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New GMOs are patentable

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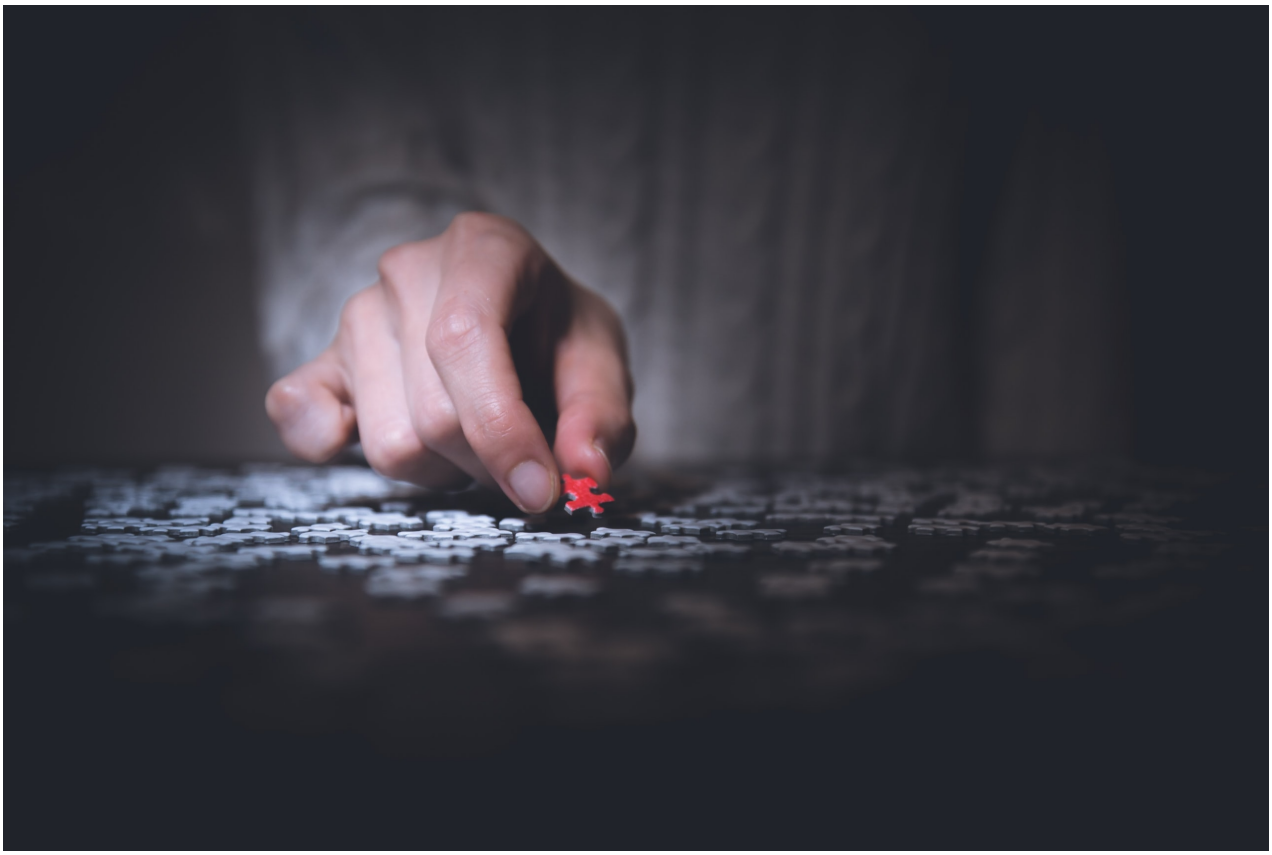

For the European Patent Office, a plant or animal cell isolated from its original organism, is a microorganism obtained by a microbiological process. The EPO considers both to be patentable [1] . Therefore, any genetic modification technique using such cells is a patentable process yielding patentable products. However, since the ruling of the French *Conseil d'État* of February 2020, new mutagenesis techniques implemented on isolated plant or animal cells cultivated *in vitro* produce GMOs. Thus, the link between Patent and GMOs areas is clarified. And in an article to be published in the coming days, Inf'OGM will tell about the tool EPO has developed to prevent such patents to be over-extended.

In May 2019, *Inf'OGM* wrote about the patentability of GMOs derived from mutagenesis. At that time, a representative of the European Patent Office (EPO) stated that a plant genetically modified

by Crispr could not be directly patented if it was identical to a plant already known but the technical process used to obtain it was patentable. Putting the new techniques of genetic modification in a category she called "*conventional plants and plant breeding technology*", the EPO representative fed the vagueness surrounding what is patentable and what is not according to the EPO [2]. On last 14th May, by declaring plants and animals resulting from essentially biological processes non-patentable, just like the processes themselves, the EPO lifted this vagueness [3]. This clarification is important in a context where companies aspire to the rights and financial benefits of patents while trying to escape from GMO regulation, especially labelling.

