

# **Plant Patent Law and Practice: Australia, North America and Europe**

## **Discussion Paper**

ARC Discovery Project DP0987639 'Promoting Plant Innovation in Australia: Maximising the Benefits of Intellectual Property for Australian Agriculture'

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# Abstract

As part fulfilment of the ARC Discovery Project DP0987639 'Promoting Plant Innovation in Australia: Maximising the Benefits of Intellectual Property for Australian Agriculture', the following is a review of plant patent law and practice in Australia, North America and Europe. The purpose is to provide an overview of relevant laws and current legal doctrines affecting plant patenting with a focus on patentable subject matter, inventive step, sufficiency and then a consideration of some of the consequences of a shift towards the use of patents to protect plant innovations. The analysis demonstrates that the contours of the intellectual property landscape relating to the protection of plant varieties, both genetically-modified and traditionally-bred, are still shifting and uncertain. This is a situation which appears likely to continue for some time to come.

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# 1 Introduction

Historically, intellectual property law has had little impact on agricultural practices. Over the past fifty years or so, however, there has been a dramatic change in the impact that intellectual property has had on plant breeding. With a few notable exceptions,<sup>1</sup> intellectual property law only began to exert a significant influence upon plant breeding with the introduction of the *International Convention for the Protection of New Varieties of Plants* (UPOV Convention) in 1961. The UPOV Convention is a *sui generis* regime of intellectual property protection specially adapted to the vagaries of plant breeding. In particular, the UPOV Convention limits the scope of protection for new plant varieties to propagating material of the variety, and exempts certain uses of propagating material from infringement, namely: the use of propagating material for private and non-commercial purposes; the use of propagating material for experimental purposes; and, the use of propagating material for the purpose of breeding other varieties. The latter exemption, known as the ‘breeder’s exception’, is a defining feature of this form of intellectual property and the cornerstone of the UPOV Convention system. In addition, the UPOV Convention also permits, as an optional exception, farmers to save propagating material harvested from a crop for the purpose of producing further crops (known as the ‘farm-saved seed’ exception). The vast majority of countries, including Australia, implemented plant variety rights protection based on the UPOV Convention model. Following the introduction of the World Trade Organisation’s *Agreement on Trade-related Aspects of Intellectual Property Rights* (TRIPS) in 1994, the protection of new varieties of plants by, at a minimum, effective *sui generis* means is required of all members of the World Trade Organization.

One of the motives which led to the adoption of the UPOV Convention was the realisation that patent law was, for a number of reasons, ill-suited to plant breeding. Prime amongst these was the idea that living organisms were beyond the purview of the patent system. To many, it was difficult to conceive of living organisms as ‘inventions’, much less manners of ‘manufacture’ (in the vernacular of Anglo-Australian patent law), a view which persists in most jurisdictions.<sup>2</sup> Moreover, complex living organisms such as plants were not regarded as being amendable to the written description and enablement requirements of patent law. That is, complex living organisms such as plants were not reducible to a written description of their features in a patent specification, nor were the essential features of a given plant invention capable of precise delineation in patent claims. Yet another reason given as to why patents were unable to protect the products of plant breeding was that the methods involved in the breeding of plants have been practised since antiquity. It was also considered difficult to show that the use of these methods involved the exercise of ingenuity that was able to satisfy the inventive step or nonobviousness requirement. The incrementalism which characterises traditional plant breeding exacerbates the difficulties of meeting this requirement. Finally, the extensiveness of patent rights was also seen to conflict with traditional agricultural practices, such as farmers saving seed from one crop for the generation of further crops, and the development of new plant varieties, which is dependent upon access to germplasm of new varieties for use in further breeding.

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<sup>1</sup> In particular, the United States (under the 1930 *Plant Patent Act*). A number of European countries also granted patents for plant varieties before the 1960s, including the Federal Republic of Germany, Belgium, France, Italy, Sweden, and Hungary. Patents were also granted for plant varieties in Japan: see Beier, F.-K., & Straus, J., ‘Genetic Engineering and Industrial Property’, (1987) *11 Industrial Property*, 447 at p. 453, n. 50.

