GJE INTELLECTUAL PROPERTY

# GNP 19 Patenting Biological Processes at the European Patent Office

Patents can be obtained for any new and non-obvious product or process, providing the invention does not fall into one of a limited number of specific exclusions from patentability. At the European Patent Office inventions that are considered to be "plant or animal varieties" or "essentially biological processes for the production of plants or animals" are excluded from patentability. This guidance note briefly explains when this exclusion bites and whether this should be of concern for life science companies.

Inventors in the medical field will be very familiar with the exclusion from patentability in Europe for "methods of medical treatment". This prevents patents from hindering the day to day activity of medical practitioners by ensuring that patents for medicaments are directed to the "products" produced by manufacturers and how they are marketed, not how they are used in the clinic. However, the European Patent Convention (EPC) contains another biological "process" exclusion that is less well known as it mainly affects plant-based inventions.

Investment in biotechnological research aimed at tackling climate change and addressing looming food security problems has been growing at an unprecedented rate. This has been aided by the rapid development of techniques available for plant genetic engineering and plant and animal cell culture. This opens up exciting possibilities, for example for the manufacture of medicaments by transgenic plants or for growing artificial meat and meat substitutes that may contribute to a reduction in global industrial and farming related carbon emissions. Indeed, growing biomass to produce food and medicines may not only reduce emissions but may also increase carbon capture.

## Essentially Biological Process and Plant Varieties

The EPC excludes from patentability inventions consisting of "plant or animal varieties" or "essentially biological processes for the production of plants or animals". It should be noted that this does not apply to microbiological processes or the products thereof, such as new bacteria that have been selected to perform a useful function. An "essentially biological process" is defined in the EPC as consisting entirely of natural phenomena such as crossing or selection.

Therefore, if an inventor produces a new variety of plant or animal through a process only involving sexual crossing, even if novel selection pressures are applied, then it may not be possible to patent that new variety in or the process for making it in Europe. However, if the process involved an artificial genetic modification, for example adding or removing a gene through engineering, then the resultant plant, animal or process could potentially be patented. This is subject to the proviso that if the result is an animal, then it is likely that other patent exclusions may prevent patenting. For example, a European patent cannot be granted for processes for modifying the genetic identity of animals, which are likely to cause them suffering without any substantial medical benefit to man or animal, or animals resulting from such processes. Further, a number of additional exclusions apply to human tissue: a European patent cannot be granted for processes for cloning humans or for modifying the germ line identity of humans, or for industrial uses of human embryos.

Alternative intellectual property rights known as Plant Variety rights are available in the European Union for the protection of new varieties of plants produced through crossing and selection.

In the context of plants, the Enlarged Board of Appeal (EBA), which is the ultimate appeal body of the European Patent Office (EPO), has previously clarified that essentially biological processes are those which contain steps of sexually crossing whole genomes of plants and subsequently selecting plants. Therefore patent claims directed only to such processes cannot be granted in Europe. However, if the claimed process involves an additional technical step (such as artificial genome modification), then the process could be patentable.

## Products of Essentially Biological Processes

While the processes are not patentable, there has been a lot of debate at the EPO as to whether the products of such processes should be patented and this is still under debate. The EBA had previously decided that the exclusion of essentially biological processes does not also exclude from patentability products obtained by such processes, provided all other requirements for patentability are met. However, this ruling was controversial with certain interest groups and with the President of the EPO due to concern that this position conflicted with the legal protection provided to plant varieties under EU plant variety legislation and in relation to access to genetic resources. The current situation as of the end of 2019 is that we are awaiting the outcome of another referral to the EBA to decide on the issue and the President of the EPO has put a stay on the examination of any patent applications directed to the products of essentially biological processes.

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## Summary

The take home message for life science companies looking to develop new products via the genetic engineering of plants and/or animals is that providing your process is new and inventive and involves more than just sexual crossing, then it is likely that you could obtain a granted patent in Europe



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