



Future of protecting plant-related innovations in Europe

Lindsey Woolley and **Frances Salisbury** consider the ongoing debate over what is patentable for plant-related inventions

Two types of IP protection are available in Europe for plant-related innovations: (i) plant variety rights (PVRs) and (ii) patents. Both types of protection may be obtained nationally or more widely, with a European patent from the European Patent Office (EPO) or with a community plant variety right (CPVR) from the Community Plant Variety Office (CPVO) under the International Convention for the Protection of New Varieties of Plants (UPOV Convention).

The legislative intent was that there should be no gaps between plant variety and patent protection. At the EPO, specific plant varieties may not be individually claimed in a patent,¹ as these can be the subject of individual PVRs. However, plants are patentable where the technical feasibility of the invention is not confined to a particular plant variety,² so a patent claim may nonetheless encompass plant varieties.

The other exclusion from patentability specific to plant-related innovations at the EPO is that of “essentially biological processes for the production of plants”.³ This exclusion is the subject of much debate in

Europe, predominantly at the EPO but also in other member states, most notably the Netherlands. It is considered further here.

EPO's interpretation of the exclusion

The term “essentially biological process for the production of plants” is defined narrowly as a process consisting entirely of natural phenomena such as crossing or selection.⁴ Considered to be unclear and self-contradictory, the scope of this exclusion was considered by the EPO's Enlarged Board of Appeal (EBA) in 2010, in the *Broccoli I* (G2/07) and *Tomatoes I* (G1/08) cases.

In *Broccoli I*, the patent claimed a method for production of glucosinolate-rich broccoli comprising steps of crossing and selection using molecular markers. In *Tomatoes I*, the patent claimed a method for breeding tomato plants with reduced water content in fruit, comprising crossing and selection steps using phenotypic analysis.

The EBA concluded that a process for the production of plants which contains the steps of sexually crossing the whole genomes of plants and of subsequently

selecting plants is in principle excluded from patentability, including where the process contains additional steps of a technical nature performed before or after the steps of crossing and selecting. A process escapes the exclusion only where it contains “within” the steps of crossing and selecting “an additional step of a technical nature, 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 crossing”.

In both cases, the methods were found to be excluded from patentability, with the EBA highlighting that “SMART (Selection with Markers and Advanced Reproductive Technologies) breeding” methods were excluded. In contrast, the EBA stated that “genetic engineering techniques applied to plants” are still patentable, on the basis that such techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant.

It is widely believed, however, that the extent of the exclusion concerning methods of producing transgenic (GM) plants remains uncertain. Critically, the EBA qualified that even in such cases, "the claims should not, explicitly or *implicitly*, include the sexual crossing and selection process". So, on a strict interpretation, the decision appears to exclude even methods of improving a plant by genetic engineering where the practicalities of achieving a commercially desirable plant involve backcrossing and selection steps, irrespective of whether those steps are specified in the claim. Ensuring that the claimed method achieves the commercial product is necessary to benefit from the protection that such a process claim affords to the products directly obtained by that process.

On a more positive note, examination practice at the EPO since the decision is that methods for making transgenic plants are considered as not excluded, on the basis that in such methods a trait is introduced into or modified in the genome by a technical step, not by sexual crossing of whole genomes.

A way to reconcile these apparent differences may be to interpret the EBA's comments such that the claims should not, explicitly or implicitly, include the process of sexually crossing whole genomes to introduce a trait into or to modify a trait in the genome by the mixing of the genes of the plants chosen for sexual crossing and selecting. This would be consistent at least with the apparent intent of the EPO. Such an interpretation, in not precluding a claim implicitly covering subsequent steps of sexually crossing and selecting whole genomes to maintain or propagate the trait introduced or modified by genetic

engineering steps, may provide a degree of comfort to those wanting to protect such methods.

Further restriction at the EPO?

Amid this uncertainty, the debate now includes whether plants produced by essentially biological processes are patentable. In both the earlier cases, the resulting amended patents claimed the plants (or their products) produced by the excluded methods. In further referrals of these cases, the EBA is now asked whether claims to the plants themselves should also be excluded under the same provision (*Tomatoes II*, G2/12 and *Broccoli II*, G3/12).

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Cases affected by this issue are currently stayed at the EPO pending the EBA's decision

Those in favour of extending the scope of the exclusion argue it would be wrong for plants produced by excluded methods to be patentable, since this would render the exclusion of essentially biological processes for the production of plants completely ineffective; the legislative intent behind the process exclusion (to exclude from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties) would thereby be frustrated. The EPO faces significant pressure to exclude the products of such processes, from governmental and non-governmental organisations.

