Food for thought

Helen Scott-Lawler and **Elizabeth Griffiths** consider the IP issues surrounding genetically modified foods and whether the opportunities outweigh the challenges

With a global population set to reach 9 billion by the middle of the century and limited natural resources available for production, the world has turned its attention to the threat of a food shortage crisis. The government's chief scientific adviser, Sir John Beddington, warned in his January 2011 report, *Global Food and Farming Future*, that the intense pressures on land, water and energy "constitute a major threat that requires a strategic reappraisal of how the world is fed". Technological advances in the ability to modify the genetic components of plants to produce improved, higher-yield crops have been put forward as one way of ensuring a sufficient food supply for the future.

Genetic modification (GM) is a process involving the alteration of an organism's genetic material in ways not occurring in nature. Typically, this involves the removal of DNA from a cell, the modification of that DNA outside of the cell, and the re-insertion of the modified DNA into the same or another organism. The result is to introduce a new trait into the genetically modified organism (GMO) which does not occur naturally in that species.

This process can enable the generation of pest, drought and herbicide resistant plants, in turn leading to increased yields. The widespread use of GM crops has been advocated by some as a breakthrough for farmers facing harsh environmental conditions.

With these technological developments, however, have come perceived risks. In the EU, the use of GM crops and food has been approached with caution and is subject to strict regulation.

For instance, Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms provides that before GM seeds or plants are released into the environment, authorisation must be obtained from the relevant body (which in the UK is Defra). This requires, amongst other things, the production of an environmental impact assessment.

Meanwhile, Regulation (EC) 1829/2003 on genetically modified food and feed regulates the placing on the market of GM food, including that grown outside the EU. Any applicant wishing to market a GM product must obtain authorisation from the Commission (taking into account the opinion of the European Food Safety Authority (EFSA)). Before authorisation is granted, EFSA must be satisfied that the GM product will have no adverse effects on human or animal health or the environment, that it will not mislead consumers and is not nutritionally disadvantageous compared to the food which it is intended to replace.

To date, only two types of GM crop are being grown the EU: an insect-resistant maize and a potato with modified starch content for industrial (but not food) use. Neither are suitable for production in the UK.

Various other pieces of legislation – such as the rules on food labelling – further increase the regulatory burden involved with growing and marketing GM crops.

Despite the regulatory barriers in place, the potential for growth in the GM food market has been recognised by biotechnology companies, and encouraged the industry to protect its growing collection of GM technology using intellectual property (IP) rights.

IP protection available

There are two main forms of IP protection for GM crops: patents and plant variety rights (PVRs). In the EU, patents are governed by the European Patent Convention (EPC) and the Biotechnology Directive, which provides that inventions containing biological material, including gene sequences, can be the subject of patent applications. The rules reflect general patenting criteria in requiring that the invention be novel, involve an inventive step and be capable of industrial application. In addition, the technology must fall outside the scope of excluded subject matter. It is this requirement which is often of most relevance to GM technologies.

• Patent protection

For instance, the EPC prevents a plant variety from being patented, even where it has been produced using GM technology rather than conventional breeding methods. However, patent claims to GM plants, gene sequences and technologies more generally are acceptable, provided that the invention is not effectively confined to a particular variety. The individual varieties themselves may be protected using PVRs. This difficult, distinction was examined in the *Novartis AG* case. Initially, the European Patent Office (EPO) rejected an application for transgenic plants which contained genes conferring pathogen resistance, on the basis that the application covered plant varieties. The EPO's Enlarged Board of Appeal overturned this decision, as the claims did not relate to a single plant variety. In doing so, it applied a narrow interpretation of the variety exclusion and effectively ruled that such GM technologies are, in general, patentable. This development did not go unnoticed by biotechnology companies, who have since filed for large numbers of patents for GM plants. Examples include herbicide resistant soybean, and "golden rice" containing enhanced quantities of vitamin A.

As well as patenting their products, biotechnology companies can patent the processes by which a plant is genetically modified. An important distinction must be drawn, however, between patentable processes and "essentially biological processes", which are not patentable. This issue came to the fore in December 2010 when the Enlarged Board of Appeal of the EPO considered the definition of essentially biological process in the *Broccoli* and *Tomato* cases. It held that conventional sexual crossing and selection of plants was not patentable – being an essentially biological process – unless an additional, technical step was taken within the crossing and selection process which of itself resulted in the introduction or modification of a trait in the plant's genome. This confirms that patent protection remains available for inserting a feature into or altering a plant's genome through genetic engineering, but the extent of the process claims may be limited: processes involving sexual crossing and selection are only patentable where a genetic engineering step occurs within the steps of crossing and selection. Where a process consists of a genetic engineering step followed by crossing, the claims may only cover the step of genetic engineering.

