PATENT-ELIGIBILITY OF PLANTS IN EUROPE

The patent-eligibility of plants has been unsettled at the European Patent Office for some 20 years. Article 53(b) EPC prohibits the patenting of plant varieties and essentially biological processes for the production of plants. When other requirements such as novelty and inventive step are met, this causes few problems for transgenic plants modified by biotechnological methods, but it has been increasingly an issue for inventions pertaining to “classically” bred ones. Several decisions of the EPO’s Enlarged Board of Appeal have however helped to clarify what claims are available in this area.

In particular, the Enlarged Board has confirmed that plants are patentable in general notwithstanding the “plant variety” exclusion and that the “essentially biological process” limb of Article 53(b) does not apply to product claims. As well as Plant Variety Rights, patent claims directed to novel and inventive plants obtained by methods which include breeding steps are therefore allowable in principle. This is positive for Applicants in the agricultural sector, but is likely to remain controversial as many lobby groups and breeders’ organisations have long argued in favour of a more restrictive position.

Early EPO Practice under Article 53(b) EPC

For many years after the EPC came into force in 1978, there were few issues under because there were few relevant filings. From around the mid-1990s, however, as genetically modified plants became more of a commercial reality, and more applications were filed, patentability of plants became increasingly controversial both legally and socially.

G1/98 - Plant Varieties

Plant varieties were considered by the highest decision-making authority of the European Patent Office (EPO), the Enlarged Board of Appeal, in Decision G1/98. This established that, although individual plant varieties are not patentable, plants in general can be patented. In particular, the Enlarged Board confirmed that claims to plants are in principle allowable as long as they are drafted at a taxonomic level
higher than that of a single variety, even though such claims may well encompass
multiple varieties that could not be claimed at an individual level. G1/98 did not
distinguish transgenic and “classically” bred plants; either sort is in principle
patentable according to its reasoning. This was extremely positive for patent
Applicants, as even though there was relatively little patenting activity at the time
regarding “classically” bred plants which have traditionally been protected more by
Plant Variety Rights, G1/98 met a growing need for the patenting of transgenic ones
and laid important groundwork for later decisions.

Even today, there remains some uncertainty around the exact scope of the plant
variety exclusion, in that it is still to be resolved exactly what degree of genetic
homogeneity is required for a plant to be excluded under Article 53(b) and
occasionally there may be cases where neither a patent claim nor a plant variety
right is available. However, this is seldom an issue in practice. Usually, it is fairly
clear whether a product claim represents a patent-ineligible plant variety or covers
plants at a more general taxonomic level and thus escapes Article 53(b) EPC.

Issued in December 1999, G1/98 did not however address essentially biological
processes. Technical Boards of Appeal then later referred questions concerning
essentially biological processes to the Enlarged Board in two cases, G2/07 and G1/
08, in 2007 and 2008 respectively.

**G2/07 and G1/08 - Broccoli and Tomatoes**

**G2/07** (the so-called “Broccoli” case) claimed a method for the production of
broccoli with elevated levels of certain compounds by crossing one of two wild
broccoli species with another broccoli breeding line then selecting the progeny with
the aid of molecular markers predictive of the presence of the desired compounds.
In **G1/08** (the “Tomato” case), the claims were to crossing tomatoes, allowing the
fruit on the resultant plants to remain on the vine past the point of normal ripening
and screening for reduced fruit water content as indicated by extended preservation
and wrinkling of the fruit’s skin, by performing a visual inspection. These Patents
both therefore claimed processes in which crossing and selection steps are enhanced
or completed by a further step of a different nature.

In both cases, Patents were granted and opposed by third parties, on grounds
including that the claims contravened Article 53(b) EPC. The Technical Boards
charged with deciding the Appeals from these Oppositions independently referred
questions of law to the Enlarged Board of Appeal. The two referrals were
consolidated and a single Decision issued in December 2010.

