February 6, 2019

The Brazilian PTO launched a public consultation inviting comments on patent applications in the biotechnology field

Dear Colleagues,

The Brazilian PTO published today a draft version of guidelines for the examination of patent applications in the biotechnology field. Any comments and suggestions regarding such draft guidelines must be submitted to the Brazilian PTO until April 07, 2019.

Besides few alterations of formal content, the new text proposes some modifications in specific sections of the current guidelines (Rule # 144/2015). In a general aspect, the Brazilian PTO reiterated and exemplified the understanding already adopted during the examination of biotech cases.

It is important to emphasize that the need to define biological materials according to their own specific sequence(s) remains a crucial point to meet clarity requirements in Brazil. Specifically concerning monoclonal antibodies, the proposed text emphasizes the need for antibody characterization according to the complementarity-determining regions (CDRs) of heavy and light chains thereof.

The main modifications in said draft guidelines are as follows:

i. Sufficiency of disclosure in general terms: experiments that are obvious and/or routine to a person skilled in the art at the time of filing, even if laborious and/or tedious, may not be considered undue experimentation. For example, standardization of the optimal conditions for the polymerase chain reaction (PCR), when the technical problem solved by the invention does not lie in the specific adjustment of those conditions may be accepted.
ii. Sufficiency of disclosure of sequence listings: degenerate nucleotide sequences may be accepted provided that they generate the same protein from a nucleotide sequence specifically defined by means of its SEQ ID NO. in the patent application as originally filed (except in cases in which the application involves the determination of preferential codons in seldom studied species or the optimization of expression in specific organisms).
iii. Markush sequences: the unity of invention requirement must be met in addition to the sufficiency of disclosure: (i) for Markush formula of amino acid sequences, the physical-chemical characteristics (polarity, size, charge, among others) of the amino acids claimed for each position, compared to the sequences shown in the specification must be evaluated and the proposed modifications cannot produce very different results with regard to the polypeptide function (examples of non-acceptable amino acid substitutions if not fully described in the application: leucine for arginine; alanine for tryptophan; and valine for proline); (ii) for Markush formula of nucleotide sequences, in the case of coding sequences, alternatives that generate the same protein are allowed, whereas for non-coding sequences, only the sequences shown in the specification are allowed.

iv. **Antibodies**: the antibody obtained from an organism naturally exposed to an antigen is deemed natural and is not accepted. In cases where the antibody would not exist without significant human intervention, depending on the exposure to the antigen in a controlled and repeated manner, it can be accepted.

v. **Polyclonal antibodies**: they are not liable to protection due to clarity and accuracy requirements, since they comprise an undetermined mixture of antibodies. However, the process of obtaining polyclonal antibodies can be accepted, provided that it is neither a natural biological process nor a therapeutic method.

vi. **"Fully human" monoclonal antibodies**: since the production thereof depends on human exposure to the antigen in a controlled and repeated manner, they can be accepted.

vii. **Antibody fragments**: fragments derived from antibodies not found in nature can still be considered natural if they contain only the constant region (Fc) of the parent antibody.

viii. **Stem cells**: there is no impediment to the patenting of products, obtaining processes and use of human embryonic stem cells. Despite the prohibition of commercialization (Article 5, § 3, of Law # 11,105/05 – Biosafety Law), such prohibition does not extend to patenting, since commercialization and patenting are distinct activities.

ix. **Genetic use restriction technologies**: since Article 6 (VII) of the Biosafety Law prohibits the use, marketing, registration, patenting and licensing of genetic use restriction technologies, the patenting of human intervention processes for the generation/multiplication of genetically modified plants involving plant sterility (even if partial) is not allowed. Further, processes involving sterile reproductive structures (pollen, ovum, stigma, anther, fruit, and their tissues) that result in seedless fruits are non-patentable either.

Should you wish to submit comments and/or suggestions to the Brazilian PTO or need any further clarification on this matter, please do not hesitate to contact us.

Best regards,

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