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'Antibody Exception' under Dispute and Waning Usage: Potential Influence on Patenting Antibodies

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Abstract : Therapeutic antibodies have become the most valuable and successful class of biopharmaceutical drugs, with a huge market potential and therapeutic advantages. Antibody patents are, accordingly, extremely important. As the technological limitation of the early stage of this field, the U. S. Patent and Trademark Offices (USPTO) have issued guidelines that suggest an exception for patents claiming a genus of antibodies that bind to a novel antigen, even in the absence of any experimental antibody production. This 'antibody exception' allowed for a broad scope on antibody claims, and led a global trend to patent antibodies without antibodies. Disputes around the pertinent patentability and written description issues remain particularly intense. Yet the validity of such patents had not been overtly challenged until Centocor v. Abbott, which restricted the broad scope of antibody patents and hit the brakes on the 'antibody exception'. The courts tend to uphold the requirement for adequate description of antibodies in the patent specifications, to avoid overreaching antibody claims. Patents following the 'antibody exception' are at risk of being found invalid for inadequately describing what they have claimed. However, the relation between the court and USPTO guidelines remains obscure, and the waning of the 'antibody exception' has led to further disputes around antibody patents. This uncertainty clearly affects patent applications, antibody innovations, and even relevant business performance. This study will give an overview of the emergence, debate, and waning usage of the 'antibody exception' in a number of enlightening cases, attempting to understand the specific concerns and the potential influence of antibody patents. We will then provide some possible strategies for antibody patenting, under the current considerations on the 'antibody exception'.

Keywords : antibody exception, antibody patent, USPTO (U. S. Patent and Trademark Offices) guidelines, written description requirement
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