. bioavailability, half-life, efficacy) relative to earlier known antibodies targeting the same antigen in order to support inventive step.

At the USTPO, making modifications to an antibody is not considered an obvious step, since that may disturb its binding properties.

- As a result, US patent scope for antibodies is usually limited to relatively narrow claims based on the specifically disclosed antibodies. Broad, functionally defined claims are not common in the US as these are not considered justified on the basis of a disclosure of a limited number of antibodies.
- On the flip side, finding alternative antibodies to those previously disclosed for a particular antigen is generally considered inventive work. As such, claims which

are evidenced by sufficient working examples tend to be straightforward to prosecute.

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Therefore, there are different challenges to overcome across these territories but having a diverse range of examples and supporting evidence can help to fulfil the requirements for widespread patenting of an antibody therapy. The type of data required and the breadth of claims accepted by each jurisdiction can be vastly different.

Differing patent office practices around the world must be navigated all the time. Considering the various practices when drafting a patent application can optimise the drafting process to give a case the best possible prospects in each jurisdiction. At EIP, we have both European and US patent attorneys and we work collaboratively in transatlantic teams during the initial patent drafting stage to ensure that the patentability requirements of both the EPO and USPTO jurisdictions are carefully considered. We advise clients throughout early-stage drug development to ensure that patent applications are filed at the right time, with the right content, in order to maximise chances of success in these important markets.