

Public hearing about the guidelines for the examination of patent applications in the biotechnology field

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On February 6, 2019, the BRPTO started public hearing proceedings regarding the revised Guidelines for the Examination of Patent Applications in the Biotechnology Field.

Interested parties have until April 06, 2019 to send their suggestions, which should be addressed electronically to the e-mail saesp@inpi.gov.br or presented directly to one of the BRPTO reception desks. These new guidelines are an updated version of the Resolution PR N° 144 of March 12, 2015.

Among the topics addressed by the revised Guidelines are:

- Better definition of undue experimentation in Biotechnology related inventions: Routine standardization methods are not necessarily considered as undue experimentation, even if such experimentation is laborious and/or tedious;
- Degenerated sequences are acceptable, and it is not necessary to present each of the possible nucleotide sequences in the sequence listing, provided that they encode the same protein. However, this understanding would not be applied for applications directed to the determination of preferential codons in poorly studied species, or the optimization of expression in specific organisms;
- The definition of “human body” encompasses from the embryo to adult forms, i.e., all stages of development of the human being;
- Applications directed to Markush formula of biological molecules must pay attention to issues related to unity of invention. In relation to the descriptive support in the specification for the alternatives of the Markush formula, the BRPTO defines the following:
 - I. Markush formula for amino acid sequences: it is necessary to evaluate (i) the physicochemical features (polarity, size, charge, etc.) of the amino acids claimed for each position, compared to what was embodied in specification; and (ii) the region where the modifications occur, since in critical areas for the polypeptide function, even conservative changes can render very different outcomes;
 - II. Markush formula for nucleotide sequences: it is necessary to evaluate if the sequences encode the same protein, being acceptable only in the case of degenerated sequences. Otherwise, all the claimed sequences must be embodied.

- Methods regarding GURTs (Genetic Use Restriction Technologies) are not patentable pursuant to Biosafety Law nº 11,105/2005 and will be rejected. Notwithstanding, intermediate products, like vectors and constructs, may be protected.

We will keep you informed on any developments on this matter, as soon as they are available. Should you have any questions or suggestions, our teams are available in Rio de Janeiro, São Paulo and Porto Alegre offices and, through the e-mail mail@kasznarleonardos.com.