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The Monsanto v Schmieser case: A European Perspective

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Abstract

The decision of the Supreme Court of Canada in *Monsanto v. Schmeiser* is a landmark case with implications for intellectual property and biotechnology. The decision has the potential to set a precedent that could be followed by other courts around the world. In Europe, the *de facto* moratorium on growing GM crops is slowly being lifted which has resulted in the issues surrounding this case receiving greater attention. Under European intellectual property legislation a farmer growing a patented GM crop, intentionally or not, without authorisation of the patent holder will almost certainly be infringing the patent.

Key Words: European Intellectual Property legislation; Patent.

Introduction

The *Monsanto v Schmeiser* case in 2004 was perhaps the first time a case involving GM crops which may have accidentally got onto a neighbouring farm, either via seed or through cross pollination, and have subsequently been grown, has come to court. The decision by the Canadian Supreme Court may set a precedent that could be followed by other courts around the world. However, the narrow majority of 5:4 suggests this may not be the case and other jurisdictions may reach different conclusions. The Supreme Court looked at a variety of issues, but perhaps the most pertinent from a European perspective were a) Is the patent valid? and b) Was there infringement? In order to answer these questions it is necessary to look at the relevant European IP legislation.

EU intellectual property legislation

Europe is perhaps unique in that there are two sources of European patent law, The European Patent Convention (EPC) and the EU Directive on the Legal Protection of Biotechnological Inventions (Directive 44/98). The EPC is not an instrument of the EU and includes countries that are not members of the EU. However, all EU countries are members of EPC and all EU national laws mirror the EPC.

The reason for this mirroring is because the function of the EPC is to enable an applicant to acquire, via a single application, a patent which is enforceable in as many Member States as the applicant wishes. The right once granted has exactly the same effect as if it had been granted by the local granting office, and it is enforceable through the national courts. In order to ensure the necessary conformity between member states, the EPC requires that the patent laws of all member states adhere to its provisions. The EPC is overseen by the European Patent Office (EPO).

The EU has no authority over the EPC. But certain decisions of the EPO have given cause for concern, not least as some decisions have been regarded as lacking in certainty. With a view to harmonising patent law within the EU and in an effort to assert control over decisions in this area of law, the EU introduced the Directive on the Legal Protection of Biotechnological Inventions which had to be implemented by Member States by July 2000. The Directive is designed to reflect the increasing importance that biotechnology and genetic engineering are playing in a broad range of

industries. The protection of biotechnological inventions is of fundamental importance for the Community's industrial development. Furthermore, the aim of the Directive is to ensure effective and harmonised protection throughout the Member States of the EU.

In order to harmonise the EPC with the Directive, the Administrative Council of the EPO in 1999 voted to amend its Implementing Rules to permit the EU Directive to be used as a Supplementary Means of Interpretation. The EPC is now to be read in light of the provisions of the EU Directive.

Patenting of Higher Life forms.

In an attempt to answer whether the ‘*Monsanto*’ would be valid it is useful to look at the history of patenting higher life forms in Europe.

Animals

In 1985 The University of Harvard applied for what has been termed the *The “Oncomouse/Harvard”* patent. Although the grant of the patent was initially refused, it was allowed through on appeal and finally granted in 1992. The case centred around Article 53 of the EPC.

Article 53 *European patents shall not be granted in respect of:*

(a) inventions, the commercial exploitation of which would be contrary to ordre public or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) Plant or animal varieties or essentially biological process for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof

Firstly, concerning Article 53(a), the exclusion on granting patents for inventions which are contrary to morality or ‘*ordre public*’ should, in the case of a claimed invention where the animals were certain to suffer some harm, be assessed by weighing up the suffering of the animals and any possible risk to the environment

against the benefits to mankind said to be conferred by the invention. It was subsequently decided that the benefits of the Oncomouse outweighed the risks, and the patent was granted.

