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Reconsidering plant variety rights in the European Union after *Monsanto v Cefetra BV*

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Regulation 2100/94 on Community plant variety rights art.13

International Convention for the Protection of New Varieties of Plants 1961 art.5

International Convention for the Protection of New Varieties of Plants 1991 art.14

Case cited: [Monsanto Technology LLC v Cefetra BV \(C-428/08\) \[2011\] Bus. L.R. 1498 \(ECJ \(Grand Chamber\)\)](#)

**387 As a consequence of the decision in Monsanto Technology v Cefetra BV, plant variety rights have been given a new lease on life. Indeed, even where biotechnology is the driving force behind plant innovation the Council Regulation on plant variety rights can play a significant role in the protection and management of that innovation, particularly in relation to harvested material and products.*

Introduction

Plant variety rights are a specific and often overlooked form of intellectual property law.¹ Indeed, despite the fact that plant variety rights schemes occupy a central position in intellectual property law, and play an important role in international policy aimed at promoting the development of new plants, they have been maligned as outdated and obsolete. More specifically plant variety rights are criticised because they are deemed unnecessary, technologically dependent and difficult, if not impossible, to effectively enforce.² As a consequence of these criticisms one of the challenges confronting international, regional and national plant variety rights schemes is that they are compared unfavourably with patent law.³ As early as the 1980s, Cornish argued that the International Convention for the Protection of New Plant Varieties (UPOV Convention) was an “outmoded impediment” that obstructed the “logical framework of protection” that is patent law.⁴ The preference for patent protection is generally related to the broader scope of protection granted under patent law, as well as the absence of broad ranging exceptions for plant breeding and saving seed from the patent law of many countries.⁵ The preference for patent protection is exacerbated by the use of biotechnology--and the development of a broad range of plant related innovations including DNA sequences, DNA molecules, promoters and plant breeding methods--in plant breeding programmes.

Importantly, though, the nature of the debates and the questions that are asked about plant variety rights are becoming more important in the European context as questions over the patentability of, and the scope of

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protection granted to, plant related innovations are interpreted and clarified. While art.53(b) of the European Patent Convention 1973 (EPC) restricts the patenting of plants, by providing an exception to patentability for “plant or animal varieties or essentially biological processes for the production of plants or animals”, legislative reform and jurisprudence has modified the way in which this exclusion operates. Notably, the laws dealing with the patentability of plants changed in 1998 with the introduction of the European Biotechnology Directive.⁶ The Biotechnology Directive deals with the patentability of biotechnological inventions and sets out the scope of protection conferred on biotechnological inventions. The Directive broadened the scope of patent protection for plant related innovations, opened up “loopholes” in the protection of plants under European patent law,⁷ and in so doing it has helped reshape the relationship between patent law and plant variety rights.⁸

One area that has been uncertain and contentious is the nature and scope of protection granted to genetic information.⁹ Though it was generally accepted that, given the genetic information satisfies the requirements of patentability, genetic information was patentable there were questions over the exact nature and scope of *388 protection granted to biotechnology patents.¹⁰ While there is some contention over the meaning and classification of genetic information,¹¹ there have been questions over if, and in what circumstances, the patenting of genetic information such as DNA sequences or DNA molecules results in protection of a plant or other products containing the patented genetic information. More specifically, even though “plant varieties” are excluded from patent protection by art.53(b) of the EPC, there have been concerns that a patentee could (indirectly) obtain protection over plants or products containing patented genetic information such as DNA or RNA sequences and molecules.

In 2010, the Court of Justice, in *Monsanto Technology v Cefetra BV*,¹² considered the nature and scope of protection granted to genetic information particularly in relation to art.9 of the European Biotechnology Directive.¹³ In the court's view, art.9 of the Biotechnology Directive only extends patent protection in circumstances in which the genetic information is present and currently performs its function in the product. While the *Monsanto* decision has a number of implications for European patent law and practice it also changes the relationship between patent law and plant variety rights in the European Union.

In light of the Court of Justice's decision this article re-examines the circumstances in which the Council Regulation on Community Plant Variety Rights (Council Regulation) protects harvested material and products.¹⁴ The article begins by briefly looking at the 2010 Court of Justice decision of *Monsanto v Cefetra*¹⁵ which has clarified a number of points relating to the protection of genetic information in plants and plant products within the European Union. The article then discusses a number of implications of the decision including the need to reconsider plant variety rights protection in the European Union.¹⁶ By examining the history of the relevant provisions of the Council Regulation, particularly in relation to the UPOV Convention, the article points out that the extension of plant variety rights to harvested material and products was introduced for reasons similar, if not identical, to those in *Monsanto v Cefetra*. The article concludes by suggesting that as a consequence of the decision in *Monsanto v Cefetra* plant variety rights have been given a new lease on life, and that even where biotechnology is the driving force behind plant innovation the Council Regulation can play a significant role in the protection and management of that innovation.