<sup>2</sup> See, for example, the decision of the majority of the Supreme Court of Canada in *Harvard College v Canada (Commissioner of Patents)* (2002) 219 DLR (4<sup>th</sup>) 577.

In these circumstances, it is not surprising that patent law had little direct impact upon the development and protection of the products of plant breeding in a majority of countries (with the exception of the plant patent regime in the United States). As a result, over much of the second half of the twentieth century plant variety rights were used as the predominant form of protection for new plant varieties in the vast majority of countries.

In recent years, however, objections to the use of patent protection for plants have been either swept away or marginalised. In part this has been prompted by the emergence of modern biotechnology, which has dramatically transformed both the legal and scientific landscape. At the same time, the scope of patentable subject matter has been liberalised,<sup>3</sup> whilst the difficulties associated with the written description and enablement requirements have largely been negated by the *Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure* (Budapest Treaty). At the same time, public expenditure on plant breeding, both in Australia and elsewhere, has declined to the point where plant breeding is predominantly privately funded.<sup>4</sup> Finally, the prohibition on the dual protection of new plant varieties by both patents and plant breeder's rights was removed from the 1991 text of the UPOV Convention (though member countries remain entitled to maintain the prohibition in their national laws). This convergence of events has been instrumental in clearing the way for the patenting of plants.

A further reason for the renewed interest in the use of patents to protect new plant varieties is dissatisfaction among some sectors of the plant breeding industry with the plant breeder's rights system as the limitations of that system have become apparent 'in the light of both experience and what is believed to be obtainable with the techniques of the new biology.'<sup>5</sup> Thus, in its first proposal for the introduction of what would become the European Biotechnology Directive,<sup>6</sup> the European Commission stated:

The UPOV-type protection which is at present available does not offer appropriate incentives. For example, it does not cover process innovation. In addition, the scope of protection provided for products encompasses only the production and commercialisation of the reproductive or propagative material, as such, of the protected variety, but not whole plants or parts of plants, such as cut flowers, as end products. Lastly, and far more importantly, plant breeders' rights are governed by the principle of independence: no authorisation is required from and no licence fees are paid to the original breeder for the use of his protected variety as a starting base for breeding and commercialising new varieties. Although this rule was designed to facilitate improvement of plant genetic diversity, it was and remains, in its broad form, an insufficient incentive to lead to investments in truly new developments.<sup>7</sup>

One of the consequences of these changes is that patents either have become, or are becoming, the predominant form of protection of new plant varieties in those countries which permit the

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<sup>3</sup> Although the decision of the United States Supreme Court in *Diamond v Chakrabarty* 447 US 303 (1980) is invariably cited as the progenitor of this movement, an Official Notice announcing the acceptance of higher life forms as patentable subject matter in Australia was published by the Commissioner of Patents in the *Australian Official Journal of Patents, Trade Marks and Designs* two months prior to the Supreme Court's decision in *Chakrabarty* being handed down: 'Patent Applications Concerned with Living Organisms', (1980) 50 *Australian Official Journal of Patents, Trade Marks and Designs* 13 (17 April 1980), p. 1162.

<sup>4</sup> Fernandez-Cornejo, J., & Schimmelpfennig, D., 'Have Seed Industry Changes Affected Research Effort?', (2004) *Amber Waves* (February); Linder, B., 'Economic Issues for Plant Breeding – Public Funding and Private Ownership', (2004) 12 *Australasian Agribusiness Review*, 6; Kingwell, R., 'Institutional Change and Plant Variety Provision in Australia', (2005) 13 *Australasian Agribusiness Review*, 5.

<sup>5</sup> Byrne, N. J., 'Plants, Animals and Industrial Patents', (1985) 16 *International Review of Industrial Property and Copyright Law*, 1, at p. 2.

<sup>6</sup> Directive 98/44 of the European Parliament on the Legal Protection of Biotechnological Inventions, [1998] *Official Journal of the European Union*, L 213/13.

