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PATENTS AND PLANT BREEDING: IMPLICATIONS FOR FOOD SECURITY

*Michael Blakeney**

1. Plant Variety Protection (PVP)

1.1 Introduction

The protection of plant varieties is a mandatory obligation for Members of the World Trade Organisation (WTO) who are obliged to implement the provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement). Article 27.3(b) of the TRIPS Agreement requires Members to protect plant varieties by patents or sui generis protection or by a combination of both. Since the commencement of the TRIPS Agreement in 1995, most countries have tended to adopt the 1991 Act of the International Convention on the Protection of Plant Varieties (UPOV Convention), by way of compliance. Thus as of April 4, 2011, the UPOV Convention has 69 signatories, with 41 of those joining after 1 January, 1995.[1]

Generally, under plant variety rights legislation the plant breeder is conferred an exclusive right to do or to license the following acts in relation to propagating material of the variety:

- produce or reproduce the material;
- condition the material for the purpose of propagation;
- offer the material for sale;
- sell the material;
- import the material;
- export the material;
- stock the material for the purposes described above.

The protection under this legislation is afforded to a “breeder” or persons claiming through the breeder who is defined in Article 1 (iv) of the 1991 UPOV Act as “the person who bred, or discovered or developed a variety”. "Breeding" is generally defined as including the discovery of a plant together with its use in selective propagation so as to achieve a result.

The general duration of plant variety rights under legislation based on the 1991 UPOV Act is 25 years in the case of trees and vines and 20 years for any other variety. During these periods the breeder or other licensee or owner of the right is entitled to exclusivity in its exploitation and commercialisation.

* Professor of Law, University of Western Australia

[1] List of Members of the International Union for the Protection of New Varieties of Plants, at: http://www.upov.int/export/sites/upov/en/about/members/pdf/pub423.pdf (14 March 2011).

1.2 Seed Saving

Usually excepted from plant variety rights is seed saved by a farmer from harvested material and treated for the purpose of sowing a crop on that farmer's own land. Thus Article 15 (2) of the UPOV Convention 1991 provides as an optional exception that "each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety...." From the perspective of farmers, this is probably the most contentious aspect of the 1991 Act. Unlike the 1978 Act of UPOV, the 1991 Act does not authorise farmers to sell or exchange seeds with other farmers for propagating purposes. This has been criticised as inconsistent with the practices of farmers in many developing nations, where seeds are exchanged for purposes of crop and variety rotation.[2] It has been suggested that for both social equity and food security reasons there are justifications for providing a 'farmer privilege' for smallholder and resource-poor farmers, especially in developing countries, whereby poorer farmers who do not represent an immediate or lucrative market would enjoy the 'farmer privilege' to save seed, while their richer counterparts would be required to pay royalties on saved proprietary seed.[3]

1.3 The Breeder's Exemption

Article 15.1(i) and (ii) of the 1991 Act of the UPOV Convention provides exemptions from liability for "acts done privately and for non-commercial purposes [and] for experimental purposes". UPOV has stated that the concept of the "breeder's exemption" reflects its view that "the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximise the use of genetic resources for the benefit of society".[4] The International Treaty on Plant Genetic Resources for Food and Agriculture in Article 13.2. (d)(ii) recognises the concept of the breeder's exemption, in that breeders are excepted from financial benefit-sharing whenever their products are "available without restriction to others for further research and breeding". Finally, UPOV 1991 in Article 17.1, provides that *"*no Contracting Party may restrict the free exercise of a breeder's right for reasons other than of public interest*."* This is in effect a compulsory licensing obligation.

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[2] D. Leskien & M. Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System', Issues in Genetic Resources 1997-6, p. 60.

[3] C. Spillane, 'Recent Developments in Biotechnology as They Relate to Plant Genetic Resources for Food and Agriculture', Background Study Paper No. 9, *Commission on Genetic Resources for Food and Agriculture*, April 1999, pp. 41-42.

[4] UPOV, 'Access to Genetic Resources and Benefit-Sharing', Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD), adopted by the Council of UPOV at its thirty-seventh ordinary session on October 23, 2003.