Limiting protection of products containing patented genetic information

In trying to manage and control the use of its Roundup Ready® glyphosate tolerant agricultural products in Argentina, and by extension in other countries that do not grant patent protection to the same or similar technology, Monsanto alleged that a number of soy meal importers had infringed their European Patent 0 546 090.¹⁷ More specifically Monsanto brought an action in the Hague District Court, and alleged that the import of the patented DNA sequence constituted patent infringement of their European patent based solely on the presence of the DNA molecules that encode the EPSP enzymes in the processed soy meal.

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In reply to Monsanto's claim, the defendants contended that it was not enough for the patented DNA sequence to be present in the soy meal. The defendants argued that Monsanto had to show that the DNA present in the soy meal also performs its function in the soy meal by making it tolerant to glyphosate. The defendants based this contention on the argument that art.9 of the Biotechnology Directive impose a limit on the circumstances in which patent protection is extended to products containing patented genetic information. Article 9 of the Biotechnology Directive states:

“The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, same as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.”

The Hague District Court made a number of determinations in relation to the facts in dispute, including that “DNA cannot perform its function in soy meal, which is dead material”¹⁸ ; however, the Court referred a number *389 of questions of law to the Court of Justice.¹⁹ Most notably, the Court of Justice was asked whether art.9 of the Biotechnology Directive²⁰ :

“[B]e interpreted as meaning that the protection provided under that provision can be invoked even in a situation such as that in the present proceedings, in which the product (the DNA sequence) forms part of a material imported into the European Union (soy meal) and does not perform its function at the time of the alleged infringement, but has indeed performed its function (in the soy plant) or would possibly again be able to perform its function after it has been isolated from that material and inserted into the cell of an organism?”

The Court of Justice interpreted art.9 of the Biotechnology Directive, as well as the Directive more broadly as it applied to national patent law. In so doing, the Court of Justice emphasised that patent protection extends to material in which a patented DNA sequence is contained if two conditions are satisfied: first, the patented genetic information such as a DNA sequence must be present in the product; and secondly, the genetic information must perform the function described in the patent. In relation to the second requirement, the court pointed out that “neither art.9 of the Directive nor any other provision thereof accords protection to a patented DNA sequence which is not able to perform its function”.²¹

The Court of Justice then applied this to the facts before them. In the court's view, the first of these requirements was satisfied as there was no disputing that the imported soy meal contained the patented DNA sequence. In answering the question of whether the DNA sequence was performing its function, the Court of Justice pointed out that the patented DNA sequence only performs its function if it makes the soy meal tolerant to glyphosate. The court concluded that the use of herbicide on soy meal is not “foreseeable, or even conceivable”, and even if it was used it could not perform its function because the soy meal is dead material.²² As a consequence, Monsanto's European Patent 0 546 090 (“Glyphosate Tolerant 5-Enolpyruvylshikimate-3-Phosphate Syntheses”) did not protect the imported soy meal, and Monsanto could not prevent the soy meal being imported into the European Union merely because it contained, in a residual state, a patented gene sequence.

The *Monsanto v Cefetra* decision is important for numerous reasons. Had the Court of Justice allowed Monsanto's patent to extend to the DNA sequence irrespective of function, patentees would be in a position to control the market of products obtained from patented genetic information regardless of whether the products performed the claimed function. As Advocate General Mengozzi pointed out, to allow such products to be protected would contradict a number of principles that underpin and inform modern patent law.²³ The first of these principles is the notion that a patent is a social contract between the patentee and the public in which the patentee must disclose how to reproduce the invention in return for gaining a temporary monopoly. The Advocate General stressed that granting patent protection to genetic information includ-

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ing DNA sequences, irrespective of the function that the genetic information performs, would breach this social contract because the invention is not being disclosed by the patentee. The second principle sustained by a purposive reading of patent claims is the dichotomy between a discovery and an invention, where on the one hand, isolating a DNA sequence independent of the DNA's function is a discovery (and is not patentable), while on the other hand, indicating a function of the DNA sequence is generally accepted as an invention (which is patentable).

On a more practical level, the decision creates greater certainty and consistency in relation to biotechnology patents.²⁴ Because the patentee of genetic information such as DNA sequences and DNA molecules does not have an absolute right against the importation of products produced outside the European Union that contain the claimed genetic information there is greater consistency and predictability in regards to the nature and scope of biotechnology patents. If the presence of the genetic information is the only requirement for the application of art.9 of the Biotechnology Directive, then patent protection would be extended to an indeterminate number of derivative products, all of which would come under the control of the patentee of the DNA sequence. This would be problematic because it is not always possible to say for how long, or up to what stage of the food or product chain, traces of the original DNA sequence are identifiable.

