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Patenting antibody-related inventions in Brazil

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The healthcare sector in Brazil is one of the most important in the world in view of the size of the population (+220 million people) and the availability of a universal public healthcare system. The action of antibodies as therapeutic agents may involve processes of neutralization, opsonization and activation of immune complement system, transforming them into a progressively desirable tool in medicine. In view of this, the interaction between IP and these innovative therapies deserves special attention.

In Brazil, antibodies are eligible for patent protection provided they are neither naturally occurring nor have a counterpart found in nature. As antibodies are specialized proteins, they are deemed to be biological materials and, as such, are subject to the provisions of article 10 (IX)[1] of the Brazilian Patent Statute. According to BRPTO's Normative Instruction #118/2020, which establishes the Examination Guidelines for Biotechnology Inventions, an antibody obtained by a subject naturally exposed to an antigen is natural. On the other hand, the antibodies obtained through a controlled and repeated antigen exposure, including the use of adjuvants, such as fully human antibodies, are not considered natural due to the significant human intervention.

Unlike their polyclonal cousins, monoclonal antibodies comprise the same amino acid sequence and are specific to the same epitope of an antigen. Hence, despite being a product of human intervention, polyclonal antibodies are not liable to patent protection in Brazil, since they represent a mixture of unknown antibodies directed to different epitopes of the antigen. Nonetheless, the process for obtaining polyclonal antibodies may be protected, provided it does not encompass an invasive step related to the immunization of the host, which would contravene the provisions of article 10 (VIII)[2] of the Brazilian Patent Statute.

Apart from the above, clarity and precision of the claims are also relevant requirements for inventions involving antibodies. According to the Examination Guidelines for Biotechnology Inventions, antibodies shall be defined by the hybridoma by which they are produced – through their corresponding biological material deposit number – as they are considered a transgenic microorganism. Alternatively, antibodies may also be defined by their specific amino acid sequences (SEQ ID NO) or by the amino acid sequences of their CDRs (the CDRs of each of the light and heavy chains), as follows: "*an antibody, characterized by comprising a heavy chain variable (V_H) that comprises complementary determining region (CDR) V_HCDR1, V_HCDR2, and V_HCDR3 sequences of SEQ ID NOs: 12 to 14, respectively, and a light chain variable (V_L) region that comprises V_LCDR1, V_LCDR2, and V_LCDR3 sequences of SEQ ID NOs: 5 to 7, respectively*".

On the other hand, functional language features such as binding as well as identity/homology (regardless of how high the identity is) are not accepted under the principle that they have broad content and cause imprecision in relation to the subject matter to be protected. Hence, functional claim languages such as "*(…) having at least 85% amino acid sequence identity to any one of SEQ ID NO: 1 to SEQ ID NO: 15*" is usually not accepted.

When the antibody is the core of the invention and is defined by its specific amino acid sequence or by the amino acid sequences of its CDRs, such sequences must be disclosed in the filing of the patent application in order to comply with the enablement and support requirements. The subsequent disclosure of sequences not disclosed in the application as originally filed cannot be included in the specification, even if they can be inferred from its disclosure, because they are considered to involve the addition of new subject matter. On the contrary, when the biological sequence is known from the state of the art and duly referenced in the specification as filed, its later inclusion in the application is acceptable.

Antibody patents may also encompass related inventions, such as the nucleic acid molecules encoding the claimed antibody. For the sake of clarity and precision, the nucleic acid molecules must be defined by their corresponding polynucleotide sequences. In this sense, redrafting DNA and protein claims unduly defined in terms of amino acid and nucleotide sequences, respectively, is only possible provided that their nucleotide and amino acid sequences have been disclosed in the patent application as filed.

As for the assessment of inventive step, although general techniques for obtaining antibodies are well-known, the development of antibody-based drugs requires years of research and investment. Accordingly, the fact that the state of the art suggests a certain type of antibody does not necessarily make the invention obvious. Due to the interaction between amino acids and cellular protein processing, it is unlikely that the immunogenic reaction and the antibody affinity to the antigen would be easily determined. This is generally indicative of inventive step.

A general disclosure in the state of the art should not be prejudicial to the novelty and non-obviousness requirements of an invention defined in specific terms. The assessment of the patentability requirements will consider the unexpected technical effects of the invention and its contribution to the state of the art.

Due to the recent developments in new antibody drugs, it is expected that the filing of patent applications related to this technology will expand over the coming years. Consequently the IP debate surrounding them, mainly considering the use and importance of such drugs in medical hotspot areas, will continue for some time to come.

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[1] **Article 10** of the Brazilian Patent Statute states that "*[t]he following is not considered invention or utility model: (…) IX. natural living beings, in whole or in part, and biological material, including the genome or germplasm of any natural living being, when found in nature or isolated therefrom, and natural biological processes*."

[2] **Article 10** of the Brazilian Patent Statute states that "*[t]he following is not considered invention or utility model: (…) VIII. operating or surgical techniques and therapeutic or diagnostic methods, for use on the human or animal body*."

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