1.4 Critiques of the PVP System

Over the last two decades commentators on the PVP system have begun to question its relevance, raising the possibility that it might have become "the Neanderthal of intellectual property systems".[5] One reason for this critique is the impact of patents upon PVP, described above. At a more fundamental level it is observed that PVP in focussing upon a phenotypic paradigm, based upon "characteristics" and "features", has become outmoded as plant breeding moves towards a genotypic approach, utilising genetic modification and molecular breeding techniques.[6] Mark Janis and Stephen Smith argue that plants should be reconceptualised as datasets that breeders manipulate to express particular characteristics, which could be better regulated by unfair competition laws rather than by a sui generis PVP scheme.[7] A related observation is that the nature of plant breeding, with the use of gene-based technologies, has changed significantly since the commencement of UPOV. However, it is also pointed out that very often new technologies are used in conjunction with (rather than instead of) traditional plant breeding methods. [8]

The existence of both the farmer's seed-saving privilege and the breeders' exemption under UPOV has been commercially inconvenient for seed companies, as both exclusions from plant variety rights means a threat to their seed sales. These exclusions in PVP laws was an early reflection of food security concerns. However, as patent statutes were formulated in a general technology rather than in an agricultural context, of course there was no call to include these kinds of exceptions, and this absence made it attractive for seed companies to shift their attention to the patent system as a means of protecting their innovations.

2. Patents

2.1 Introduction[9]

Patent protection was considered and rejected as a means for the protection of plant varieties. Prior to the development of recombinant biotechnology, the

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[5] C. Fowler, *Unnatural Selection: Technology, Politics, and Plant Evolution*, Switzerland and Langhorne Pa: Gordon and Breach 1994, p. 152.

[6] M. Janis & S. Smith, 'Technological Change and the Design of Plant Variety Protection Regimes', *Chicago Kent Law Review* 2007-82, pp. 1566–70.

[7] *Idem* at pp. 1607–1614. See also L. Helfer, 'The Demise and Rebirth of Plant Variety Protection: A Comment on Technological Change and the Design of Plant Variety Protection Regimes' (2007) *Chicago Kent Law Review* 82- 1619 and the discussion in J. Sanderson, 'Back to the Future: Possible Mechanisms for the Management of Plant Varieties in Australia' *University of New South Wales Law Journal* 2007-30, pp.690–6.

[8] J. Brown & P. Caligari, *An Introduction to Plant Breeding*, Oxford: Blackwell 2008.

[9] M. Blakeney, 'Plant Variety Protection, International Agricultural Research, and Exchange of Germplasm: Legal Aspects of Sui Generis and Patent Regimes' in Anatole Krattiger *et a*l. (eds.) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices,* Oxford: MIHR 2007, p. 4, accessed at http://www.iphandbook.org/handbook/ch04/p07/ (5 August 2011).

breeding of a new variety did not meet the legal test of inventive step required for patenting because such innovations as were made could be considered to be obvious rather than inventive. However with the extension of patent protection to recombinant methods, isolated DNA and DNA fragments used in the production of transgenic plants and the methods and processes used in genetic engineering have begun to assume an increasing significance in the development of new plant varieties and the propertisation of these innovations. The broader ambit of patent rights is a particular advantage for agricultural innovation, covering, as it does, plants, seeds and enabling technologies. The scope of plant variety rights, on the other hand, is more limited as they are highly specific to the variety and their protection is limited to the physical (propagating) material itself, combined with the description of the variety given in the documentary grant of the rights.

Genetic engineering has permitted the expeditious introduction of a wide range of desirable traits into plants. These include:

* pest control traits such as insect, virus and nematode resistance as well as herbicide tolerance; post-harvest traits such as delayed ripening of spoilage-prone fruits;
* agronomic traits such as nitrogen fixation and utilisation, restricted branching, environmental stress tolerance,
* male and/or seed sterility for hybrid systems; and
* output traits such as plant colour and vitamin enrichment.

The production of transgenic plants has become possible through the development of a number of enabling and transformation technologies. These technologies, together with the introduction of beneficial plant traits, have become the subject of intellectual property protection, as a consequence of the favourable decisions of courts in the USA and Europe.