Microbiological material and microbiological processes are patentable

One would be wrong to believe that what exists in Nature cannot be patented due to being neither new nor invented. For the EPO, the general rule is that "*inventions which concern a product consisting of or containing biological material, or a process by means of which biological material is produced, processed or used*" are patentable (Rule 26 EPC) [4]. Thus, the very fact of isolating an element of the human body or obtaining it by a technical process may result in a "*patentable invention*" if it is susceptible of industrial application (Directive 98/44, Article 5). It does not matter whether this element may be identical to a natural element.
Within the living matter, the EPO distinguishes two categories of processes and products: essentially biological processes and their products on one hand, both non-patentable, and microbiological processes and their products, which are patentable, on the other. It is precisely in this late category of microbiological processes and their products that lay the link between Patent and GMO fields.

In its Guidelines intended for patent applicants [5], the EPO defines microbiological processes as "*any process involving or performed upon or resulting in microbiological material*". It specifies that it concerns "*not only processes performed upon microbiological material or resulting in such, e.g. by genetic engineering, but also processes which as claimed include microbiological and non-microbiological steps*".

Once this general definition has been provided, the EPO also specifies that "*isolated plant or animal cells or in vitro plant or animal cells cultures are treated as microorganisms*" because they can be propagated and manipulated in a laboratory. These isolated cells, considered as microorganisms, "*can be protected* per se *as it is a product obtained by a microbiological process*" [6]. This EPO rule establishing that plant or animal cells isolated *in vitro* are micro-organisms obtained by a microbiological process therefore links with the new GMOs.

The new GMOs are derived from microbiological processes...

Since the decision of the French *Conseil d'État* in February 2020, it has been established in France that mutagenesis applied on isolated cells cultivated *in vitro* produces regulated GMOs. This mutagenesis is a technique whose material's base is a set of isolated cells cultivated in laboratory, the same cells that the EPO considers to be obtained by a microbiological process. It can therefore be understood that techniques using *in vitro* cultured cells are patentable techniques as well as their products. New GMOs resulting from techniques using cells isolated from *in vitro* cultivated plants are products of microbiological processes and are therefore patentable under the EU and the EPO law.

In short, new GMOs are patentable because their material is biological and obtained by microbiological technical processes and that they are also can be subject to industrial application. And this even if they are announced by their producers as similar to organisms that Nature can

produce [7]. For the EPO, this resemblance (which remains purely theoretical) does not obliterate the technical nature of the methods of production, regardless of their degree of importance in the line of production of the patented invention.

Above all, the EPO considers that the addition to an essentially biological process of a "*technical step* (...) *which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing*" makes the general process patentable. No matter how important this technical step may be in obtaining the invention, the whole will not be considered as a product resulting from an essentially biological process [8]. Thus new GMOs, in particular those resulting from mutagenesis associated with *in vitro* cell cultures, cannot be considered as being obtained by conventional selection to which a simple technical step would have been added.

... and are therefore patentable

In the current state of the art, all regulated GMOs are therefore patentable. However, not all patentable techniques produce regulated GMOs. The EPO considers mutagenesis to be a patentable technical process, whether applied *in vivo* or *in vitro*. Namely either on whole plants, parts or tissues of plants (in which case it does not produce regulated GMOs) or on plant cells (in which case it produces regulated GMOs) [9]. Companies seem to feel that this window left to a few plants that are patentable and not regulated as GMOs is still too narrow and would therefore like to widen it. This is why they have been lobbying very hard since the ECJ decision of July 2018 to amend the EU directive so that the same patentable processes of directed mutagenesis would be exempted from the application of the GMO regulation on the grounds that they would be indistinguishable from what nature or traditional breeding techniques can produce. Since the ruling of the [Conseil d'État] in February 2020, it extends this lobbying to the exemption of mutagenesis processes applied to isolated cells cultivated *in vitro*.

This situation, hopped for by companies who would like a genetically modified plant to be patentable because it is invented, but not regulated as a GMO because nature or traditional breeding techniques can also do so, is paradoxical and complex. But, in its directives, EPO has already anticipated this situation but requesting additional informations preventing patents from being applied to products obtained by other processes, whether patentable or non-patentable as Inf'OGM will detail in an article to come. But more generally, this situation exists today because living matter have been declared partly patentable. In order to do so, living matter has been fragmented to correspond to different technical classifications. The result is highly artificial and has complicated and blurred limits as we have seen. For some in the debate, the simplest solution to all headaches would be to declare all living matter non-patentable.

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[1] Article 27-3 of the WTO Agreement on Trade-Related Industrial Property Rights - TRIPS - considers all microorganisms to be patentable

[4] The EPO understands under biological material any "*material containing genetic information and capable of reproducing itself or being reproduced in a biological system*". And "*Microbiological process*" means "*any process involving or performed upon or resulting in microbiological material*" (Rule 26 EPC)

[5] Guidelines for Examination in EPO, Part G, Chapter II, point 5.5.1

[6] The same applies to "*plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa*".

[7] The idea put forward by companies that new GMOs are not detectable and traceable has however been denied, see in particular

[8] G 03/19, page 40.

[9] However, these non-microbiological technical processes must be reproducible in order to be susceptible to industrial applications, which is not always the case with so-called random mutagenesis

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