<sup>7</sup> Commission of the European Communities, *Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions*, COM(88) 496 final – SYN 159 (17 October 1988), *Official Journal of the European Union*, C 10, 13 January 1989, p. 27 (para. 48).

granting of patents for plants.<sup>8</sup> This trend is particularly notable in the United States and Europe, and has also been observed in Australia, particularly in relation to genetically-modified plants.<sup>9</sup> Since the early 1980s, there has been a sharp increase in the number of patents granted in respect of agricultural biotechnology by both the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO).<sup>10</sup> In the United States, during the period 1976-2000, the rate of growth in the patenting of innovations relating to agricultural biotechnology generally surpassed the upward trend in overall patenting during the same period;<sup>11</sup> in respect of plant biotechnology in particular, the growth in the number of patents granted by the USPTO since the early 1980s has been ‘exponential’.<sup>12</sup> Importantly, this trend is not limited to genetically-modified varieties of plants,<sup>13</sup> but applies to traditionally bred plants. According to a recent study, at least 35 patents have been granted by the EPO in respect on non-GM plants since 2000.<sup>14</sup>

It has accordingly been argued that ‘plant variety protection now stands at a critical juncture’.<sup>15</sup> In particular, fears have been raised that, following decisions in the U. S. and Europe that have confirmed that utility patents may be granted in respect of plant varieties, plant breeders and seed companies in those two jurisdictions may be drawn away from plant variety protection systems, at least in the area of major cereal crops.<sup>16</sup> This has led to a situation described by one commentator as ‘protection creep’.<sup>17</sup>

This Discussion Paper analyses the transformations in legal doctrine in Australian, North American and European patent law that have facilitated this phenomenon. It also analyses the application of the criteria of patent validity to plant varieties, and discusses those areas in which the application of this criteria remains unsettled. It concludes by analysing the outcome of recent case law that may affect the patenting of plants, particularly genetically modified varieties.

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<sup>8</sup> It has been argued that irrespective of what improvements are made to plant variety laws, the protection is unlikely ever to reach the level offered by patents because it inherently lacks generic character, being always pitched at the level of specific varieties: Crespi, R. S., ‘European Union’, in Erbisich, F. H., & Maredia, K. M. (ed.’s), *Intellectual Property Rights in Agricultural Biotechnology* (2<sup>nd</sup> Ed.), Oxford: CABI International, 2004, pp. 261-277, at p. 276.

<sup>9</sup> See Hubicki, S., & Sanderson, J., *Recent Trends in the Patenting of Plants and Animals in the United States, Europe and Australia*, Canberra: Rural Industries Research and Development Corporation, 2009.

<sup>10</sup> King, J., & Heisey, P., ‘Ag Biotech Patents: Who’s Doing What?’, (2003) *Amber Waves* (November).

<sup>11</sup> Ibid.

<sup>12</sup> Graff, G. D., Cullen, S. E., Bradford, K. J., Zilberman, D., & Bennett, A. B., ‘The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology’, (2003) *21(9) Nature Biotechnology*, p. 989.

<sup>13</sup> Heisey, P. W., King, J. L., & Day, K., ‘Patterns of Public-Sector and Private-Sector Patenting in Agricultural Biotechnology’, (2005) *8(2&3) AgBioForum*, pp. 73-82, at p. 79.

<sup>14</sup> No Patents on Seed, ‘Patents on Normal Plants’, available from: [http://www.no-patents-on-seeds.org/index.php?option=com\\_content&task=view&id=69&Itemid=20](http://www.no-patents-on-seeds.org/index.php?option=com_content&task=view&id=69&Itemid=20). The patents in question are collected on the same site.

<sup>15</sup> Janis, M. D., & Smith, S., ‘Technological Change and the Design of Plant Variety Protection Regimes’, (2007) *82 Chicago-Kent Law Review*, 1557, at p. 1559.

<sup>16</sup> Ibid.

<sup>17</sup> Lesser, W., ‘From Penury to Prodigal: Protection Creep for U.S. Plant Varieties’, (2009) *14 Virginia Journal of Law and Technology*, 235.