Most patent systems draw a distinction between a patentable invention and a non-patentable discovery. A discovery is considered non-patentable because it is the unearthing of causes, properties or phenomena already existing in nature. In the early history of patent law an invention was thought to involve some kind of technical innovation and a distinction was drawn between patentable inventions and non-patentable discoveries. The TRIPS Agreement provides no guidance as to what is a patentable invention. The US Supreme Court in *Diamond* v. *Chakrabarty*[10] ruled that a bacterium genetically engineered to degrade crude oil was an invention. The European Parliament in its Biotechnology Directive has provided that biological material which is isolated from its natural environment or produced by means of a technical process is deemed to be an invention even if this material previously occurred in nature.

The patentability of genetic materials and gene fragments, such as expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs), as well as

[10] Diamond v. Chakrabarty, 447 US 303 (1980).

enabling gene-based technologies led to what has been described as a "genomic gold rush" in the 1990s as vast numbers of gene-based patent applications were filed, particularly in the USA.[11] Significant misgivings were expressed by numerous commentators. Probably the most influential among these were Heller and Eisenberg who suggested that genetic research tool patents could create a "tragedy of the anticommons" in which multiple patent owners would tie up genetic materials in a thicket of IP patent rights.[12] This was perceived to be a particular problem for the genetic improvement of crops since this is an incremental process and each new patent would constrain the "freedom to operate" particularly of public agricultural research institutes.[13]

2.2 Patent Infringement

The cultivation by farmers of GM crops has on occasion led to IPR liability, where GM seed is patented and the cultivation was unauthorised. The cases are divided into those where farmers knowingly cultivate patented GM seed and those where the cultivation of patented seed is apparently inadvertent, for example where crops are apparently polluted by pollen drift.
The IP liability of farmers for the knowing use of patented genetic material is illustrated in the US decision in *Monsanto Co. v. Scruggs*[14] which concerned Monsanto's US patent for glyphosate-tolerant soybeans and cotton seeds.[15] This was marketed as Roundup Ready® (RuR). A farmer, Mitchell Scruggs, purchased small quantities of RuR soybeans and cotton seed for the 1996 crop season. Through saving seed from all subsequent crop seasons, Mr Scruggs by 2000 had enough RuR seed to plant more than 8,000 acres of soybean and in excess of 2,000 acres of cotton. The court found that Scruggs had infringed Monsanto's patent relying both on the admission of Scruggs that he had purchased patented soybean and cotton seed and on the results of a series of scientific tests which demonstrated that the 2000 soybean and cotton crops contained patented RuR biotechnology.

The leading case dealing with the apparently inadvertent cultivation of patented seed is the Canadian litigation between Monsanto Canada, Inc. and a farmer, Percy Schmeiser. This concerned Monsanto's patented RuR canola.[16] Schmeiser had never purchased RuR Canola nor did he obtain a licence to plant it. Tests of his 1998 canola crop revealed that 95-98 per cent of Schmeiser's

[11] Y. Joly, 'Accès aux mèdicaments: le système international des brevets empêchera-t'il les pays du tiers monde de bénéficier des avantages de la pharmacogénomique' *Les cahiers de Propriété intellectuelle* 2003- 16.
[12] M.A. Heller & R.S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' *Science* 1998-280, p.700.
[13] See the authorities referred to in C.M. Correa, 'Trends in Intellectual Property Rights Relating to Genetic Resources for Food and Agriculture', Background Study Paper 49, *Commission on Genetic Resources for Food and Agriculture*, October, 2009, p.2.
[14] Monsanto Co. v. Scruggs, 342 F. Supp 2d 584 at 591(2004).
[15] US Patent 5,352,605.
[16] Canadian Letters Patent No. 1,313,830.

1000 acres of canola crop was RuR Canola. [17] The court emphasised that "it was not concerned here with the innocent discovery of 'blow-by' patented plants" on Schmeiser's land.[18] The plants may have been derived from RuR seed that was collected from plants that survived after he had sprayed Roundup herbicide around the power poles and in bordering ditches. Monsanto brought an action for patent infringement claiming that by planting glyphosate-resistant seeds Schmeiser was said to use, reproduce and create genes, cells, plants and seeds containing the genes and cells claimed in the plaintiffs' patent.
At the trial of the case Schmeiser argued that by the unconfined release of the gene into the environment Monsanto did not controlled its spread, and did not intend to do so, and they had thus lost or waived their right to exercise an exclusive patent over the gene.[19] The trial judge observed that Schmeiser had grown canola from seed which he knew was Roundup-tolerant and that growing seed which reproduced the patented gene and cell, and sale of the harvested crop constituted taking the essence of Monsanto's invention and using it without permission infringed the patent.