Those in favour of patentability argue that the legislation explicitly refers to processes not products, and the EPO should not try and extend the exclusion to subject matter which the legislation does not require; issues of patentability should be determined strictly in relation to the claimed subject matter, being distinct from issues of scope of protection and rights conferred by a granted claim.



Guidance from the Dutch courts?

In fact the same question has already been considered in the Dutch courts in *Taste of Nature v Cresco*,⁵ in which the European patent claimed a radish plant obtainable by crossing and selection steps. The issues and arguments for and against were very similar to those before the EBA in the pending referrals.

In the end, the District Court of The Hague found for patentability of a plant obtained by an excluded essentially biological process, reversing the first instance findings. The key findings were that: (i) the exclusion of Article 53(b) EPC refers only to processes, and the EPC makes a consistent distinction between processes and products; (ii) granting of patents for plants produced by excluded essentially biological processes does not erode the exclusion, since a process claim cannot necessarily be converted to a product claim because of the fundamental difference in patentability requirements between the two; and (iii) only the claimed subject matter (a plant) must comply with the patentability criteria, not activities falling within the rights conferred by a granted claim (producing the claimed plant by the essentially biological process). In concluding that plants produced by essentially biological processes are not themselves excluded from patentability, the court noted that any political reasons for why the patenting of plants is considered undesirable cannot lead to a different conclusion.

While the EPO is unlikely simply to follow this decision, the decisive legal arguments are similarly applicable in the EPO proceedings. Among those filing *amicus curiae* briefs in *Tomatoes II* with such similar arguments in favour of patentability is the president of the EPO. It is hoped that it should be difficult for the EBA to reasonably dismiss such arguments.

What to do in the interim?

Advice amid this debate is to claim a plant-related invention diversely, covering all possible aspects of the invention to try to cover various outcomes.

Consider whether the following claim types, for example, may be suitable: methods for selecting or screening plants using markers, use of markers to select plants, or selection markers per se; a (non-natural) cDNA transgene or nucleic acid transformation construct, where in the desired commercial product this biological material will retain the ability to perform its function; new downstream products obtained from the plant (eg, a seed oil or

meal) or methods of preparation of such products.

Also consider patents and PVRs as a tool kit. While plant innovators generally protect classical breeding innovations by PVRs and GM innovations by patents, try to utilise all available IP tools in respect of any given innovation.

Such a flexible approach to protection is particularly important for innovations involving new breeding technologies that do not sit neatly in either one or other of the established categories (for example, using targeted trait-modification combined with classical crossing and phenotype selection).

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Contrasts with other jurisdictions

At present, Europe falls somewhere midway in the spectrum of differing IP protection that is available for plant-related innovations in different countries.

The US, Japan and Australia offer broader protection, in that there is no limitation on patentability of plant-related inventions. In the US for example, there is a wider framework of IP protection available than in Europe, including PVRs, plant patents and utility patents. While PVRs (for sexually reproduced plant varieties)⁶ and plant patents (for asexually propagated plant varieties)⁷ together provide the protection available under a PVR in Europe, utility patents may be directed to any plant-related subject matter, product or process. For example, a claim to a plant variety or to a classical method of breeding a plant, are not excluded from utility patents in the US.

In contrast with a much broader exclusion, neither plants nor classical methods of plant breeding are patentable in India, China and Brazil, for example.

As an interesting side note, generally, there is a tendency for there to be a mismatch between the availability of plant-related IP protection and the restrictions imposed by regulatory frameworks and/or consumer opinion for commercialising those innovations. For example, Brazil, India and China are just behind the US as the biggest producers of transgenic crops⁸ yet do not provide direct IP protection for those plants. Even in the US, which historically has not faced the opposition to GM technology that exists in Europe, there is increasing pressure for greater regulation of GM crops.

It is hoped then that a decision from the EBA referrals does not cause Europe to move towards the broader exclusion group in which there is a wide gap in protection.

Footnotes

1. Article 53(b) EPC.
2. Rule 27(b) EPC.
3. Article 53(b) EPC.
4. Rule 26(5) EPC.
5. *Taste of Nature Holding BV v Cresco Handels-BV*, District Court The Hague, The Netherlands, 8 May 2013, Case No / Docket No 416501 / KG ZA 12-452 (the Radish-sprout case).
6. PVPA 7 USC § 57.
7. 35 USC § 161.
8. *Nature Biotechnology* Volume 30 Number 3 March 2012.

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