Public consultation on biotech patent examination guidelines

On 6 February 2019 the National Institute of Industrial Property (INPI) launched its long-awaited public consultation on a proposal for new examination guidelines for patent applications in the biotechnology sector. The guidelines – published under Resolution Number 144 – have been in force since March 2015.

Considering that advances in biotech are the primary drivers of economic growth in the life sciences sector, it is critical that the relevant IP laws properly promote innovation. The proposal aims to further clarify and define the INPI's understanding of these advances, which will result in a more qualified technical examination. Further, it could reduce the INPI's backlog (estimated at 10.17 years' worth) of biotech patent applications.

Articles 10 and 18 of the current IP Law establish the distinction between non-patentable matter and statutory exclusions from patentability. Matters that are not considered an invention, and therefore non-patentable, include:

- natural living beings (in whole or in part);
- biological material**,** including the genome or germ plasm of any natural living being (found in nature or isolated therefrom); and
- natural biological processes.

Further, inventions that are neither non-patentable nor statutorily excluded from protection are subject to patent examination under Article 8, which defines patentability requirements as 'novelty, inventive step and industrial application'. In Brazil, confusion has arisen as to the difference between patenting a method and patenting a biological material, which is prohibited by Article 10(IX). For example, the scope of protection of a patent for a method to extract an enzyme sequence does not refer to the biological material found in nature *per se*, but rather to the process developed by the applicant, provided that the patentability requirements have been met.

Taking into consideration the legal provisions, the main amendments proposed in the public consultation include:

- the description of the standardisation of experiments will be accepted (even if they are obvious or routine experiments);

- sufficient description of sequence listing – degenerated nucleotide sequences will be accepted, provided that they generate the same protein (which can also be precisely defined). Presentation of each of the possible nucleotide sequences in the sequence listing will not be necessary. Moreover, since the codons preferably used in most of the organisms of interest are already well established (eg, Escherichia coli, Saccharomyces cerevisiae, Arabipodsis thaliana, Zea mays, Glycine max, Drosophila melanogaster, Caenorhabditis elegans), determining what would be the degenerated sequences in each organism will not be considered undue experimentation;
- characterisation of biological sequences – in order to clearly define the subject matter, the INPI emphasises that DNA and RNA must be defined by its nucleotide sequence, while a protein must be defined by its amino acid sequence;
- sequences in Markush formulae – biological sequences may be presented as Markush formulae. However, the following criteria will be evaluated:
    - physicochemical features (eg, polarity, size and charge) of claimed amino acids for each position over those disclosed in the specification; and
    - the position wherein the modification occurred, since even conservative modifications can generate very different results in critical areas for the polypeptide function. With regard to Markush formulae of nucleotide sequences, it will be necessary to evaluate whether the sequence is a protein codifying one.
- patentability of antibodies – according to the proposal, only antibodies that are produced by significant human intervention will be considered to be inventions. Therefore, when the antibody sequence already exists in nature or when it is obtained from an organism that is naturally exposed to the antigen, the antibody will not be entitled to protection. The INPI emphasises that the correct form to define an antibody is by its sequence identifier (SEQ ID NO) or its deposit of biological material. In addition, the description of processes for obtaining polyclonal antibodies will be considered sufficient when all process steps are mentioned in the draft specification. With regard to monoclonal antibody claims, the sequence of all three complementarity-determining regions (CDRs) comprised in the chain must be defined (eg, the antibody comprising CDRs (CDR1, CDR2 and CDR3) consisting of SEQ ID NO: X, SEQ ID NO: Y and SEQ ID NO: Z in light chain and SEQ ID NO: A, SEQ ID NO: B and SEQ ID NO: C in heavy chain and constant regions of human chain γ);
- the allowance of compositions, obtaining processes and applications of human embryonic stem cells; and

- genetic use restriction technologies (GURTs) for the generation or multiplication of genetically modified plants involving GURTs will be excluded from patent protection, which complies with Article 6 VII of the Biosafety Law.

The INPI will receive online comments and suggestions until 6 April 2019 via a form available on its official website.