The case was appealed to the Federal Court of Appeal which by a majority of 5:4 ruled that Schmeiser had infringed Monsanto's valid patent.[20] The majority ruled that Schmeiser's saving and planting patented seed, then harvesting and selling plants that contained the patented cells and genes was "utilization" of the patented material for production and advantage, within the meaning of the Canadian Patent Act. The argument that the infringing seed had merely grown, as the result of wind pollination or through the pollinating activities of birds and bees, was rejected by the majority judges as denying "the realities of modern agriculture".[21] What was at stake in this case was sowing and cultivation, "which necessarily involves deliberate and careful activity on the part of the farmer".[22] He actively cultivated RuR Canola as part of his business operations and thus had infringed the patent by using the patented genes and cells.

Patent infringement may possibly arise from the importation of patented genetic material, even where a patent might not exist in the exporter's country. This situation has been addressed by a number of European courts before which Monsanto brought actions against importers of its patented RuR soy. In 1996 Monsanto had obtained a European Patent claiming, inter alia, a method of making transgenic plants into which an enzyme EPSPS[23] had been inserted to render them resistant to glyphosate. Monsanto had inserted a gene encoding this enzyme into soy. Some 90% of the soy meal exported from Argentina contained this enzyme, but Monsanto had not obtained a patent in that

[17] Monsanto Canada, Inc and Monsanto Company v. Percy Schmeiser and Schmeiser Enterprises 2001 FCT 256, para. 12.
[18] Ibid.
[19] Ibid., para. 12.
[20] Monsanto Canada, Inc. v. Schmeiser [2004] 1 S.C.R. 902, 2004.
[21] *Ibid*., at para. 92.
[22] *Ibid.*
[23] An enzyme called 5-enolppyruvylshikimate synthase, which confers glyphosate resistance to a plant in which the enzyme is expressed.

country. In June 2005 and March 2006 Monsanto had used the EU border control regulation to have the cargo of soy meal on two ships arriving in Rotterdam from Argentina detained and tested. The tests revealed the presence of a DNA molecule in the meal which contained EPSPS. Monsanto brought actions against importers in the Netherlands, the UK and Spain.

In the Dutch litigation Monsanto sought an injunction prohibiting the infringement of the patent in all European countries.[24] The importer denied infringement, relying on Article 9 of the EU Biotechnology Directive which confers protection upon material "in which the genetic material is contained and performs its function". It argued that as a result of the processing of soy beans to produce the meal, the DNA was dead material and could not perform its function of expressing the EPSPS enzyme. The District Court of The Hague submitted a number of questions to the ECJ to obtain an interpretation of the relevant provisions of the Biotechnology Directive. In the Spanish proceedings, this argument was effective in defeating Monsanto.[25] To meet this argument Monsanto argued that the application of Article 9 derogated from the patent protection to which it was entitled under Dutch patent law and under Article 27 of the TRIPS Agreement.

In the UK the trial judge in the High Court found that as the defendant had not infringed the plaintiff's patent as the defendant had not isolated the patented DNA, nor had it constructed recombinant DNA molecules, nor had it transformed plants and it had not produced and farmed glyphosate-resistant soy plants. It was merely the importer of a derivative product of beans produced from such plants. The judge observed that the DNA in the soy meal was dead material in the sense that it did not perform the function (disease resistance) for which it had been patented. [26]

The ECJ, in its consideration of the Dutch Court's questions considered whether Article 9 of the Biotechnology Directive could be interpreted as meaning that the protection provided under that provision can be invoked even in a situation where a patented DNA sequence formed part of a material imported into the EU, but did not perform its function at the time of the alleged infringement, while it would possibly again be able to perform its function after it has been isolated from the soy and inserted into the cell of an organism.[27] The Court ruled that the protection provided for in Article 9 of the Directive was not available "when the genetic information has ceased to perform the function it

[24] Monsanto Technology LLC v. Cefetra BV and the State of Argentina, District Court of The Hague 249983/HA ZA 05/2885, 19 March 2008.