The Enlarged Board held that a process for the production of plants which is based on
the sexual crossing of whole genomes and on the subsequent selection of plants, in
which human intervention, including the provision of a technical means, serves to
enable or assist the performance of the process steps, remains excluded from
patentability as essentially biological. A breeding process thus remains a breeding
process even if technical steps, such as marker-aided selection, are incorporated into
it and it should not be possible avoid the exclusion simply by adding ancillary
technical steps to what is fundamentally a breeding process. The Decision did not
directly address methods for producing animals but similar conclusions would
presumably apply.

The Enlarged Board confirmed that processes for the production of transgenic plants are in principle patentable, indicating that patentable subject matter resides in method steps that introduce a trait into the plant genome or modify a trait in the plant genome such that this introduction or modification is not the result of the mixing of the genes of the plants chosen for sexual crossing. However, it went on to say that, in such situations, the claims should not, explicitly or implicitly, include the sexual crossing and selection process, otherwise Article 53(b) could be circumvented simply by adding upstream or downstream steps.

G2/12 and G2/13 - Broccoli and Tomatoes II

Since the first “Tomato” and “Broccoli” decisions, it has in general become impossible to obtain process claims containing crossing/selection steps. Even claims that begin with a non-breeding (e.g. transformation) step but then includes breeding steps downstream have consistently been objected to by EPO Examiners under Article 53(b). Product claims therefore came to be seen as the better option. Claims to transgenic plants generally cause no difficulty under Article 53(b) EPC, and it was possible in principle to obtain product claims to “classically” bred plants. Even though Article 53(b) EPC prohibits patents on essentially biological processes and on plant varieties as products, it does not explicitly prohibit patents on the products of essentially biological processes as long as those products are not plant varieties as defined in earlier Decision G1/98 (see above).

Consequently, following the issuance of G02/07 and G1/08, re-formatting claims to “classical” breeding/selection methods for producing plants as product-by-process claims directed to plants obtainable by the “classical” breeding/selection method became the standard approach to address essentially biological process objections under Article 53(b) EPC. This approach was endorsed by the Technical Boards of Appeal in Decision T1854/07 (sunflowers), and before the Dutch national Courts in Taste of Nature vs Cresco.

In March 2015, the Enlarged Board of Appeal unambiguously confirmed this approach in the so-called “Tomatoes II” and “Broccoli II” cases (G2/12 and G2/13). In particular, the Enlarged Board ruled that the exclusion of process claims containing crossing/selection steps does not impact product claims. Thus, the Enlarged Board confirmed that the “essentially biological process” limb of Article 53(b) only applies to process claims. Claims directed to novel and inventive plants obtained by methods which include breeding steps are in principle allowable, whether claimed in product per se or product-by-process format. In practice, these cases often involve other patentability challenges, for example in terms of novelty or sufficiency of disclosure, so relatively few such patents have actually been granted to date. However, their patent-eligible status under Article 53(b) EPC is now clear.

T1729/06 - Triploid Watermelons

As discussed above, since the “Tomato” and “Broccoli” decisions it has in general become impossible to obtain process claims containing crossing/selection steps. However, the “Broccoli” decision does state that a claim may be allowable under
Article 53(b) EPC if certain special circumstance apply. In particular, the Board of Appeal stated that a claim may be allowable if:

“it contains within the steps of sexually 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 sexual crossing”

Following on from this Decision, the Technical Board of Appeal in T1729/06 found that method claims comprising a pollination step to be allowable. This decision was reached on the basis that the claimed methods did not involve breeding in the sense of the mixing of whole genomes. In particular, T1729/06 relates to a method of crossing a triploid watermelon plant with a diploid polliniser to produce seedless watermelon fruit. The Technical Board of Appeal found that such methods:

“...do not involve successful meiosis in the triploid plant flowers. Rather, they merely concern the pollination of the sterile female flowers of the triploid watermelon plant with pollen of the diploid polliniser plant. They do not concern sexually crossing two whole genomes of plants (implying meiosis and fertilisation) and the subsequent selection of plants.”

Thus, this claim was held to be directed to a method of producing a fruit, as opposed to a plant. The Board also commented that it had not been the legislator’s intention to exclude all horticultural as agricultural processes from patentability.

