Analysing current plant protection rules in Mexico and future challenges

Verónica Avilez of **Dumont** assesses the current law on plant protection in Mexico and the issues facing plant breeders as a result

Background

Home to more than 10% of the world's plant diversity, Mexico is considered one of the mega-diverse countries in the world. Theoretically, this biological advantage should easily place Mexico as a leading country in terms of intellectual property rights covering plants. However, lack of amendments and clarity in Mexican law and practice has put Mexico in a weak position in comparison with some less diverse countries.

While it is true that Mexico has gone through many stages of refinement and development with respect to the protection of plants in the last 30 years, the laws protecting plants as intellectual property are still unclear in some respects and this needs to be taken care of in order to ensure a fair solution for all parties involved. The present article aims to provide a brief panorama of the protection of plant material in to the two legal instruments addressing the matter in Mexico.

Patent protection

The Mexican Institute of Industrial Property (IMPI) is responsible for granting patents to all inventions meeting the following requirements: industrial applicability, novelty and inventive step. Besides complying with the aforementioned requirements, all applicants seeking patent protection for plant-related inventions must also consider the Industrial Property Law's (IPL) statutory bar in Article 16. This explicitly excludes patentability of essentially biological processes for obtaining, reproducing and

propagating plants; biological and genetic material as found in nature; and plant varieties.

The IMPI's position tends to be influenced by the criteria established in foreign jurisdictions, such as the United States Patent and Trademark Office (USPTO) or the European Patent Office (EPO). This approach, which usually contributes to expediting the examination of patent applications is, to some extent, supported by Article 54 of the IPL, which states that the IMPI may accept or request the findings of substantive examinations or the equivalent thereof conducted by foreign patent offices. Given the foregoing, by the end of 2017, the patentability criteria related to plant protection changed due to amendments to the EPC Regulations.

For the sake of clarity, the following comments intend to exemplify the criteria being applied to plant-related inventions in Mexico.

Verónica Avilez

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Cases related to products that have been obtained by an essentially biological process

The IPL, as currently drafted, fails to define an essentially biological process for obtaining, reproducing and propagating. However, from what can be understood from the position taken by Mexican examiners during substantive examination of patent applications, a plant selected from sexually crossing the genomes of two plants is enough to fall within the scope of an essentially biological process. Even though our legislation only excludes from patentability the process itself, the new criteria implies that plants and parts thereof, such as cells or fruits, are also regarded as non-patentable inventions regardless of the claim drafting used. Hence, plants comprising an introgression of a particular sequence from a plant of a donor line having the desired trait would be excluded from patentability. This criteria considerably impacts the assessment of pending patent applications, all the more so if we consider that the MX examiners' position has become stricter regarding this topic.

Cases related to methods for producing plants with a certain trait

Although methods for producing plants are considered patentable with the proviso that they comprise a technical step which mandatorily requires human intervention, the examiner's position towards this technical step serving to assist or enhance crossing the chosen plant's genomes, is to reject the obtained plant.

Thus, a method comprising the step of crossing plants to obtain a progeny comprising the technical feature X will result in the rejection of the plant. This is the case if the inclusion of the desired trait is the result of sexual crossbreeding, for example, plant A having a desired trait (e.g. resistance to a plague) comprising in its genome introgressed sequences from plant B (which confers such resistance). A similar scenario will be faced by plants obtained from crossing a transgenic plant and a wild type plant, plants produced by marked-assisted breeding or plants characterised by new genetic markers, even if an essentially biological process is not explicitly claimed. Likewise, using a plant for generating other plants would also be unacceptable under this criteria.

On the other hand, if both plants to be crossed are transgenic, the progeny comprising the desired trait will be regarded as patentable. In that vein, it would seem that genetic engineering techniques (which do not necessarily have to involve recombinant DNA) are mandatory to acknowledge the technical nature of the step of introducing a desired trait into a plant. For example, a plant would be regarded as patentable, if the desired trait is integrated by tilling or electroporation. The same approach will apply if the technical step is impairing or silencing the expression of a particular protein in a plant.

Given the enforcement loopholes, it has been observed that arguing that the claimed methods shall be evaluated by the sum of their steps rather than by each step, could result in a favourable outcome. Nevertheless, such particular patent applications, as well as those comprising other breeding techniques, would have to be assessed individually. In addition to the foregoing, for the sake of completeness and clarity, it is highly recommended that plant-related patent applications contain representative examples that demonstrate that the methods for obtaining the plants indisputably involve human intervention.

Cases related to the selection or the identification of a plant having a desired trait

A very different approach applies to the identification or

selection of a plant comprising a desired trait since the way by which the sequences of interest have been introduced into the claimed plants plays no role in such methods. Consequently, it is clear that a method of detection or selection of plants, wherein the step of detection/identification of a certain allele is a technical step, suggests that it is not an essentially biological process. The above, with the proviso that it complies with the remaining patentability requirements, will almost certainly be allowed.

A method for detecting a plant A made up of sequences from plant B (said sequences conferring the desired feature) comprising the step of detecting a genetic marker in a sample of the plant would be patentable. Thus, since such type of claims neither cover a method of making a plant, nor a plant itself, the result of the method is not a new plant but the characterisation of a plant which already exists and is not claimed as such.