[25] See C. Baldock, 'Monsanto Puts Biotech Directive Under the Spotlight' *Bioscience Law Rev* 2006/2007- 4, p. 161.

[26] Monsanto Technology LLC v Cargill International S.A [2007] EWHC 2257 (Pat), per Pumphrey J.

[27] Monsanto Technology LLC v. Cefetra BV and others, Case C-428/08, 6 July 2010

performed in the initial material from which the material in question is derived."[28]

2.3 Patenting of Plant Varieties

A subject which is of some significance in the area of food security is the possibility that plant varieties might be patented. As we have seen, the plant variety protection legislation provides an exception for farmers who save seed for future plantings as well as an exception for researchers to develop further varieties. These exceptions are absent from patent legislation. Therefore where varieties can be patented, both seed saving and future research might be compromised.

In Europe Article 53(b) of the European Patent Convention (EPC) excludes plant varieties from patent protection. Article 4(1) para. 2 of the European Biotechnology Directive permits the patentability of inventions concerning plants, where "the technical feasibility is not confined to a particular plant (…) variety". This qualification was addressed by the Technical Board of Appeal of the European Patent Office in *Novartis/Transgenic Plant.*[29] The patent application in that case concerned a patent containing claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which resulted in the production of antipathologically active substances, and to methods of preparing such plants. The EPO had originally refused registration, on the ground that art.53(b) denied the patentability of an invention which could embrace plant varieties and this refusal had been upheld by the EPO's Technical Board of Appeal. The Enlarged Board of Appeal ruled in favour of the application because it did not specifically refer to the protection of a plant variety. The Enlarged Board of Appeal noted that the claimed transgenic plants in the application were defined by certain characteristics which allowed the plants to inhibit the growth of plant pathogens. No claim had been made for anything resembling a plant variety. It contrasted the fact that in the case of PVR protection an applicant had to develop a plant variety which met the tests of homogeneity and stability, whereas in the case of a biotechnological invention, patent protection was offered when DNA or a DNA fragment was inserted into the genome of a specific plant.

The USA has never excluded biological material, including plant varieties from the scope of patentable subject matter. Plant varieties can be protected in the USA under a system of plant patents, or under a system of utility patents or under the Plant Variety Protection Act (PVPA). The Plant Patent Act[30] makes available patent protection to new varieties of asexually reproduced plants. Under this scheme a plant variety must be novel and distinct and the invention, discovery or reproduction of the plant variety must not be obvious. One of the disadvantages of the scheme is that only one claim, covering the plant variety, is permitted in each application. In practice, this scheme has been in decline

[28] *Ibid.*, at para. 38.
[29] Novartis/Transgenic Plant [2000] *O.J. EPO* 511.
[30] Plant Patent Act , 35 U.S.C. §§ 161-164 (1994).

since the *Hibberd* decision of the Patent Office Board of Appeals and Interferences opened up the normal patent system to applications which covered plant varieties.[31]

In the USA the Federal Circuit resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act (PVPA) in its decision in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc*.[32] Pioneer held patents cover the manufacture, use, sale, and offer for sale of the company's inbred and hybrid corn seed products as well as certificates of protection under the Plant Variety Protection Act for the same seed-produced varieties of corn. The defendants argued that the enactment of the Plant Variety Protection Act had removed seed-produced plants from the realm of patentable subject matter of the Patents Act. The Federal Circuit rejected this argument, noting that the Supreme Court held that "when two statutes are capable of co-existence, it is the duty of the courts (…) to regard each as effective".