# 2 Patentable Subject Matter

## 2.1 Introduction

In general terms, a patent is an exclusive right granted by the State for an invention that is new, involves an inventive step and is capable of industrial application. A patent gives its owner the exclusive right to prevent (or stop others from) making, using, offering for sale, selling or importing a product, based on the patented invention, without the owner's prior permission. There is no such thing as a worldwide patent: a patent is granted by a national patent office and is valid only within the territory in which the patent is granted. Further, the term of a patent is for a limited amount of time, generally 20 years from the filing date of the application.<sup>18</sup>

TRIPS sets out the minimum requirements for patent protection which members of the World Trade Organization must implement in their national patent laws. Article 27(1) provides that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.<sup>19,20</sup> To this general rule of patentability, Articles 27(2) and 27(3) provide a number of limited exceptions. Article 27(2) provides that WTO members may refuse to grant patents for inventions the commercial exploitation of which would be contrary to *ordre public* or morality.<sup>21</sup> In particular, WTO members may refuse to grant patents for inventions where this is necessary to protect human, animal or plant life or health or to avoid serious prejudice to the environment. Article 27(3) further provides that WTO members can exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. Members must, however, provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

The majority of countries have chosen to exclude plants (and animals) from their national patent laws. Notable exceptions include the United States, Europe, Japan and Australia. However, in none of these countries has the process of extending patent protection to plants (and animals) been seamless or free from controversy. In this section we consider the path followed by three of these jurisdictions – the United States, Europe and Australia – towards acceptance of plants and animals as patentable subject matter.

## 2.2 Plants as Patentable Subject Matter in the United States

Three types of patents are available in the United States: utility patents, design patents and plant patents. A utility patent may be granted to 'whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvements thereof',<sup>22</sup> subject also to meeting the novelty, nonobviousness, utility and written description

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<sup>18</sup> The patent laws of WTO members provide for the term of protection in relation to patents for pharmaceutical compounds to be extended for a further term of up to five years. This is intended to compensate for delays in obtaining regulatory approval to market the drug.

<sup>19</sup> In Australia and the United States the industrial applicability requirement is known as the utility or usefulness requirement.

<sup>20</sup> Australian patent law also requires as an additional requirement of patent validity that the invention must not have been secretly used by the inventor or with his/her consent prior to the date on which the patent application was filed. In essence, an invention will fall foul of this requirement where the inventor derived a commercial benefit from his/her invention before the filing date of the patent application.

<sup>21</sup> *Ordre public* is a French term which roughly equates to 'public order' in English.

<sup>22</sup> 35 USC §101.

requirements. Utility patents are so named because of the requirement that the subject matter of the patent must be useful or have ‘utility’. In contrast, design patents are granted for ‘any new, original and ornamental design[s] for an article of manufacture’.<sup>23</sup> A plant patent may be granted to ‘whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state’.<sup>24</sup> Of these three forms of protection, only plant and utility patents are relevant to plants and will therefore be the focus of this section.

The United States was the first country to explicitly legislate to provide patent protection for plants. In 1930, the US Congress passed the *Plant Patent Act* (PPA) which, as noted above, provides protection for asexually-reproduced plants. In particular, a plant protected according to the Act provides the inventor with the right to exclude others from asexually reproducing the protected plant, and from using, offering for sale, or selling the protected plant so reproduced, or any of its parts, throughout the United States, or from importing the protected plant, or any parts thereof, into the United States.<sup>25</sup> At the time when the PPA was introduced, a number of features of plant breeding were thought to render plants unsuitable for utility patent protection. First, plants were thought to be unpatentable because US Patent Office precedent prohibited patents being granted for ‘products of nature’.<sup>26</sup> Secondly, concerns were raised about the ability of inventors of new plant varieties to comply with the written description requirement of the utility patent statute. To obtain a valid utility patent, an inventor must file a specification containing ‘a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention’.<sup>27</sup> This requirement was regarded as posing an insurmountable obstacle to the patenting of plants for a number of reasons. The first relates to the general difficulty of describing in writing complex living organisms such as plants. An associated problem related to the difficulty in distinguishing new varieties of plants from existing varieties, especially where the difference relates to subtle variations in colour, fragrance or taste. It was also considered to be cumbersome and impractical to provide a detailed description of the new variety and the manner in which it was reproduced so as to enable third parties to reproduce the variety after the patent term had expired. This problem was especially acute in relation to sexually-reproduced plants, which could not at the time the PPA was being considered be reproduced true-to-type through seedlings.<sup>28</sup>

In view of the difficulties associated with conforming to the utility patents regime, the PPA incorporated a number of requirements designed to assuage these problems. In order to overcome the ‘products of nature’ objection, the PPA specified that only cultivated plants

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<sup>23</sup> 35 USC §171.

