

ORT.29 - Patentability of monoclonal antibodies in Brazil: analysis of non-obviousness requirement

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Introduction: Monoclonal antibodies (mAbs) market is growing fast and protection through patents is required to continue stimulating research and development of new and improved mAbs. Recognizing non-obviousness requirement (also so-called inventive step) is more complex than novelty and industrial applicability, and thus, understanding, in practice, the objections made by Brazilian Patent and Trademark Office (BRPTO) and respective Applicant's replies, is necessary to delineate strategies when filing a patent application in Brazil.

Objective: Delineate the main strategies to be adopted to fulfill the non-obviousness requirement when patenting monoclonal antibodies-related inventions in therapeutic field.

Methodology: The BRPTO's database was used to detect patent applications and patents claiming monoclonal antibodies through the advanced search filter options, selecting "monoclonal antibody" and "monoclonal antibodies" as key-words, A61K (related to medical or veterinary science and hygiene) as IPC (International Patent Classification) and January 1st, 1995 to July 10, 2018 as time range (date from which Brazil began to accept patenting of inventions in the medical field until the last access prior to the analysis beginning). From the total, only cases with first instance decision issued by BRPTO (Order codes 9.1 or 9.2) and all relevant documents available at database were analyzed.

Results: BRPTO usually rejects the inventiveness of mAbs binding known targets (PI 0207068-5), especially if it is for the treatment of the same disease, explaining that it is obvious to manufacture a mAb in possession of target's amino acid sequence. Successful strategies to overcome these objections were: demonstrate that the claimed mAb binds to different epitope (PI 0715660-0), mainly conformational epitope, which is more difficult to predict (PI 0214188-4); unexpected properties (highlighting improved properties, if present); demonstrate that the specific SEQ ID NO: or hybridoma of claimed mAb was not previously disclosed or suggested (PI 9607171-0); and clinical success (PI 9609035-9). Comparative data are often required for non-obviousness verification, but if the claimed mAb shows well-known improved properties, such as absence of cytotoxicity, BRPTO may accept the inventiveness of claimed new mAb without further comparison (PI 9505980-6). BRPTO also considers as obvious mAbs manufactured through well-known methods in the art, but if the mAb itself is being claimed, the focus should be the achieved mAb, not methodology (PI 9609035-9). Humanization may be considered obvious since it is expected that humanized mAbs show less side effect than murine ones. However, for instance, losses at framework region may reduce mAb's affinity and specificity, rendering this discussion more relevant than the humanization itself (PI 0507433-9).

Conclusion: In order to increase the chances of successfully patenting new mAbs in Brazil, developing approaches based in previous BRPTO's decisions is fundamental to avoiding and, when it's the case, overcome objections for non-obviousness.

Keywords: therapeutic monoclonal antibodies; patentability; non-obviousness