Another reason why the *Monsanto v Cefetra* decision is important is because it will impact on the way in which patent claims are constructed. Rather than claiming rights over the soy meal itself, Monsanto's principle claim was for the protection of the patented DNA sequence contained in the soy meal, which Monsanto alleged was protected under art.53 of the Netherlands Law on Patents 1995. As a result of this decision, in the future patentees will be more likely to directly claim products such as plants or products such as soy meal without reference to a particular DNA sequence. A successful claim to a product per se is a claim to that product however it is made, which means that any subsequent use of the product is an infringement regardless of how the product is *390 obtained. In addition to claiming products, patentees may construct claims in such a way as to include product-by-process claims whereby a product is defined with reference to the process by which it is made.²⁵

While it is possible that future patent applications dealing with plant innovations will include product and product-by-process claims the success of these claims will be largely contingent upon the way in which the claims are constructed, as well as on the nature of the product being claimed. In *Kirin-Amgen Inc v Transkaryotic Therapies Inc (No.2)*²⁶ the House of Lords considered the scope of patent claims owing to a dispute over the similarity of technologies producing the hormone erythropoietin. The House of Lords stated that if a product is defined with reference to a process, the product itself must fulfil the requirements of patentability and there must not be any information in the patent application which would enable the applicant to define the product satisfactorily by reference to its composition, structure or some other parameter that can be tested. On this basis, the House of Lords concluded that the erythropoietin was generally not the invention, but rather a mere discovery on which the production method was based.²⁷

Yet another reason, and the focus of the remainder of this article, why *Monsanto v Cefetra* is important is because it highlights the significance of plant variety rights in the European Union for the protection of plant related innovations. On an international, national and regional level, one of the most often cited advantages of plant variety rights schemes is that they provide a more targeted approach to the protection of plant varieties. On this basis alone plant variety schemes are often a more attractive option for countries that must "provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by a combination thereof" under their obligations pursuant to art.27.3(b) of the TRIPS Agreement.²⁸ Indeed, as a consequence of the *sui generis* nature of plant variety rights, plant variety rights schemes may be available in circumstances where patent protection is not.²⁹ This is the case in Argentina, for example, where some form of plant variety rights protection has been in place since 1973, and where the Argentine Government became a member of the UPOV Union in 1994.³⁰

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In addition to the possibility of obtaining plant variety protection in countries in which patents are not available, *Monsanto v Cefetra* changes the relationship between patent law and plant variety rights in the European Union. While patents protect a wide range of inventions--covering a range of plant related innovations including gene sequences, promoters and plant breeding methods--patent protection is not absolute, and does not automatically extend to plants or other products containing the patented genetic information. As a consequence, genetic information such as a DNA sequence and products containing the DNA sequence may be left unprotected and a patentee may not have a right against the importation of harvested goods produced outside the European Union that are produced using the genetic information.³¹ In clarifying this point, the decision of *Monsanto v Cefetra* serves as a useful reminder of the important role of the Council Regulation on Plant Variety Rights in the protection of plant related innovations. Indeed, it highlights why plant variety rights offer a viable alternative or conjunctive intellectual property protection to that granted under European patent law; even for plants containing patented genetic information. In light of the court's decision it is, therefore, necessary to reconsider the Regulation on Community Plant Variety Rights.

Council Regulation on Community Plant Variety Rights

The Council Regulation on Community Plant Variety Rights was introduced in 1994 to enable plant breeders to protect new varieties of plants.³² Despite a steady stream of applicants to the Community Plant Variety Office--since 1995 there have been an average of approximately 2,400 applications per year³³--plant variety rights are sometimes maligned as outdated, unnecessary and inferior to patent protection. Broadly speaking, the key criticisms of the Council Regulation concern the difficulty of ensuring adequate remuneration for the use of protected plant varieties and the effective enforcement of community or national rights.³⁴ More specifically criticisms of plant variety rights schemes tend to focus on the effectiveness of a sui generis, industry specific legal scheme to provide adequate protection particularly in light of advances in science and technology. There are also concerns over the limited nature of protection under plant variety rights owing to the plant breeding and farm saved seed exemptions contained in plant variety rights schemes.³⁵ Such criticisms of plant variety rights have been compounded by the use of biotechnology in plant*³⁹¹ breeding and the availability of patent protection for plant related innovations. That said, owing to the way in which the patentability of plant related innovations is changing, and the significance of promoting the development of new plants, the Council Regulation can play a significant role in protecting harvested material and products obtained from protected plant varieties.

Plant varieties, harvested material and products

One of the ways in which the Council Regulation can be used to protect genetically modified plants is by providing, in certain circumstances, protection to harvested material and products directly obtained from a protected variety. More specifically art.13(2) and 13(3) of the Council Regulation protect harvested material such as grain, cut flowers or soybeans:

“[I]f this was obtained through the unauthorized use of variety constituents of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said variety constituents.”