Picture: Osipava Alena / Shutterstock

• Plant variety rights

The second major form of IP protection is PVRs, which can protect individual plant varieties, whether generated by traditional breeding methods (involving the crossing and selection of individual plants with improved traits) or GM techniques. In the UK, these are available either as a Community Plant Variety Right, or as a national Plant Breeders' Right.

The criteria for protection are different from those for patents: the variety must fulfil the criteria of distinctness, uniformity, stability and novelty. These criteria can cause some difficulties for GM plants however. For example, a variety is distinct if it is clearly distinguishable by reference to the expression of one or more of its characteristics from any other variety in existence. This is assessed largely against morphological features. Many GM varieties, though, are characterised by economically valuable internal traits, such as herbicide resistance, which are not reflected in distinct morphological characteristics, limiting the availability of PVR protection for such GM plants.

PVRs are subject to the so-called "breeder's privilege" – which enables breeders to use protected varieties as a starting point for the breeding of further varieties – and by the "farmer's privilege". The latter allows farmers to save their seeds from certain protected varieties (set out in a list in the legislation) for use in subsequent sowing on their own farms, provided they meet specified conditions (typically involving the payment of "equitable remuneration" to the IP owner). As a result of the Biotechnology Directive, the farmer's privilege also applies to patent rights.

Finally, it is worth mentioning that an additional layer of protection can be obtained to cover product names and other branding related to the underlying GM technology.

Effectively exploiting IP rights available

Having considered the availability of IP rights, companies which have developed GM crops need to look at how they can exploit their products. One key element of this is to understand how far IP rights can extend in restricting the use of protected technologies by parties such as farmers.

In the EU, for example, the Biotechnology Directive states that a patent over a product containing genetic information extends to "all material…in which the product is incorporated and in which the genetic information is contained and performs its function". However, this broad definition was recently given a restrictive interpretation in *Monsanto v Cefetra*, which concerned a Monsanto patent relating to enzymes which, when expressed in a plant, confer herbicide resistance. Monsanto sought an injunction against imports of soy meal (from Argentina, where there was no patent protection) which contained some of the patented seed traits. The Court of Justice of the European Union (CJEU) held that Monsanto's patent protection did not extend to the soy meal because the DNA sequence covered by the patent performed its function of herbicide resistance in the soy plant, not in the meal. In other words, although the DNA sequence was present in the meal its effect lay elsewhere, so the patent could not prevent imports of the meal.

"Despite the regulatory barriers in place, the potential for growth in the GM food market has been recognised by biotechnology companies, and encouraged the industry to protect its growing collection of GM technology using IP rights."

A further limitation to patent enforcement in the EU is provided by the farmer's exception described above.

It is not always the case, however, that a restrictive approach is taken. In many cases, particularly outside the EU, the right to exploit a patent has been interpreted widely. An example of this can be found by looking at a Canadian case, *Monsanto Canada, Inc v Schmeiser*, in which the Supreme Court allowed Monsanto to enforce its patent against a farmer whose canola crops were found to contain its patented "Roundup Ready" gene. The farmer argued that he had deliberately chosen not to use Monsanto's patented crop – which had been developed to be resistant to its Roundup herbicide – but that Monsanto seed blown from neighbouring farms had cross-pollinated with his own crops. The court ruled this explanation was insufficient, and the overwhelming presence of the herbicide-resistant trait in Schmeiser's crops implied that he must have intentionally selected for it, by saving seed from areas on and adjacent to his property where Roundup had been sprayed. The court held that by using seeds that he must or should have known derived from Roundup Ready canola, Schmeiser infringed the patent.

