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Patentability requirements for inventions related to transgenic plants.

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The Brazilian Patent and Trademark Office (PTO) issued technical note BRPTO/CPAPD No 01/2023 on May 9, 2023, intending to provide technical rules to be followed by PTO examiners when analyzing the patentability of inventions linked with transgenic plants; particularly, to processes of genetic transformation, known as elite events.

Related Background: According to the provisions of Article 10 (IX) of the Brazilian IP Law # 9,279/96, natural living beings (animals and plants), in whole or in part (such as cells), as well as biological material, when found in nature or isolated therefrom, are not considered to be inventions. Further, Article 18 (III) of the IP Law excludes from patent protection natural living beings, in whole or in part, even if modified/recombinant – it is only possible to seek protection for transgenic microorganisms.

Since the current Biotechnology Guidelines do not fully cover this matter, the Brazilian PTO published a first technical note in March 2022 clarifying the patentability requirements for inventions related to transgenic plants, particularly transgenesis processes, which are named elite events, and issued a Public Consultation to review such subject matter.

The current Technical Note commented herein is the outcome of Public Consultation No. 01/2022, in which opinions and recommendations from users were received and analyzed by the Expert Technical Group.

Content and interpretation: As a result, Technical Note BRPTO/CPAPD No 01/2023 defines an elite event as a transgenic plant modification event (1) by insertion of exogenous DNA (2) using molecular tools, such as, for instance, a genetic construct (3), where this insertion has been performed in a stable manner at a specific location in the plant genome, which is explicitly determined by disclosure of the polynucleotide sequences that flank the insert (4), which gives the plant a superior technical effect when compared to the other transformation events, and is not the result of arbitrary selection.

Accessory inventions related to an elite event may be liable to patentability. On the contrary, plants resulting from the elite event, like any transgenic plant, are not patentable under IP Law art. 18 (III), which prohibits patenting all or part of living beings except transgenic microorganisms. Nevertheless, the transgenic plant resulting from an elite event is at the heart of the unique inventive concept of said genetic transformation, and connects the main invention (i.e., elite event) to the accessories (methods, uses, compositions, and biological sequences).

From this point of view, examination of the biological material in terms of novelty and inventiveness, even if not patentable, is required for granting the main and accessory inventions.

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Novelty. For the assessment of the novelty requirement of an elite event, the PTO states that the elite event will lack novelty if all four features (1) to (4) mentioned above are already disclosed in a single prior art document.

Inventive activity. If no single document is found containing all the technical features of the transgenic transformation, then the inventiveness of the elite event will be examined taking into account the technical problem to be solved, the technical solution given and the closest prior art.

It should be borne in mind that, for an elite event, the technical solution that solves the technical problem does not need be claimed or even patentable per se, as is the case with transgenic plants. However, the patentability requirements of this plant need to be analyzed, not only in the case of the main invention (i.e. the elite event), but also when the application contains several interrelated inventions within the same inventive concept; once the inventive step of the transgenic plant is recognized, it extends to the interrelated inventions.

To establish the state of the art, when searching, the examiner should look for a plant of the same species with the same or similar phenotype. If the same plant cannot be found, searches for plants from other species that share the same phenotype should be performed, taking into account their evolutionary distance from the plant under examination. And, if transformations in plants cannot be found, searches for other descriptions, such as transformations in plant cells, yeasts, bacteria, etc., should be performed to establish the state of the art. In all, the plant/biological material obtained from an elite event must be the object of evaluation for the patentability of the transgenic process, even if not patentable. For reference, the PTO provides the following non-exhaustive list of examples for evidence of inventive step concerning a transgenic plant/elite event:

- i. a phenotype improvement (i.e., increased herbicide resistance or increased seed size); and
- ii. an association by gene linkage of a phenotype (i.e., glyphosate resistance) with another phenotype of interest (for example, increased yield).

In addition, the PTO also provides the following non-exhaustive list of examples for evidence of a lack of inventive step:

- i. the simple fact that the transformation did not harm the agronomic characteristics of the plant or the mere selection of a plant for characteristics not linked to the transgene;

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- ii. molecular analysis of parameters, such as integration of the cassette inserted in the genome, transgene copy number, detection of transgene expression, identification of the place of insertion in the genome without the association of these parameters to a non-obvious technical effect; and
- iii. the existence of modifications in the transgene or the construction per se, as well as the information on a new place of insertion in the genome, even if they confer novelty, do not necessarily give inventiveness to the matter; for this, experimental data are required that relate these modifications to the non-obvious technical effect obtained. Otherwise, the new gene, the new construction or the new site will be considered as equivalent to those described in the state of the art and, therefore, not inventive.

Sufficiency of disclosure. Whenever an application claims matter which, at the time of filing/priority, had been obtained by techniques whose reproduction involved randomness, according to the description, it will be necessary to deposit the seed or equivalent with a Depository Center for Biological Material. Furthermore, the deposit information must be mentioned in the wording of the claims. If the claimed matter could be reproduced at the time of filing/priority just from the sequence, the deposit of biological material is not required.

Furthermore, for sufficiency of disclosure, the specification must disclose the sequence utilized in gene creation, i.e., both the coding region and the regulatory elements of gene expression, in addition to the adjacent chromosomal regions upstream and downstream.

Conclusion/Summary: Given all the above, and in light of Technical Note BRPTO/CPAPD No 01/2023 on May 9, 2023, it is concluded that a transgenesis (elite) event may be patentable if it solves a given technical problem in a new and inventive way. However, plants resulting therefrom and their parts (i.e., seeds, cells, etc.) are not patentable under art. 18 (III) of the LPI, as it happens for any transgenic plant.

However, when assessing the patentability of an elite event and its accessory inventions (methods, uses, compositions, and biological sequences), the properties and technical effect achieved by the resulting biological material/plant must be evaluated to measure the inventive step. First of all, because the properties of the plant/biological material must be searched when defining the state of the art for the event. Secondly, because the inventiveness of any eventual accessory invention inherently depends on the inventiveness of the main invention, and the resulting plant is an essential part of the inventive concept that link the main and accessory inventions.

If you have any questions, please feel free to contact us. We will be glad to help you with this matter.