In addition, art.13(4) of the Council Regulation extends plant variety protection to products obtained directly from material of the protected variety, if:

“[S]uch products were obtained through the unauthorized use of material of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said material. To the extent that the provisions of paragraph 2 apply to products directly obtained, they shall also be considered to be ‘material’.”

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To fully appreciate the application of art.13(2), 13(3) and 13(4) of the Council Regulation it is helpful to consider the history of the scope of protection granted by the UPOV Convention; on which the Council Regulation is based. During the negotiations for the UPOV Convention in the 1950s a major concern for plant breeding organisations was that the scope of protection granted to plant breeders, which was primarily over propagating material, was problematic because the destination of a plant crop was not always known at the time of production. This concern was encapsulated by professional groups such as the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants (CIOPORA), who at the UPOV Diplomatic Conference of 1957-1961 argued that limiting protection to propagating material was “illusory” for vegetable production because plant breeding is a heterogeneous activity and the destination of the crop was not always known.³⁶ The often-cited example was of ornamental cut flowers that were sometimes used to produce more flowers. More specifically it was argued that while plant variety rights may be granted in one country, the cut flowers could be taken to other countries (that did not provide plant variety rights protection) where they were propagated and multiplied. The flowers could then be imported back into the country of origin where the plant variety owner had legal rights over the propagating material, but not over the harvested cut flowers.

Owing to such concerns, concession was made for ornamental flower varieties in UPOV 1961. While UPOV 1961 generally limited protection to the propagating material of protected plant varieties, art.5(1) of UPOV 1961 provided the option of extending protection to “ornamental plants or parts thereof” when they were used commercially as propagating material, even if the plants were “normally marketed for purposes other than propagation”. Importantly, though, this did not amount to a general extension of protection beyond the propagating material of protected varieties because the harvested material of other plants was:

“[A]n element of the food supply and participating countries were not willing to be required to extend the right of the breeder to the end product of the variety on a mandatory basis.”³⁷

Further questions over the scope of the protection were raised at the UPOV Diplomatic Conference of 1978.³⁸ And again it was the professional organisations such as the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL), the International Seed Trade Federation (FIS) and CIOPORA that led the discussions on the scope of protection. The professional organisations argued that art.5(1) of UPOV 1961 was easily misunderstood and needed to be amended, or at the very least clarified; because of the heterogeneous nature of plant breeding, restricting protection to propagating material was not appropriate for all plant breeding activities. CIOPORA argued that restricting protection to propagating material was “illusory and that the problem arising is not only one of ‘extending’ this right but also of ensuring that the minimum right may be normally exercised”.³⁹ More specifically CIOPORA argued that for numerous ornamental species (such as chrysanthemum, carnation and rose) the aim was to produce cut flowers, not propagating material. It was also argued the trade in cut flowers often occurred across international borders, and because there were so few UPOV Member States, this trade often involved countries that were not members of the UPOV Convention.

Despite the pleas of the breeder organisations at the Diplomatic Conference of 1978, the secretary-general of UPOV stated that at least part of the agitation on art.5 of *³⁹² UPOV 1961 was “based on misunderstandings”.⁴⁰ One obstacle to the success of the argument for extending protection to other plant material was that, while consistent in message, the arguments were specifically related to the interests of particular plant breeders and industries, namely the ornamental and cut flower industries. Most importantly, though, the decision on extending the plant variety right was mediated by the overall aim, of making UPOV 1978 more attractive to potential Member States, of the Diplomatic Conference of 1978. It was generally accepted that extending the scope of protection would make UPOV less attractive to potential members and that “an ‘extension’ of the minimum protection provided for in Article 5(1) could compromise ratification of the revised text or accession to it”.⁴¹

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It was not until the Diplomatic Conference of 1991 that Member States resolved to strengthen plant variety rights. This meant that the reluctance to provide protection beyond the propagating material was overcome, and one of the main areas used to strengthen the position of the plant variety owner was the scope of protection.⁴² Although there was overwhelming support for strengthening the scope of protection provided by UPOV, the proposed change to extend protection to the harvested material and products made from the protected propagating material prompted a number of alternatives.⁴³ Most notably, questions related to whether plant variety owners should be granted automatic and absolute discretion to exercise their right at any stage of production, namely either over the protected propagating material, the harvested material or products derived from the harvested material. One argument against automatically granting absolute and discretionary protection over harvested material and derived products was that it would create inconsistency and unpredictability in the relationship between plant variety owners and the users of plant varieties.⁴⁴ The Spanish delegation unsuccessfully argued that any extension to harvested material should be optional as this would “permit the special circumstances of each county--social and political--to be taken into account”.⁴⁵ The Japanese delegation proposed a so-called cascade principle in which the plant variety owner did not have absolute discretion over the point at which they exercised their right; rather the extension of the right would be contingent upon the variety owners' actions at an earlier stage of production.