<sup>24</sup> 35 USC §161. Acceptable modes of asexual production include, but are not limited to, rooting cuttings, apomictic seeds, division, layering, runners, tissue culture, grafting and budding, bulbs, slips, rhizomes, corms, and nuclear embryos: United States Patent and Trademark Office, *Manual of Patent Examining Procedure* (2008) [1601].

<sup>25</sup> 35 USC §163.

<sup>26</sup> Although advocates of the patenting of modern biotechnology frequently recall the patent granted to Louis Pasteur by the US Patent Office in 1873 for ‘yeast, free from organic germs of disease’ in support of claims that patents over biological materials have a well-established pedigree, the rhetorical appeal of this argument is tempered by the fact that the US Patent Office and the courts subsequently cast doubt over the patentability of ‘products of nature’. In *Ex parte Latimer* Dec. Comm. Pat. 123 (1889), the US Commissioner of Patents held that in order for material found in nature to be patentable, the applicant must show that the material has been changed from its natural state, by giving it some new quality or function which it does not possess in its natural condition. The product of nature doctrine has been approved by the US Supreme Court: *Funk Brothers Seed Co v Kalo Inoculant Co* 333 US 127 (1948).

<sup>27</sup> 35 USC §112.

<sup>28</sup> *Diamond v Chakrabarty* 447 US 303 (1980).



qualified for protection. The PPA also relaxed the written description requirement for plant patents. In particular, the PPA provided that no plant patent shall be declared invalid for non-compliance with the written description requirement as long as the description of the plant ‘is as complete as is reasonably possible’.<sup>29</sup> A specification for a plant patent will generally be considered to comply with this provision where it provides a description of the characteristics of the claimed plant that distinguish it from other known varieties and its antecedents. The specification should also include the origin or parentage of the plant and the manner in which the plant variety has been asexually reproduced, as well as the genus and species designation of the plant variety.<sup>30</sup> The content of a plant patent specification is thus similar to the requirements for an application for plant breeder’s rights.<sup>31</sup>

It has been argued that the exclusion of sexually-reproduced plants from the plant patents scheme was ‘as much a matter of political expediency as it was a matter of biology’.<sup>32</sup> In respect of the latter, the exclusion of sexually-reproduced varieties was said to be a product of the scientific understanding of the times: ‘in 1930 no consensus existed as to whether sexually propagated plants could in fact be distinguished from naturally occurring plants’.<sup>33</sup> As to the matter of political expediency, Janis and Kesan (2002) point to the fact that the chief lobbying influence advocating patent protection for plants consisted of major nursery operators. These nurserymen persuaded seed companies, who saw themselves predominantly as brokers rather than developers of new varieties, to relinquish their efforts to obtain patent protection for sexually-produced plants. The nurserymen convinced the seed companies that recognition of the rights of plant breeders would best be served by lobbying for limited protection. Once this ‘fundamental principle’ was established, it would be ‘much easier’ to obtain patent protection for sexually-produced plants.<sup>34</sup>

Consequently, in ensuing decades, the United States industry continued to press for patent protection for sexually-reproduced plants. These efforts culminated in a number of attempts during the 1960s to have the PPA amended to incorporate within its scope sexually-reproduced varieties, attempts were ultimately unsuccessful. Instead, these efforts to secure broader patent protection for plants ‘matured into’ the *Plant Variety Protection Act 1970*, which provided ‘UPOV-like’<sup>35</sup> protection for sexually-reproduced varieties of plants.<sup>36</sup> Ultimately, however, it was the courts, rather than the legislature, that were responsible for extending the scope of patent protection for plants. Three decisions, in particular, were pivotal to establishing patent protection for sexually-reproducing plants: the decisions of the United States Supreme Court in *Diamond v*

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<sup>29</sup> 35 USC §162.