This decision was followed by the US Federal Circuit Court in *Monsanto Co. v. McFarling.*[33] Monsanto had developed genetically modified plants which were resistant to glyphosate herbicides such as its Roundup brand herbicide. The herbicide could be sprayed, killing any weeds but not harming the resistant crops, which resulted in substantial savings in labour costs for weed control. Monsanto patented the glyphosate-tolerant plants, the genetically modified seeds for such plants, the specific modified genes, and the method of producing the genetically modified plants.[34] Monsanto required that sellers of the patented seeds obtained from purchasers a ''Technology Agreement,'' in which they agreed that the seeds were to be used ''for planting a commercial crop only in a single season'' and that the purchaser would not ''save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting.'' Mr McFarling, a farmer in Mississippi, purchased Roundup Ready soybean seed in 1997 and again in 1998; he signed the Technology Agreement. He saved 1,500 bushels of the patented soybeans from his harvest during one season, and instead of selling these soybeans as crop he planted them as seed in the next season. He repeated this activity in the following growing season. This saved seed retained the genetic modifications of the Roundup Ready seed. Mr McFarling did not dispute that he violated the terms of the Technology Agreement but claimed that the contractual prohibition against using the patented seed to produce new seed for planting, when he produced only enough new seed for his own use the following season, violated the seed saving provision of the PVPA[35], which permits farmers to save seeds of plants registered under the PVPA. The Court applied *Pioneer Hi-Bred International Inc.*

[31] Hibberd, 227 *USPQ* 443 (1985).
[32] Hi-Bred International Inc. v. J.E.M. Ag Supply Inc., 200 F.3d 1374 (Fed. Cir. 2000), *cert. granted,* 148 L. Ed. 2d 954 (2001)
[33] Monsanto Co. V. McFarling, 302 F.3d 1291 (Fed. Cir. 2002).
[34] U.S. Patents Nos. 5,633,435 and 5,352,-605.
[35] Section 2543 the Plant Variety Protection Act (PVPA) 7 U.S.C. paras. 2321-2582

v. J.E.M. Ag Supply Inc., declining to limit the patent law by reference to the PVPA. Consequently Mr McFarling was found to have infringed Monsanto's patent.

Given the interrelationship between patents and plant variety protection there is the possibility that a plant breeder in developing a new variety might infringe a patent. To deal with this situation, the EU Directive on Protection of Biotechnological Inventions in Article 12 provides for compulsory cross-licensing in situations where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent. In such instances, the breeder may apply for a compulsory licence for non-exclusive use of the patent, which will be granted "subject to payment of an appropriate royalty". Reciprocally, a compulsory licence also applies in situations where a patent holder cannot exploit an invention without infringing a plant variety right.
On 6 May 2009, Plantum NL, the Dutch association for breeding, tissue culture, production and trade of seeds and young plants, announced its position on the relationship between patents and plant breeders' rights.[36] It stated that:

> 1. Biological material protected by patent rights should be freely available for the development of new varieties.
> 2. The use and exploitation of these new varieties should be free, in line with the 'breeders' exemption' of the UPOV Convention.
> 3. The aforementioned free availability, use and exploitation should not be allowed to be obstructed in any way, either directly or indirectly, by patent rights.

The association notes that contemporary plant breeding involves the use of various high-tech procedures which serve to improve and/or speed up the selection process, such as EMS mutagenesis, gene mapping, embryo rescue, double haploidisation and selection based on DNA markers. Since patent laws in general do not have a provision which can be compared to the breeders' exception, varieties containing patented traits or which have been developed using a patented process are not freely available for further breeding. Plantum NL notes the significant increase in the number of plant-related patent applications[37] and that although France and Germany have included an exemption for plant breeding in their national patent law, since 2004, a number of companies with strong patent portfolios have been advocating that this position should be changed to disallow further breeding of progeny containing a patented trait. It claims that this agitation "has resulted in some companies explicitly requesting that their competitors abandon plant breeding programmes which allegedly infringe their patent applications with the "immediate effect of dramatically hampering innovation and posing a threat to those companies which are trying to develop competitive varieties." Plantum

[36] Plantum NL, 'Position on Patent and plant breeders rights' http://www.plantum.nl/plantum/documenten/Standpunt%20Octrooi%20en%20Kwekersrecht%20samenvatting%20ENG.pdf, (5 August 2011)
[37] 4500, most of which have been filed in the past 10 years.

NL concludes that “these developments pose a threat to the tried and tested system of open innovation within the plant breeding sector.”