It was decided by delegates at the Diplomatic Conference that the plant variety owners' right should remain primarily over the propagating material of the protected plant variety. This is established by art.14(1)(a) of UPOV 1991, which provides protection to protected propagating material for most uses of the plant variety including production or reproduction (multiplication), conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting and importing the protected plant variety.⁴⁶ Nevertheless, after some discussion, Member States adopted cascading protection and extended the variety right in a number of ways.⁴⁷ One way in which protection is extended is to the harvested material obtained through the unauthorised use of protected propagating material. This is achieved by art.14(2) of UPOV 1991, which states:

“Subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.”

A further (optional) extension made to the scope of protection under UPOV 1991 is to products derived directly from the harvested material. The extension of the scope of protection to “products derived directly from harvested material” generated a great deal of opposition. One concern was that exercising rights in relation to such products was “impossible or at least extremely difficult” because the identification of the protected plant variety would be difficult.⁴⁸ Despite such concerns it was generally agreed that any problems associated with proof and evidence were not sufficient reason to refuse extending the plant variety right, and thus, Member States were given the option of extending protection to products made directly from harvested material by art.14(3) of UPOV 1991 which states:

“Each Contracting Party may provide that, subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of products made directly from harvested material of the protected variety falling within the provisions of paragraph (2) through the unauthorized use of the said harvested material shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested material.”

***393 Has the breeder had a “reasonable opportunity” to exercise their right?**

Incorporating these provisions into EC law, arts 13(2), 13(3) and 13(4) of the Council Regulation give

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European plant variety owners the ability to exercise their rights in relation to harvested material and products obtained directly from a protected plant variety. Though most of the arguments for the extension to harvested material and products of protected varieties focused on ornamental plant varieties, the extension has wider application. It has been suggested that arts 13(2), 13(3) and 13(4) of the Council Regulation provide “protection for such derivatives of plants as essential oils (used in the perfume and aromatherapy industries) and medicines (for example, herbal remedies and vaccines)”.⁴⁹ In the context of this article, arts 13(2)-13(4) could also be used to protect the soy meal produced from the unauthorised use of soy plants containing DNA sequences or other genetic information that is imported into the European Union.

The role of the Council Regulation in protecting plant varieties that are used outside of the European Union is reflected in the Preamble to the Council Regulation which explains that:

“[T]he scope of protection should be extended, compared with most national systems, to certain material of the variety to take account of trade via countries outside the Community without protection.”⁵⁰

The intention of arts 13(2) to 13(4) of the Council Regulation, however, is not to provide a right over the whole plant, entire plant variety, harvested material or products such as soy meal. Rather, as we saw in relation to the UPOV Convention, the extension of protection is based on a cascading principle and is conditional upon two factors. First, the harvested material or products obtained directly from the protected variety need to be obtained through the unauthorised use of the protected plant variety. The requirement that there is the unauthorised use of the protected plant variety is relatively straightforward. For instance, in situations similar to those in *Monsanto v Cefetra* (and assuming there was a valid Community plant variety right) where the owner makes a number of unsuccessful attempts to control and manage the use of their intellectual property directly with farmers and the government, the use of that material is unauthorised.

The second requirement for the extension of a Community plant variety right is that the plant variety owner has not had a “reasonable opportunity to exercise his right” in relation to the protected plant material. Importantly, then, in order to determine whether protection extends to harvested material or products obtained from the protected variety it is necessary to consider what constitutes a “reasonable opportunity”. The question of whether a plant variety owner has had a “reasonable opportunity” to exercise their right over the protected plant material was considered by the German Supreme Court in relation to the importation of the garden plant *Calluna vulgaris* (commonly referred to as ling or Scotch heather). The dispute involved two *Calluna vulgaris* plant varieties, one of which was protected by a Community plant variety right and the other by a German plant variety right.⁵¹ The holder of the plant variety right brought an infringement action against a German retailer who allegedly infringed the owners' rights by selling both of the *Calluna vulgaris* varieties without permission. In determining the issue, the German Supreme Court had to decide whether the alleged infringement fell within the scope of protection of art.13(3) of the Council Regulation and the similarly worded art.10(2) of the German Plant Variety Protection Law 1997. The court had to determine whether protection extended to the harvested material of the *Calluna vulgaris* varieties and in doing so the court considered whether the plant variety owner had a “reasonable opportunity” to exercise their right in relation to the propagating material of the protected *Calluna vulgaris* varieties.

