Patentability of Chemical and Biotechnology Inventions according to the New Mexican Law

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In order to harmonize and adapt the Mexican legal intellectual property framework to obligations undertaken under different international treaties, a new "Federal Law for the Protection of Industrial Property" (FLPIP) entered into force on November 5, 2020. Regarding chemical and biotechnology inventions, patent eligibility criteria has been further defined and clarified.

One of the most important and unique features of the Mexican law has been that it has a statutory definition of "invention". The definition is maintained in Article 46 of the FLPIP, which specifies that "*It shall be considered as invention, every human creation that allows to transform the matter or energy that exist in the nature, for the use by mankind in the satisfaction of a concrete human need*". By this definition granting protection to naturally available things is in principle avoided in Mexico.

The FLPIP establishes in Article 48 the general requirements of novelty, inventive step and industrial applicability as requisites for obtaining a patent for an invention, as defined above. Further, in its Article 45, fraction I, the FLPIP expressly states that "*patentability is allowed for any substance, compound or composition comprised within the prior art, as long as its use is new*", keeping open the possibility of protecting inventive second medical uses.

Moreover, in its Article 47 includes a list of matters which are not regarded as inventions in Mexico, including among others: discoveries, theoretical and scientific principles; mathematical methods; biological and genetic material as found in nature (*i.e.*, it has not been isolated and/or it has not been made useful for mankind); juxtaposition of known inventions or combinations of known products, except when they cannot function separately or their characteristic qualities or functions of the known inventions or products are modified to obtain an industrial result or a use that is not obvious for a skilled person. It is remarkable that, according to the

of humans and products thereof when they imply the possibility of developing a human being; the use of embryos for industrial or commercial purposes; and procedures modifying the genetic identity of animals if they imply suffering to animals without substantial veterinary or medical usefulness for mankind or animals.

Further, Article 49 excludes plant varieties and animal breeds (except microorganisms); essentially biological processes for obtaining "vegetables"(formerly " plants") or animals and products resulting thereof, if they are not microbiological or do not imply any other *technical procedure* or a product obtained thereof; diagnostic, surgical or therapeutic methods applied to the human or animal body; the human body in the different stages of its constitution and development or the mere discovery of one of its elements, including the full or partial sequence of a gene. Significantly, the word "parts" is omitted from the prohibition to patent the human body, opening the possibility to patenting organs (in consistency with TRIPS). Also, it is clarified that isolated biological material obtained through a technical procedure can be patented even if it previously existed in nature, and that in the case of a partial or full sequence of a nucleic acid or protein the industrial application must be expressly disclosed to avoid protection of the mere discovery of gene sequences.

Chemical and biotechnology patents are at the essence for the life sciences and pharmaceutical sectors. These sectors have had a significant impact on life expectancy and the quality of life of humanity in the last century. Thus, it is positive that the FLPIP establishes more clearly what is not considered an invention and what inventions are excluded from patentability, bringing more certainty to innovators. However, as revised there are several modifications that need to be closely followed by practitioners and stakeholders to address a proper implementation.

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