Challenges faced by plant inventors

The shift in the IMPI's criteria lacks legal basis and, arguably, should be appealed before higher instances in order to push Mexican authorities to provide clarity and certainty about how the eligibility of plant-related inventions should be assessed. If the only statutory bar in Mexican legislation relates to essentially biological processes, it is not clear how such a restriction would also apply to the products obtained thereof, which belong to an entirely different invention category and must be evaluated according to their technical features instead of those aspects connected to a process. Furthermore, the IMPI's interpretation regarding the relevance and impact of a technical step outside the context of genetic engineering must also be defined. Up to now, there is no evidence that a resolution related to an appeal concerning this matter has been issued.

Although in 2018 the IPL underwent major amendments regarding several aspects, none of them addressed provisions related to patent applications directed to plants. Moreover, until date, it seems that there are no bills waiting to be approved to clarify the issue. This situation not only deprives plant inventors of their right to claim any desired subject matter that happens to fall within the aforementioned assumptions but also may affect patent owners in the event of a possible counteraction from a third party. In this regard, IMPI examiners have unofficially made clear that the scope of protection of granted patents will remain the same, i.e. this new criteria will not invalidate granted patents. However, this uncertainty is an unnecessary burden for applicants and stakeholders who were not informed about the changes in the IMPI's criteria.

Plant variety protection

While plant varieties are non-eligible for patent protection, they may be protected in Mexico by a sui generis protection system. The authority in charge for the enforcement of plant variety rights in Mexico is the National Service of Certification and Identification of Seeds (SNICS), which in turn depends on the Secretariat of Agriculture and Rural Development (SADER). Plant varieties are regulated under the Federal Law of Plant Varieties (FLPV), which states that the plant variety must be new, distinctive, uniform/homogeneous and stable. That is to say, the FLPV, unlike the IPL, does not envisage the protection of a method for producing a plant. In order to better protect a plant variety, every single technical feature of it must be clearly described in the varietal description. Such description provides a set of morphological, physiological, biochemical and some other phenotypic features that are able to define and differentiate the plant variety.

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The current FLPV is in line with the International Union for the Protection of New Varieties of Plants (UPOV) Act of 1978. Nonetheless since 2012, Mexico has been discussing its eventual adhesion to the UPOV Act of 1991. The main differences between the 1978 UPOV agreement and the UPOV Act of 1991 are the following: the extension of the content of the breeders' rights to the harvest product made from it, the protection of essentially derived varieties and the inclusion of the farmer's privilege. The current Mexican legislation provides protection to the plant varieties but not to the harvested material thereof. It is worth mentioning that the so-called "farmer's privilege" allows a farmer using a protected variety to save seed and replant on the farmer's own holdings, subject to certain conditions (mainly those that explicitly exclude a commercial purposes). This probable addition has led to divided opinions among Mexican stakeholders. While some of them are sure that this update aims to ensure local and international competitiveness and fair agricultural development, others are of the opinion that this addition will be beneficial only to the private sector but detrimental to small and medium-scale local farmers.

Challenges to be faced by plant breeders

Although the definition set out in the UPOV Act defines essentially derived varieties as those plants that retain the

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expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety but which are clearly distinguishable from the same, it is mandatory that the Mexican law better defines them in terms of a measurable genetic distance threshold clearly indicating that such essentially derived plants are different to a significant degree from those plant varieties already known. Therefore the law must be clear so as to allow proper implementation. That is to say, the definition of an essentially derived variety should, as far as possible, not be subject to diverse interpretations.

Given the above-mentioned scenario, some might say that the uncertainty in Mexican law is worrying. This is exacerbated by the fact that the Mexican landscape faces some other peculiarities. For example, the enforcement of plant variety rights is not similar to those of other signatories to the UPOV Treaty (only administrative actions are available), and most of the Mexican infringers are financially limited or completely ignore the plant breeder's rights and/or the plant varieties that are protected in Mexico. Given the country's panorama in terms of agricultural development and scientific research, as well as the lack of clear knowledge of the scope of the plant breeder's rights that some applicants have, these concerns come as no surprise. However, extensive meetings are being held to clarify the current panorama.

Final thoughts

The indiscriminate adoption and application of foreign criteria by Mexican authorities does not seem to take into account the country's particularities and current legal framework. Hence, questions about how the Mexican authorities will adapt their legal regulations in the current fast-growing and changing environment so as to fill the gaps of the current regulations remain unsolved. In this regard, the main task of practitioners is to advise applicants on the best pathway to follow to ensure correct protection of their creations.

In order to avoid the possible environmental drawbacks of poorly regulated plant inventions/varieties (such as loss of biodiversity, undesirable genetic exchange, pollution and endangering of endemic species) as well as the effects of legal uncertainty (such as a lack of enforcement of IP rights and biopiracy), a thorough and well supported interpretation and application of the Mexican laws is essential to assure applicants in the plant production field that their efforts will be fairly rewarded. Given the global increase in interest of applicants in biological-related fields, such regulations are crucial for economic and scientific growth in Mexico.

No change in Mexican Law can be entirely accepted or rejected without taking into consideration all the relevant aspects that will be affected by amendments. It is obvious that there is still room for improvement, and it is certain that an appropriate level of protection of plant breeder's and patent applicant's rights will bring many advantages for agricultural development in Mexico. This will boost the economy and competitiveness of the country. In the meantime, an exhaustive revision is essential to address the expectations of Mexican and foreign stakeholders. Hopefully, the Mexican authorities will soon create clearer laws and guidelines that will allow applicants to obtain protection which meets their needs.