The use of second-generation seeds of patented crops raises interesting questions regarding the extent of patent protection for self-replicating technologies. In the US case of *Monsanto v Bowman*, the defendant farmer purchased seeds from a grain elevator (which mixes seeds received from multiple farmers and re-sells them in batches of undifferentiated "commodity seeds"), used them for late-season planting, saved the seeds produced and replanted them in subsequent years. Monsanto found that the soybeans grown from the commodity seeds contained its patented Roundup Ready technology and sued for patent infringement. Despite finding that Monsanto authorises growers to sell seed to grain elevators as a commodity without placing restrictions on the subsequent sales of the seed, the court held Bowman liable. The court found that although Monsanto's patent rights in the commodity seeds may have been "exhausted" at the point of sale to the elevator (as Monsanto had permitted this sale), rights in the subsequent generation of seeds were not exhausted, as once a grower plants commodity seeds containing Monsanto's Roundup Ready technology and the next generation of seed develops, the grower has created a newly infringing article. This principle – that a patented technology's ability to replicate itself does not give a purchaser the right to use replicated copies of the technology – is extremely valuable to companies such as Monsanto in ensuring that they can sell new seeds to farmers each growing season.

The background to the *Bowman* case also highlights another important tool in the biotechnology company's armoury: the use of

contracts. The restrictive regulatory regime in the EU means that instances of exploitation in practice are currently rare, so most examples come from outside the EU; although the principle of controlling exploitation of IP rights through contracts applies equally in the EU.

One such example is Monsanto's US Technology Agreement which grants growers a limited licence to purchase and plant seeds containing its patented technology. This allows Monsanto to control its rights in a number of ways: growers may only use the seeds for planting a single commercial crop; they are prevented from saving second-generation seeds for replanting the next year, and from supplying any first or second-generation seed to third parties for planting; and they may not use seeds for crop breeding or research. The use of these technology agreements – combining a licence of patented technology with a set of further restrictions – provides an effective mechanism enabling companies to further commercialise their technologies. By combining contracts with IP rights (and subject to any competition law considerations), companies can obtain robust protection of GM crop technology alongside control over the exploitation of their products.

Biotechnology companies have found greater difficulty with protecting their interests in countries which have a strong tradition of planting second-generation seeds. In such jurisdictions, it may not be possible or practical to enforce IP and contract rights. In reaction to this, companies have developed technological, rather than legal, tools. One example is Genetic Use Restriction Technology (GURT) – also known in some cases as "terminator" technology. Here, plants are modified so that the second generation seeds that they produce are either sterile (preventing the use of such seeds for planting and forcing farmers to purchase new seeds each year), or require treatment with a chemical to promote germination or activate a trait (such as herbicide resistance). The first patent on terminator technology was granted to the Delta and Pine Land Company (now owned by Monsanto) and the US Department of Agriculture in 1998. Such technologies could effectively allow biotechnology companies to work around the current restrictions on the scope of their IP protection and solve problems with enforcing contractual rights.

Despite its obvious advantages for biotechnology companies, concerns over its use, and in particular its effect on farmers in developing countries who depend on farm-saved seed, have meant that the GURT technology has never been field-tested and is not commercially available. In 1999, Monsanto pledged not to commercialise sterile seed technology in food crops. In 2000, the United Nation's Convention on Biological Diversity imposed a moratorium on field trials and commercial use of terminator technology which was upheld in 2006.

"This principle – that a patented technology's ability to replicate itself does not give a purchaser the right to use replicated copies of the technology – is extremely valuable to companies such as Monsanto in ensuring that they can sell new seeds to farmers each growing season."

What the future holds

To summarise, the proliferation of GM technologies brings with it both opportunities and challenges. The prospect of hardy crops and increased yields has been cited as a potential panacea to the impending global food crisis, and biotechnology companies have been quick to realise the potential gains to be made. Intellectual property law in the EU and elsewhere has generally been supportive of these developments, allowing the protection of GM plants, gene sequences and GM processes. The use of contractual mechanisms further allows companies to commercialise their technologies.

Against this background, however, concerns and uncertainty remain. The regulatory regime in the EU is strict, and courts and intellectual property offices have not always come down on the side of industry. As and when more GM crops are grown in the EU, it will be interesting in particular to see whether biotechnology companies enjoy the same relatively widespread success that they have enjoyed in North America when enforcing their rights against farmers in the EU.

Authors

Helen Scott-Lawler is head of IP at Burges Salmon. Her work includes protection, structuring, management and exploitation of IP, as well as IP development and consortia arrangements.

Elizabeth Griffiths is a senior associate in Burges Salmon's IP team. She specialises in commercial contracts involving IP and has acted on several transactions involving the acquistion or licensing of plant variety rights.