<sup>30</sup> United States Patent and Trademark Office, *Manual of Patent Examining Procedure*, Chapter 1600: Plant Patents, at pp. 1600-5.

<sup>31</sup> Indeed, an application for a plant patent may rely upon an earlier application for plant breeder’s rights filed in a UPOV member country for the purpose of establishing priority: 35 USC §119(f).

<sup>32</sup> Janis, M. D., & Kesan, J. P., ‘US Plant Variety Protection: Sound and Fury?’, (2002) *39 Houston Law Review*, 727 at p. 736. Likewise, the authors contend that plant variety protection under the PVPA ‘owes its existence as much (or more) to expediency in the politics of plant breeding as to a clear-eyed normative vision of the appropriate range of protection for types of plant innovation’: *ibid.*, at p. 737.

<sup>33</sup> Roberts, M. T., ‘*J.E.M. Ag Supply Inc v Pioneer Hi-Bred International Inc*: Its Meaning and Significance for the Agricultural Community’, (2003) *28 Southern Illinois University Law Journal*, 91 at p. 99.

<sup>34</sup> Janis, M. D., & Kesan, J. P., *supra* n. 32, pp. 736-7.

<sup>35</sup> The prohibition on dual protection of plant varieties both by patents and plant variety rights prevented the US from ratifying the UPOV Agreement until 1999. The *Plant Variety Protection Act* conforms to the 1991 text of the UPOV Agreement.

<sup>36</sup> Janis and Kesan argue that, just as the *Plant Patent Act* was very much a product of political expediency, ‘the PVPA emerged not because it was necessarily compelling on its own merits, or because it was an inevitable compliment to existing patent protection, but because it appeared to be the politically least objectionable alternative when no consensus could be found for including plants explicitly in the utility patent statute’: Janis, M. D., & Kesan, J. P., *supra* n. 32, at pp. 743-4.

*Chakrabarty* 447 US 303 (1980) and *JEM Ag Supply v Pioneer Hi-Bred International Inc* 534 US 124 (2001), and the decision of the United States Patent Office Board of Appeals and Interferences in *Ex parte Hibberd* 227 USPQ 443 (1985).

In *Diamond v Chakrabarty*, the US Supreme Court decided that a genetically-modified bacterium that was capable of degrading crude oil constituted patentable subject matter for the purpose of a utility patent. The fact that the subject matter claimed was living was held by the Court to be not a bar to patentability. The Court held that the relevant distinction is not between living or non-living things, but between products of nature, whether living or not, and human-made inventions. In considering whether the claimed bacterium was patentable, the Court referred to a Congressional Committee report which indicated that ‘anything under the sun made by man’ was intended by Congress to be patentable. However, the Court recognised that there are some limits upon the types of subject matter that can be patented. In particular, the Court stated that only products of human ingenuity are patentable, whilst natural laws and physical phenomena cannot be patented. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter, nor could Einstein have patented his theory of special relativity, expressed in the formula  $E=mc^2$ , or Newton the law of gravity. According to the Court, such discoveries are ‘manifestations of nature, free to all men and reserved exclusively to none’. The Court held that the claimed bacterium was not naturally occurring, but was a product of human ingenuity having markedly different characteristics from any found in nature, and had the potential for significant utility. Accordingly, it was patentable.

Despite the sweeping language used employed by the Supreme Court in *Chakrabarty* to describe the scope of patentable subject matter, the US Patent and Trademark Office (USPTO) continued to refuse to grant utility patents for plants, at least in respect of new varieties that would qualify for protection under the PPA or the PVPA. The USPTO took the view that the PPA and the PVPA were intended by Congress to be the exclusive forms of legal protection for the types of plants covered by those Acts. However, if the plant claimed was not capable of protection by either the PPA or the PVPA, the USPTO policy did not apply and the plant qualified for protection by utility patent. Accordingly, plant material such as hybrid seeds, plant cells, tissue cultures, plant and other DNA, genes and proteins, as well as breeding methods, were also capable of being protected by a utility patent.

