Brazilian PTO Issues New Examination Guidelines for Patent Applications in the Field of Biotechnology

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The Brazilian Patent and Trademark Office (Brazilian PTO) issued on December 1st, 2020 the Normative Instruction No. 118/2020, that sets new examination guidelines for patent applications in the field of biotechnology and comes into effect immediately. The last update on the guidelines of this technological field were issued in 2015 and, after public consultations, the Brazilian PTO concentrated efforts on the subject to produce this new version.

While the updated guidelines do not significantly change the PTO's general understanding on patentable matter[1] and the characterization of biological sequences, they do improve clarity to the understanding of relevant and often controversial matters, including inventions involving stem cells, fertility modification in plants, and antibodies, as well as aspects regarding sufficiency of disclosure. Further, a number of new claim examples were added throughout the document, aiming at a more objective guidance on the PTO's examination procedures.

Particularly, the guidelines introduce better-defined criteria to assess inventions related to products and processes subject to regulation by the Brazilian Biosecurity Law No. 11,105/2005.

Regarding technologies involving human embryonic stem cells, although the Biosecurity Law imposes restrictions to research and commercialization of these technologies, the Brazilian PTO's examination will not take such restrictions into consideration and will only rely on the patentability requirements of the related products/processes. Thus, examples of patentable claims include: a composition containing stem cells and other ingredients (such as cells associated with growth factors); composition containing mixtures of different types of stem cells; and uses of stem cells for the preparation of medicaments.

On the other hand, the prohibition of genetic use restriction technologies[2], as defined by the Biosecurity Law, extends to patent protection. Thus, inventions defining processes to generate/multiply genetically modified plants with sterile reproductive structures are forbidden and the related applications shall be rejected by Brazilian Examiners. The guidelines highlight, however, that intermediate products (such as vectors and constructs) are patentable. So are processes to reestablish fertility based on gene activation/inactivation, as long as they do not involve the use of external chemical inducers, physical mechanisms being allowed (for example, subjecting the plants to a temperature between 25 and 32°C).

In the section dedicated to inventions involving biological sequences, the document defines clear criteria to distinguish patentable antibodies from

those considered of natural occurrence, which is often a subject of controversy during examination procedures. In summary, whenever the antibody sequence already exists in nature, the antibody is considered to be natural, which is unequivocal. Further, when the antibody is obtained from an organism naturally exposed to the antigen, the Examiner will consider the antibody to be natural as well.

However, in many cases the antibody would not exist without significant human intervention, as it would depend on exposure to the antigen in a controlled and repeated manner, including use of adjuvants, to ensure the activation of specific cells for the humoral response. Thus, such an antibody and its obtaining process are not considered natural, as human intervention is decisive for the final result.

Further, according to the guidelines, while a monoclonal antibody can be clearly defined in terms of its composition, polyclonal antibodies comprise an indeterminate mixture of antibodies, resulting in a lack of clarity and precision of related claims. In this sense, when executing an obtaining method, a skilled person would not arrive at the same final product even when the method itself is clearly disclosed on the specification. Hence, polyclonal antibody claims are considered to lack clarity. However, claims directed to methods of obtaining polyclonal antibodies can be allowable, provided that method steps are sufficiently disclosed and do not include natural biological processes. In either case, the guidelines reinforce that antibodies must be defined by the respective SEQ IDs or the deposit of biological material, which must be presented at the earliest filing date of the application.

The understanding of sufficiency of disclosure requirements for biological sequences was also detailed in some aspects with the new guidelines. For instance, the document explicitly introduces the possibility to claim degenerated nucleotide sequences without defining each possible sequence on the sequence listing besides the original DNA or RNA sequence, provided that they generate the same protein. Further, the guidelines define examples of model organisms, including *Escherichia coli*, *Saccharomyces cerevisiae*, *Arabidopsis thaliana*, *Zea mays*, *Glycine max*, *Drosophila melanogaster* and *Caenorhabditis elegans*, that could constitute basis to dismiss undue experimentation objections in defining the preferred codons for such organisms.

Therefore, the revised version of the guidelines for patent applications in the field of biotechnology will optimize the technical analysis by Examiners and favor a greater harmonization of decisions, allowing applicants to assess with improved clarity the chances of success when prosecuting patent applications in Brazil. The movement comes in a period of multiple improvements to the Brazilian innovation environment, including those of patent examination and granting, initiated by the examination backlog reduction program, and showcases the importance of continuous actions by the Brazilian PTO to keep up with high-paced technology evolution.

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NOTES:

[1] Unpatentable subject matter is defined on articles 10 and 18 of the Brazilian Law No. 9,279/1996 (Brazilian IP Law).

“Art 10. The following are not considered to be inventions or utility models: (...)

IX - natural living beings, in whole or in part, and biological material, including the genome or germ plasm of any natural living being, when found in nature or isolated therefrom, and natural biological processes.”

“Art. 18. The following are not patentable: (...)

III - living beings, in whole or in part, except transgenic micro-organisms meeting the three patentability requirements - novelty, inventive activity and industrial application - provided for in article 8 and which are not mere discoveries;

Sole Paragraph - For the purposes of this law, transgenic micro-organisms are organisms, except the whole or part of plants or animals, that exhibit, due to direct human intervention in their genetic composition, a characteristic that cannot normally be attained by the species under natural conditions.”

[2] Genetic Use Restriction Technology – GURT: “any human intervention process for the generation or multiplication of genetically modified plants to produce sterile reproductive structures, as well as any form of genetic manipulation aimed at the activation or deactivation of genes related to plant fertility by external chemical inducers”. (Sole paragraph of article 6 of the Brazilian Biosecurity Law No. 11,105/2005)

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