Patenting of Plant Breeding Methods

The exclusion by the European patent legislation of “essentially biological processes for the production of plants or animals” defined in Article 2.2 of the Biotechnology Directive as consisting “entirely of natural phenomena such as crossing or selection”, would have been thought to deny patent protection to plant breeding methods, but this was tested recently by the EPO Enlarged Board of Appeal in two decisions. One concerned whether a process involving crossing and selection of broccoli[38] could be patentable. Another referral concerned a similar type of invention relating to crossing and selection of tomatoes.[39]

The broccoli patent application was filed at the EPO by Plant Bioscience Ltd. (Norwich/UK) for a "method for selective increase of the anticarcinogenic glucosinolates in brassica species".[40] The tomato patent application was filed at the EPO by the Israeli Ministry of Agriculture for a "method for breeding tomatoes having reduced water content and product of the method".[41] Both of the patent applications were opposed by interested parties. These oppositions were heard by the EPO’s Technical Board of Appeal which referred a number of questions to be determined by the EBA. The critical questions to the EBA[42] were:

> 1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?
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> 2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

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[38] Case G2/07, 9 December 2010, available at http://documents.epo.org/projects/babylon/eponet.nsf/0/791D677646A4A968C12577F4004C3445/$File/G2_07_en.pdf, (5 August 2011)

[39] Case G1/08, 9 December 2010 available at http://documents.epo.org/projects/babylon/eponet.nsf/0/E72204692CFE1DC3C12577F4004BEA42/$File/G1_08_en.pdf, (5 August 2011)

[40] Patent specification EP 1069819, published 24.7.2002.

[41] Patent specification EP 1211926 published, 26.11.2003.

[42] The questions can be found in the transcripts of the determinations cited at notes 38 and 39 above.

The questions raised in respect of the tomatoes referral[43] were:

> 1. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?
>
> 2. If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?
>
> 3. If question 2 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

The EBA answered the questions as follows:

1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.
2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.
3. If, however, such a process 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, then the process is not excluded from patentability under Article 53(b) EPC.
4. In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a

[43] Ibid.

> fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.[44]

The EBA identified from the jurisprudence the following elements which had been enumerated as relevant to determining whether a process is not essentially biological:

> 1. The totality of human intervention and its impact on the result achieved is to be determined.
> 2. This has to be judged on the basis of the essence of the invention.
> 3. The impact must be decisive.
> 4. The contribution must go beyond a trivial level.
> 5. The totality and the sequence of the specified operations must neither occur in nature nor correspond to the classical breeders' processes.
> 6. The required fundamental alteration of the character of a known process for the production of plants may lie either in the features of the process, i.e. in its constituent parts, or in the special sequence of the process steps, if a multistep process is claimed.[45]

It had been argued in the proceedings that crossing and selection should be understood to mean only crossing and selection as they take place in nature. In particular, the term “selection” did not address the selection made by man in a breeding process but only the selection that takes place in nature and is not controllable by man, and that determines which plants survive in nature. The EBA ruled that, applying the principles of treaty interpretation, the meaning of a term of a treaty could not be established in a purely semantic manner but its interpretation must be made in good faith, in accordance with the ordinary meaning to be given to the terms of the treaty in their context.[46] Thus it observed that the abovementioned definition completely disregarded the fact that the context of the terms crossing and selection in the provisions of the EPC is given by the processes for the production of plants: the terms "crossing" and "selection" refer to acts performed by the breeder. These are characterised by the fact that the breeder intervenes in the processes in order to achieve a desired result. Hence, in that context, crossing and selection are not natural phenomena but are method steps which generally involve human intervention.

A study published in March 2011[47] pointed out that the EPO's Board of Appeal decided in May 2010 that conventionally-bred plants, their seed and products of harvests were patentable, even if the process for breeding them was not[48]

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[44] *Ibid*.
[45] Case G1/08, at p.35.
[46] *Ibid.*, at pp. 38-39.
[47] C. Then & R. Tippe, *Seed monopolists increasingly gaining market control Applications and granting of patents in the sphere of animal and plant breeding in 2010*, March, 2011, at: http://www.no-patents-on-seeds.org/sites/default/files/news/patente_report_2011_final_en.pdf, (13 March 2011)
[48] EPO Board of Appeal Case T1854/07, patent on sunflowers granted to Consejo Superior de Investigationes Cientificas in Spain (EP 1185161).

and that following the Broccoli and Tomatoes decision the EPO was notifying patent applicants of this. The study noted that of over 30% of 350 applications made for patents on plants to WIPO under the Patent Cooperation Treaty (PCT) covered the conventional breeding of plants, such as for marker-based selection, regeneration and reproductive processes, measuring constituent substances, hybrid breeding and mutagenesis, as well as for material used in breeding such as seed, genes and parts of plants, whole plants, their harvests and products (sometimes processed) like food, feedstuff and biomass.