In *Ex parte Hibberd* the Board of Patent Appeals and Interferences held that the PPA and PVPA are not the exclusive forms of intellectual property protection available for plants in the United States. The Board therefore rejected the USPTO’s policy and decided that both sexually and asexually reproduced plants are eligible for utility patent protection regardless of whether or not they otherwise qualify for protection under the PPA and the PVPA. The Board noted that the Supreme Court in *Chakrabarty* had stated that plants were thought to be unpatentable under the utility patent statute for two reasons. The first was the belief that plants, even those artificially produced, were unpatentable products of nature. Secondly, plants were not considered to be amenable to the written description requirement. As noted above, the first objection was overcome by limiting the scope of protection under the PPA to asexually-reproduced cultivars. The introduction of the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure* in 1977 had also facilitated the removal of the last remaining obstacle to patent protection for plants, the written description requirement. As noted above, in relation to asexually reproduced plants, the PPA relaxed the written description requirement that applied to utility patents. However, applicants for utility patents for plants must adhere to the heightened level of disclosure required for utility patents. Although the Treaty applies only to microorganisms, it served as a model that was adopted by patent offices worldwide to deal with the problem of adapting the written description requirement to complex biological materials, in

particular living organisms. The solution proffered by the Treaty to the problem of complying with the written description requirement in relation to claims over novel microorganisms is for applicants to deposit the claimed microorganism with a publicly accessible depositary authority. The USPTO and other patent offices around the world then extended the application of the *Budapest Treaty* to plants and other biological materials. Thus, the description requirement with respect to plants could be satisfied by depositing seeds of the claimed plant(s) with a publicly accessible depositary authority.

Following the Board's decision in 1985, the USPTO commenced granting utility patents for plants. Though controversial, this practice continued unchallenged until the late 1990s, when Pioneer Hi-Bred commenced patent infringement proceedings against JEM Ag-Supply in respect of certain of its patents for hybrid and inbred corn seeds and plants. In reply, J.E.M. attacked the validity of the patents and, in doing so, reopened the question of whether plants were patentable subject matter under the utility patent statute. In *JEM Ag Supply v Pioneer Hi-Bred International Inc*, a majority of the US Supreme Court conclusively determined that plants are covered by the utility patent statute. Like the Board in *Hibberd*, the majority in *JEM Ag Supply* rejected the argument that the PPA and the PVPA represented the exclusive forms of protection available for plants. The majority noted that as the Supreme Court had done in *Chakrabarty* that Congress had utilised broad language to define the boundaries of patentable subject matter. The majority also reasoned that the decision to exclude sexually-reproduced plants from protection under the PPA merely reflected the reality of plant breeding at the time: according to the majority, sexually-reproduced plants were excluded from the PPA because new varieties could not be reproduced true-to-type through seedlings. However, this no longer represents the realities of modern plant breeding. Finally, the majority concluded that the differences between the requirements for, and coverage of, utility patents and PVPA certificates do not represent irreconcilable conflicts because the requirements for a utility patent are more stringent than those for a PVPA certificate, and the protections afforded by a utility patent are greater than those afforded by a PVPA certificate.

At the time of the US Supreme Court's decision in *JEM Ag Supply*, over 1,800 utility patents had been granted for seed and plant-related patents. The main differences between the various forms of plant variety protection in the US can be summarised as follows:<sup>37</sup>

- The PPA limits protection to asexual reproduction. Neither the PVPA or utility patent statutes contain any such limitation;
- A utility patent permits the applicant to claim multiple parts of the plant, including plant genes coding for non-plant proteins. Under the PPA protection is limited to reproduction of the entire plant, as well as selling and using parts of the plant so reproduced. Moreover, unlike utility patents, plant patents are not available in respect of methods of producing plants;
- A utility patent may be used to claim multiple varieties. Such is not the case for the PPA or the PVPA;
- The scope of protection under the PPA and the PVPA is limited to individual plants. Depending on the language and type of claim, the scope of protection under utility patents may extend to other plant varieties;
- The scope of protection granted by the PVPA is subject to a number of exceptions, including farm-saved seed, experimental use, and the breeder's exemption. In contrast, the

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<sup>37</sup> Mills, O., *Biotechnological Inventions: Moral Constraints and Patent Law*, Aldershot: Ashgate Publishing Ltd., 2005, at p. 120.

only exception to the scope of protection granted by a utility or plant patent is experimental use, which the courts have defined narrowly.