Although the exact parameters of the essentially biological process exclusion are still not yet fully clear, there may therefore be some special circumstances where processes comprising steps of plant crossing are allowable under Article 53(b) EPC. Generally, however, Examiners at the EPO object under Article 53(b) EPC to every process that contains a crossing step.

Some Practical Points

Practice in the patenting of plants varies widely worldwide. Some jurisdictions, notably the USA, are more liberal than the EPO, others less. Especially as the EPO is strict on added subject matter when making amendments, it is therefore helpful to consider its requirements under Article 53(b) at the stage of drafting the specification. In most cases, it is however possible to reformulate patent-ineligible claims into patent-eligible ones. Notably, it is now often possible to claim a “classically” bred plant as a plant that contains a certain trait, as plant “obtainable by” a certain breeding process or as the progeny of a cross. In the latter two cases, it is important to avoid claiming the plant such that it represents a single plant variety but this can usually be achieved by that defining at least one of the parents broadly, such that the progeny is not confined to a single variety.

Satisfying all other patentability requirements is however then frequently a challenge for “classically” bred plants. In some cases, there are issues with novelty as a new breeding process that cannot be claimed in method form may lead to a known result that cannot be claimed as a product, and the incremental stepwise nature of plant
breeding is such that inventive step can be an issue too. Defining a genetic trait clearly in the absence of molecular data can also be difficult. In terms of sufficiency of disclosure (enablement), a deposit is usually required. So sometimes Applicants find that the claims they are forced to adopt for patent-eligibility requirements are not optimal for other reasons.

Nevertheless, the net result of the Enlarged Board of Appeal’s case law since G1/98 is that a fair scope of protection is usually available in cases where there is a strong invention. New technology is also helping, because as well as making traditional biological deposits (usually of seeds in this area) under the Budapest Treaty, Applicants are now more often able to include in their specifications molecular marker and/or other sequence data. This sort of information is always helpful as it assists in defining a novel and inventive trait in more concrete terms than can be achieved if only genetic information is available as in breeding processes in the past.

It is also always worth considering plant variety rights (PVR) protection, for which Europe has both individual national systems and a centralized EU one. These can grant long-lasting (25 years from grant in most cases, 30 years for trees, vines and potatoes) protection for individual varieties of any species that are distinct, stable, uniform and new in the sense that they have not been commercialized in the EU more than one year prior to filing, or more than four years prior outside (six years for trees and vines). The rights concerned generally considered to be weaker than patent rights but should not be discounted for that reason alone, because they may be all that is available, or a valuable compliment to a patent whose scope has to be restricted in some way because of Article 53(b) EPC or other patentability provisions. Applicants sometimes speak of a choice between patents and PVRs but the better view is to consider them as two parts of one integrated strategy.

Conclusions

The patent-eligibility of plants is therefore now much more settled at the European Patent Office than it has been for many years. In particular, it is now clear that:

- Individual plant varieties are not patentable. Instead, protection for such products is available via Plant Variety Rights (PVRs).

- Claims to transgenic plants are however seldom problematic under Article 53(b) EPC and it is easier to satisfy the clarity and sufficiency requirements in these cases too, because transgenic technology lends itself more readily to clear definitions by reference to sequences which also assists with sufficiency (enablement).

- Processes involving breeding (in the sense of mixing of whole genomes) are not patentable, even if other steps such as transformation are also present. Marker-aided selection processes will also in general not be patentable.

- Non-breeding processes (such as transformation, antisense or RNA, suppression, mutagenesis, targeted modification) may be claimed, so long as no breeding step is specified, and again so long as other patentability criteria are fulfilled.
Plants may, however, be claimed as products so long as they are not individual varieties, and so long as other patentability criteria are fulfilled. This applies whether the plants are transgenic, mutant, or “classically” bred, and whether the plants are being claimed in “straight product” or product-by-process format.

If you would like to discuss any of the above issues further, please feel free to contact your usual J A Kemp attorney, or Andrew Bentham or Huw Jenkins in our Plant Science and Agriculture team.

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