The German Supreme Court concluded that the plant variety owner did not have a “reasonable opportunity” to act on the propagating material because the plant varieties were not protected in France. The two *Calluna vulgaris* varieties were reproduced and grown in France, where there was no plant variety protection, and were then imported back to Germany to be sold as plants. As a consequence it was only when the plants were sent back to, and traded in, Germany as harvested material that the plant variety owner was able to exercise their rights. In the court's view the plant variety owner did not have any opportunity, let alone a “reasonable opportunity”, to exercise their right over the propagating material. As a result legal protection extended to the harvested plant material and the retailer had infringed the owners' plant variety right.⁵²

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Considering the reasoning of the German Supreme Court, as well as the Preamble to the Council Regulation, it would be difficult if not impossible to successfully argue that a plant variety owner--in a similar position to Monsanto's in which the plants are reproduced, grown and harvested outside the European Union--had a "reasonable opportunity" to exercise their Community plant variety right over the protected plant material. As the soy plants were reproduced outside the European Union and were then imported into the European Union as soy meal to be used as animal feed, the facts in *Monsanto v Cefetra* are similar to those considered by the German Supreme Court. Even though Monsanto *394 sought commercial arrangements with the defendant companies, and with the Argentinian Government, there was little that they could do to manage and control the use of the soy plants containing the DNA sequence which makes the plant glyphosate tolerant.⁵³

While the central argument of this article is that the Council Regulation can, in certain circumstances, protect harvested material and products containing genetic information in light of the Court of Justice's decision, there is another observation worth making. The generally accepted view is that plant variety right schemes do not protect genetic information. While this is true for the majority of UPOV Member States, who provide plant variety rights protection principally over the propagating material such as seeds, bulbs and cuttings of protected varieties, art.13(2) of the Council Regulation grants protection to "variety constituents" of the protected plant variety.⁵⁴ While the use of the term "variety constituents" makes the Council Regulation unique among UPOV Member States, the term has attracted little scholarship or commentary.⁵⁵ In limited circumstances granting protection to "variety constituents" could help ameliorate the notion that the Council Regulation is unsuited or unable to protect biotechnological innovations. It is possible that elements of a plant including genetic information are eligible for protection under the Council Regulation in the European Union, as long as the genetic information is considered a "variety constituent" because it is capable of reproducing the plant variety. It has been suggested by van der Kooij that:

"[I]f a single plant cell were capable of producing an entire plant, a grouping of such plant cells could form a variety; these plant cells would be treated in the Regulation as 'variety constituents'."⁵⁶

Conclusion

In recent years, in the European Union, the nature of the relationships between patent law and plant variety rights has been clarified and interpreted. Although unsurprising, the decision of the Court of Justice in *Monsanto v Cefetra* makes it clear that the patentee of genetic information such as DNA sequences and DNA molecules does not have an absolute right against the importation of products produced outside the European Union that contain patented genetic information. One notable consequence of the decision will be on the way plant related inventions are characterised, and future patent claims are likely to include "direct claims to harvested goods and derived products such as soya meal".⁵⁷ More broadly, though, *Monsanto v Cefetra* serves as a reminder that, while plant variety rights have been criticised as outdated and obsolete, in some respects at least, plant variety rights are better able to deal with the protection of plant related developments. The Council Regulation on Plant Variety Rights plays an important role in the protection of plant varieties. Though further consideration needs to be given to practical, operational and administrative issues, such as eligibility for protection, variety identification and establishing the origin of the plant material, in the push to promote agricultural research and to encourage the development of new plants it is vital to acknowledge the role that plant variety rights can play; even in cases in which plant varieties contain specific genetic information. Indeed, the Council Regulation provides an avenue of protection over plants and derivative products that is not available under European patent law.

Also, BAppSc (VUT), BA (UQ), LLB (Hons) (QUT), PhD (UQ); Member of ACIPA.

1. Referring to the "non-conformist" image of plant variety rights Sherman suggests that plant variety rights

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schemes are “outsiders that are begrudgingly tolerated” and “are sufficiently different to be categorised differently”: B. Sherman, “Taxonomic Property” (2008) 67(3) *Cambridge Law Journal* 560, 560.

2. See, e.g. Mark Janis and Stephen Smith, “Technological Change and the Design of Plant Variety Protection Regimes” (2007) 82 *Chicago Kent Law Review* 1557.

3. The importance of plant variety protection is reinforced by art.27(3)(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which states that “[m]embers shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof”. See G. Dufield, *Food, Biological Diversity and Intellectual Property: The Role of the International Union for the Protection of New Varieties of Plants (UPOV)*, Quaker United Nations Office (February 2011), pp.10-11.

4. W. Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 2nd edn (London: Sweet and Maxwell, 1989), p.148 fn.37.

5. For a discussion of the differences between plant variety rights and patent law see M. Llewellyn and M. Adcock, *European Plant Intellectual Property* (Portland: Hart Publishing, 2006), pp.8-37.

6. Council Directive 98/44 on the legal protection of biotechnological inventions [1998] OJ L213/13 (Biotechnology Directive), which entered into force on July 30, 1998.

7. E. Kranakis, “Patents and Power: European Patent System Integration in the Context of Globalization” (2007) 48(4) *Technology and Culture* 689, 722.