The Technical Requirement for Patentable Inventions

The Broccoli and Tomato decisions of the EBA raise the underlying question of what botanical innovations constitute a patentable invention for the purposes of patent law. The answer to this question will differ according to the national patent law in force. In the USA in *Diamond v. Chakrabarty*[49] the Supreme Court held that some human intervention was required to render a biological innovation as patentable.[50] The European Patent Office focuses upon the necessity for a claimed invention to have a "technical" character. Rule 27 Implementing Regulations to the Convention on the Grant of European Patents defines patentable biotechnological inventions as those which concern:

> (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;
> (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;
> (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

This requirement that inventions have a technical character was considered by the EBA in the Broccoli and Tomato cases to be an important matter in its consideration of whether plant breeding methods were patentable. In examining the historical documents which led up to the formulation of the EPC in 1960, the EBA observed that with the creation of new plant varieties, for which a special property right was going to be introduced under the subsequent UPOV Convention in 1960, the legislative architects of the EPC were concerned with excluding from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time. These conventional methods included in particular those based on the sexual crossing of plants deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired trait(s). These processes were characterised by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis. This phenomenon determined the genetic make-up of

[49] Diamond v. Chakrabarty, 447 US 303 (1980).
[50] *Ibid.*, p. 310.

the plants produced, and the breeding result was achieved by the breeder's selection of plants having the desired trait(s). That these were processes to be excluded also followed from the fact that processes changing the genome of plants by technical means such as irradiation were cited as examples of patentable technical processes.

The EBA also referred to the explanations given in the memorandum of the Secretariat of the Committee of Experts for agreeing to the replacement of the words "purely" biological by the word "essentially." This replacement was deliberate as it reflects the legislative intention that the mere fact of using a technical device in a breeding process should not be sufficient to give the process as such a patentable technical character. The EBA concluded that the provision of a technical step, be it explicit or implicit, in a process which is based on the sexual crossing of plants and on subsequent selection does not cause the claimed invention to escape exclusion if that technical step only serves to perform the process steps of the breeding process.[51]

The decision of the EBA was 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, is excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC. The EBA observed that "if a process of sexual crossing and selection includes within it 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, then that process leaves the realm of the plant breeding and, consequently, is not excluded from patentability.[52] This principle applies only where the additional step is performed within the steps of sexually crossing and selection, independently from the number of repetitions, otherwise the exclusion of sexual crossing and selection processes from patentability could be circumvented simply by adding steps which do not properly pertain to the crossing and selection process, being either upstream steps dealing with the preparation of the plant(s) to be crossed or downstream steps dealing with the further treatment of the plant resulting from the crossing and selection process. The EBA noted that for the previous or subsequent steps *per se* patent protection was available. This will be the case for genetic engineering techniques applied to plants which differ from conventional breeding techniques as they work primarily through the deliberate insertion and/or modification of one or more genes in a plant.

[51] *Ibid*., pp.66-67.

[52] Case G2/07 at p.69, 9 December 2010, available at http://documents.epo.org/projects/babylon/eponet.nsf/0/791D677646A4A968C12577F4004C3445/$File/G2_07_en.pdf, (5 August 2011)

It is important to note that the EBA disallowed the patenting of methods of plant breeding. It has been pointed out that the products of plant breeding remain patentable.[53] An analysis of the examination reports for recent patent applications at the EPO indicate that claims in relation to the breeding of plants would have to be deleted, but that the plants themselves (sunflowers[54] and coreless tomatoes[55]) were patentable.

[53] Then & Tipp 2011, *supra* note 47.
[54] EP 1793661 application by the Biogemma company.
[55] EP 1026942, application by Seminis company.