Secondly, concerning Article 53(b), the fact that the words 'animal varieties' were used, rather than merely 'animals' or 'animals as such', meant that this exclusion did not have the effect of excluding animals *per se* from patentability and the exception must be construed narrowly. It was eventually decided that animals which had been genetically altered did not in themselves constitute animal varieties, and they were not therefore excluded from patentability.

This was a landmark case in the patenting of animals and clearly demonstrated that transgenic non-human animals are patentable subject matter.

The original patent which covered all mammalian species with a transgenic oncogene, was restricted to rodents in 2001 and further limited to mice in 2004.

Plants

The landmark decision concerning the patenting of animals led to a series of cases being brought before the EPO regarding the patenting of plants (see *Plant Genetic Systems v Greenpeace* (T356/93) [1995] European Patent Office Reports 357 and *Lubrizol/hybrid plants* [1990] O.J. EPO 545).

This culminated in the ruling (Decision G01/98) by an Enlarged Board of Appeal (EBA) of the EPO in 2000. The '*Novartis*' case permits the patenting of plants in Europe provided a technical invention can be shown (plant contains a novel gene) and plant varieties are not claimed specifically.

The decision can be summarised as:

- A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), EPC even though it may embrace plant varieties.

- When a claim to a process for the production of a plant variety is examined, Article 64(2) EPC is not to be taken into consideration.
- The exception to patentability in Article 53(b), first half-sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.

A claim which is directed to a variety or a group of plants, which can be defined as a variety, whether they are genetically modified or not, is not patentable.

In essence the decision separates the subject matter of the claim from the scope of the claim. Simple because an application for a patent may within the scope of the claim cover plant varieties does not mean that the claim should be rejected. In addition, if an application is made for a process patent and a plant variety falls within the scope of the claim for a process, this does not mean that the process itself is not patentable. Therefore, the 'Novartis' case permits the patenting of plants provided a technical invention can be shown and plant varieties are not claimed specifically. Patents over plants are now permitted under the EPC.

This case was the first to be heard in which the EU Directive was used as a supplementary means of interpretation in helping to make the judgement. In particular Articles 4 of the EU Directive were used to justify the decision.

Article 4 states:

1. The following shall not be patentable:

(a) plant and animal varieties,

(b) essentially biological processes for the production of plants and animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Therefore, the ‘Novartis’ decision is completely in line with EU policy.

It is clear that within member states of the EPC, and especially those within the EU, higher life forms are patentable. Therefore, the ‘Monsanto’ patent would undoubtedly be valid.

The second question the Canadian Supreme Court addressed was whether Schmeiser had infringed the ‘Monsanto’ patent. Within the European context four Articles of the EU Directive, which govern the scope of protection of a patent, are particularly relevant.

Article 8 of the EU Directive states:

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Paragraph 1 of Article 8, with respect to plants, this means that a patent granted over a gene which codes for a particular characteristic (for example herbicide tolerance) will extend to any plants in which the patented gene is found. This raises an interesting question. It may be argued that the reference to the derived material *possessing* the same characteristic means that the patented information (e.g. a gene) merely has to be

present in the derived material but not necessarily performing any specific function. Is the presence of the gene in other plants captured by the patent? The wording of Article 8 would appear to indicate that this is the case. The fact that the EU Directive is intended to allow a patent to capture even a latent or passive inclusion of the patented technology become more evident when Article 8 is read alongside Article 9 which is discussed later.

Paragraph 8(2) builds on Article 64(2) EPC and underlines the fact that that not only will protection extend to the first generation of material produced using the patented process, but also where the first generation material is used to produce further material. Furthermore, the patented process does not itself have to have been used to produce the further material. The only relevant factor is that the future derived material must have a causal connection to the process by possessing the same specific characteristics as the initial invention produced using the patented process (e.g. herbicide tolerance).

This means that where a patented process has been used in order to produce a plant with a specific characteristic, and that plant is then used in an ordinary breeding programme (which does not involve the patented process) or any selection programme, the patent over that process will reach through to any resulting plant material. The protection conferred by the patent over the process will extend through the generations until such time as the plant material ceases to possess the same characteristics as the plant originally produced by the patented process.