8. For the history of the Biotechnology Directive see *Kingdom of the Netherlands v European Parliament and Council of the European Union* (C-377/98) [2001] E.C.R. I-7079; [2001] 3 C.M.L.R. 49. See also G. Kamstra, M. Döring, N. Scott-Ram, A. Sheard and H. Wixon, *Patents on Biotechnological Inventions: The E.C. Directive* (London: Sweet and Maxwell, 2002).

9. There have been issues in relation to various aspects of art.53(b) of the EPC including “plant variety” and “essentially biological”. For a discussion of “plant variety” see Llewellyn and Adcock, *European Plant Intellectual Property* (2006), pp.294-316. For a discussion of “essentially biological” see the so-called Broccoli (G 2/07) and Tomato cases (G 1/08) handed down by the Enlarged Board on December 9, 2010. For a discussion of these cases, see A. Hubel, “Essentials on Essentially Biological Processes for the Production of Plants: Decisions G2/07 (Broccoli Case) and G1/08 (Tomato Case) of the Enlarged Board of Appeal of EPO” [2011] E.I.P.R. 328.

10. For a discussion of the patentability of genes in Europe see J. Pila, “Bound Futures: Patent Law and Modern Biotechnology” (2003) 9 *Boston University of Science and Technology Law* 326.

11. See, e.g. Š. Predrag, “Crick's Notion of Genetic Information and the ‘Central Dogma’ of Molecular Biology” (2007) 58 *British Journal for the Philosophy of Science* 13; U. Stegmann, “Genetic Information as Instructional Content” (2005) 72(3) *Philosophy of Science* 425.

12. *Monsanto Technology LLC v Cefetra BV* (C-428/08) [2011] All E.R. (EC) 209; [2011] F.S.R. 6.

13. *Monsanto v Cefetra* [2011] All E.R. (EC) 209; [2011] F.S.R. 6. The Court of Justice also considered: (1) whether art.9 of the Directive effects an effective harmonisation of the protection it confers, with the result that it precludes national patent legislation from offering absolute protection; (2) whether art.9 effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product regardless of whether it performs its function in the material containing it; and (3) whether arts 27 and 30 of the TRIPS Agreement effect the interpretation given of art.9 of the Directive. See M. Kock, “Purpose-Bound Protection for DNA sequences: In Through the Back Door?” (2010) 5(7) *Journal of Intellectual Property Law and Practice* 495.

14. Regulation 2100/94 on Community plant variety rights [1994] OJ L227, as amended.

15. *Monsanto v Cefetra* [2011] All E.R. (EC) 209; [2011] F.S.R. 6.

16. For a detailed description of the decision see V. Mohan-Ram, R. Peet and P. Vlaeminck, “Biotech Patent Infringement in Europe: The ‘Functionality’ GateKeeper” (2011) 10 *John Marshall Review of Intellectual Property Law* 540; Kock, “Purpose-Bound Protection for DNA sequences” (2010) 5(7) *Journal of Intellectual Property Law and Practice* 495.

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17. The particular invention in dispute centred on a “DNA molecule comprising DNA encoding a kinetically efficient, glyphosate tolerant EPSP synthase”, for which there were a total of 34 claims encompassing a range of inventions including DNA sequences, isolated DNA sequences, DNA molecules, methods of producing glyphosate tolerant plants and the glyphosate tolerant plants: European Patent 0 546 090 (“Glyphosate Tolerant 5-Enolpyruvylshikimate-3-Phosphate Synthases”).
18. *Monsanto v Cefetra* [2011] All E.R. (EC) 209; [2011] F.S.R. 6.
19. See above fn.13.
20. For a discussion of the four questions referred to the Court of Justice see Kock, “Purpose-Bound Protection for DNA sequences” (2010) 5 (7) *Journal of Intellectual Property Law and Practice* 495.
21. *Monsanto v Cefetra* [2011] All E.R. (EC) 209; [2011] F.S.R. 6 at [49].
22. *Monsanto v Cefetra* [2011] All E.R. (EC) 209; [2011] F.S.R. 6 at [37].
23. Opinion of A.G. Mengozzi, *Monsanto v Cefetra* March 9, 2010 at [31]-[32].
24. Contrast with G. Van Overwalle, “The CJEU's Monsanto Soybean Decision and Scope -- Clear as Mud” (2011) 42(1) *International Review of Intellectual Property and Competition Law* 1.
25. See G. Grant, “The Protection Conferred by Product-by-Process Claims” [2010] E.I.P.R. 635.
26. *Kirin-Amgen Inc v Transkaryotic Therapies Inc (No.2)* [2004] UKHL 46; [2005] R.P.C. 9.
27. *Kirin-Amgen* [2004] UKHL 46; [2005] R.P.C. 9 at [76]. For a discussion of the case see N. Holder, “Exogenous Equals Endogenous? Claim Construction after the Amgen Decision” (2006) 37(6) *International Review of Intellectual Property and Competition Law* 662.
28. TRIPS art.27(3)(b). See Dutfield, *Food, Biological Diversity and Intellectual Property* (February 2011), pp.10-11.
29. As long as the plant variety satisfies the requirements of protection namely the variety is new, distinct, uniform and stable.
30. Argentina became a member of UPOV 1978 on December 25, 1994. For a discussion of the Argentinean plant breeder's rights scheme see UPOV, *UPOV Report on the Impact of Plant Variety Protection* (Geneva: UPOV, 2005), pp.35-43.
31. Kock, “Purpose-Bound Protection for DNA sequences” (2010) 5(7) *Journal of Intellectual Property Law and Practice* 495.
32. Council Regulation on Community Plant Variety Rights, Preamble.
33. While there were 3,191 applications in 1995, there have generally been between 2,000 and 3,000 applications each year from a range of industries. In 2011, there were 3,184 applications coming from the agricultural (27.6%), vegetable (14.5%), ornamental (52.4%) and fruit (5.6%) industries. For complete statistics of Community applications see http://www.cpvo.europa.eu/statistiques/yearly_2011.pdf [Accessed March 22, 2012].
34. More broadly it is suggested that UPOV suffers from a lack of transparency and participation, as well as from limited assessment of the impacts of joining UPOV. See Dutfield, *Food, Biological Diversity and Intellectual Property* (February 2011).
35. For a detailed discussion of the issues surrounding the Regulation see Llewellyn and Adcock, *European Plant Intellectual Property* (2006), pp.218-245.
36. UPOV, *Actes des Conférences Internationales pour la Protection des Obtentions Végétales 1957-1961, 1972*, UPOV Publication No.316 (Geneva: UPOV, 1972), p.92.
37. M. Thiele-Witting and P. Claus, “Plant Variety Protection--A Fascinating Subject” (2003) *World Patent Information* 243, 245.
38. UPOV, Diplomatic Conference of 1978, *Records on the Geneva Diplomatic Conference on the Revision of the International Convention for the Protection of New Varieties of Plants 1978*, UPOV Publication No.337(E) (Geneva: UPOV, 1981).
39. UPOV, *Records on the Geneva Diplomatic Conference on the Revision of the International Convention for the Protection of New Varieties of Plants 1978* (1981), p.90.
40. UPOV, *Records on the Geneva Diplomatic Conference on the Revision of the International Convention*

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for the Protection of New Varieties of Plants 1978 (1981), p.179.

41. UPOV, *Records on the Geneva Diplomatic Conference on the Revision of the International Convention for the Protection of New Varieties of Plants 1978* (1981), p.90.

42. For a summary of the changes made by UPOV 1991 see, B. Greengrass, "The 1991 Act of the UPOV Protection" [1991] E.I.P.R 466.

43. UPOV, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants 1991*, UPOV Publication No.346(E) (Geneva: UPOV, 1992), pp.28-31.

44. While the "cascading" principle was supported by Spain, Canada and Australia, it was opposed by the US: UPOV, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants 1991* (1992), pp.314-315.

45. UPOV, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants 1991* (1992), p.311.

46. Importantly, though, the plant variety right is subject to arts 15 and 16 of UPOV 1991.

47. Protection was also extended to essentially derived and dependent varieties.

48. UPOV, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants 1991* (1992), p.406.

49. Llewellyn and Adcock, *European Plant Intellectual Property* (2006), p.224.

50. Council Regulation, Preamble.

51. February 14, 2006, No. X ZR 93/04. For a summary of the case see UPOV, *Plant Variety Protection Gazette and Newsletter*, No.100 2006), http://www.upov.int/en/publications/gazette/pdf/gazette_100.pdf [Accessed January 26, 2012].

52. The German Supreme Court also concluded that retailers specialising in the trade of plants have an obligation to check for the existence of intellectual property rights and to ensure that there is no infringement of such rights.

53. In Australia, the Federal Court of Australia identified a number of indicia of "reasonable opportunity" including knowing that the crops were being grown and harvested, and knowledge that there had been no agreement to grow such crops. See J. Sanderson, "Back to the Future: Possible Mechanisms for the Management of Plant Varieties in Australia" (2007) 30(3) *University of New South Wales Law Journal* 686, 692-696.

54. There are also questions about whether such varieties might be distinct.

55. Notable exceptions are Llewellyn and Adcock, *European Plant Intellectual Property* (2006), pp.215-216; P. van der Kooij, *Introduction to the EC Regulation on Plant Variety Protection* (London: Kluwer Law International, 1997), p.13.

56. Van der Kooij, *Introduction to the EC Regulation on Plant Variety Protection* (1997).

57. Kock, "Purpose-Bound Protection for DNA sequences" (2010) 5 (7) *Journal of Intellectual Property Law and Practice* 495, 513.

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