Article 9 of the EU Directive states that

The protection conferred by a patent containing or consisting of genetic information shall extend to all material (except the human body) in which the product is incorporated and in which the genetic information is contained and performs its function.

As mentioned above, Article 8 can be read as extending protection to passive or latent inclusion. This is because Article 9 specifically states that the patent rights extend to material in which the patented technology *performs its function*. If Article 8(1) was

intended to apply to an active as opposed to passive use of the patented technology then there would be no need for Article 9.

The effect of Article 9 is simply to extend the patent to any material within which the patented technology is placed (for example a gene within a plant) where that technology performs the function for which the patent has been granted (for example, herbicide tolerance).

Articles 8 and 9 protection conferred by a patent will extend to any plant material in which the invention is found whether that invention (for example a gene for herbicide tolerance) is performing its function or not. This strongly suggests that there is no exhaustion of the rights of the patent holder.

Article 10 states:

The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication .

Article 10 qualifies the extension of protection provided under Articles 8 and 9. The Article appears to indicate that where patented plant material, such as seeds have been bought and sown then the first issue of that sowing will not be a violation of the rights of the patent holder. However, it would seem that any further multiplication or replication would constitute an infringing act. This suggests that a farmer, who has, for example, purchased seeds, can grow plants from the seeds, harvest, but cannot retain any seeds from the plants for the purpose of further multiplication or propagation nor sell any products from the second set of plants. However, this has to be read in conjunction with Article 11 which covers farmers' privilege.

Article 11 states that:

The sale or other form of commercialisation of propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

In essence Article 11 permits farmers, in certain instances to retain from one year to the next reproductive, or breeding, material obtained from a patented plant. This right, often referred to as Farmers Privilege, is restricted, however in respect of plant material. The Directive makes an explicit reference to the EU Regulation on Community Plant Variety Rights. Article 14 of the Regulation states that farmers may use protected material (other than a hybrid or synthetic variety) for propagating purposes on their own holding however - this right is limited in that

The farmer can only retain propagating material for this purpose from one of the following categories: a) Fodder plants; b) Cereals; c) Potatoes; d) Oil and fibre plants. Farmers' privilege does not apply to any other plant varieties. In addition, the farmer must pay an equitable remuneration sensibly lower than the amount originally charged - the common figure across the EU is 50% of the original price. The only exemption from this obligation is the small farmer who remain free to retain seed from one year to the next without making an additional payment.

However, Article 10 still has several implications for farmers. The main implication is the emphasis on the need to show that the *first* multiplication or propagation must *necessarily* result from the application or use of the material, that being the purpose for which it was placed on the market. This implies that any inadvertent second multiplication or propagation is likely to be an infringement, for example, where patented material is sown in a field and transfers to a neighbouring field where it replicates itself.

Discussion

Traditionally under patent law using a patented invention without the authorisation of the patent holder, infringes the patent. Infringement can be defined as “*any act that interferes with the full enjoyment of the monopoly granted to the patentees, if done*

without the consent of the patentee". However, analysis of the relevant Articles of the EU Directive suggest that under a variety of different scenarios a farmer will be guilty of infringement. Simply the presence of the patented invention (e.g. a gene for herbicide tolerance), whether the invention is performing its function or not, in plants on the farmers land will constitute infringement. In addition, if the process of transferring the trait into a plant is patented, then similarly the patent will extend to cover all plants containing the patented invention. Furthermore, the presence of second or subsequent generation plants on a farmers land or even a neighbouring farmers land will also be covered by the patent irrespective of how the invention got there, and will constitute infringement. In all these cases there is no requirement of intention, or it appears, even knowledge, for the farmer to be infringing the patent. In addition, the fact that you are not 'using' the technology associated with the invention is also irrelevant with regards to infringement. All the scenarios outlined above will constitute infringement under the current European intellectual property legislation.

However, it is important to mention that there is a degree of lack of clarity in these provisions and the full extent of the scope of protection of the patent will only become clear once a case has come to a national court or by a pronouncement by the European Court of Justice.