## 2.3 Plants as Patentable Subject Matter in Europe

The law relating to patentable subject matter, and the requirements for the grant of a valid patent, is for most countries in the European Economic Community governed by the *European Patent Convention* (EPC).<sup>38</sup> As with the United States, there is no general exclusion of living organisms from the scope of patentable subject matter under the EPC.<sup>39</sup> However, the situation regarding the patentability of plants in Europe is considerably more complicated than in the United States or Australia, for a number of reasons. First, the EPC expressly prohibits the granting of patents in respect of plant varieties.<sup>40</sup> This exclusion reflects the fact that at the time the EPC was negotiated and entered into force the UPOV Convention contained a prohibition on dual protection of plant varieties both by patent law and plant variety rights. Whilst the prohibition on dual protection has since been removed from the 1991 text of the UPOV Convention, the exclusion has been retained in the EPC. Secondly, the EPC prohibits the granting of patents in respect of ‘essentially biological processes’ for the production of plants.<sup>41</sup> Finally, the EPC provides that patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to ‘*ordre public*’ or morality.<sup>42</sup> Whilst the scope of the exclusion of plant varieties from protection is now reasonably settled, doubts remain over the scope of the prohibitions relating to ‘essentially biological processes’ and inventions the publication or exploitation of which would be contrary to public order or morality.

### 2.3.1 *The Prohibition on Patents for Plant and Animal Varieties*

The exclusion of plant varieties from the scope of patentable subject matter under the EPC is explicable on the basis that the EPC was drafted in light of the UPOV Convention. In order to ensure that plant breeders were not able to obtain patent protection and plant variety protection for the same plant variety, it was decided that the two conventions should be mutually exclusive: a person could be given a plant variety right or patent protection, but not both.<sup>43</sup> As such, the exclusion of plant varieties from the EPC reflected the then existing prohibition in the UPOV Convention upon dual protection of plant varieties.

The first decision of the EPO to consider the ambit of this provision was *Ciba-Geigy/Propagating Material*.<sup>44</sup> In *Ciba-Geigy*, the EPO decided that the exclusion ‘prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety’. The term ‘plant variety’ was to be given the same meaning as it has in UPOV. On the other hand, plant innovations ‘which cannot be given the protection afforded to varieties are still patentable if the general prerequisites [of novelty, inventive step, and industrial application] are met’. This interpretation was necessary to ensure there is ‘no conflict between the areas reserved for national protection of varieties and the field of application of the EPC’.<sup>45</sup> The effect of this

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<sup>38</sup> As of 1 January 2008, the EPC has 34 member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

<sup>39</sup> *Ciba-Geigy/Propagating Material* T49/83 [1979-85] EPOR C758, at p. 759.

<sup>40</sup> EPC, Article 53(b).

<sup>41</sup> EPC, Article 53(b). This does not include microbiological processes or the products thereof.

<sup>42</sup> EPC, Article 53(a).

<sup>43</sup> Sherman, B., & Bently, L., *Intellectual Property Law*, 2<sup>nd</sup> Ed., Oxford: Oxford University Press, 2004, at p. 426.

<sup>44</sup> T49/83 [1979-85] EPOR C758.

<sup>45</sup> This interpretation was followed in *Lubrizol/Hybrid Plants* T320/87 [1990] EPOR 173, in which a claims to hybrid seed and plants were held to be patentable on the basis that at least one of the parent plants is heterozygous with

interpretation was to preserve the availability of patent protection for plants which are not capable of protection by plant variety rights, as well as inventions which relate to more than one variety, and methods of breeding plants that are not ‘essentially biological’.

Although the prohibition on dual protection of plant varieties was omitted from the 1991 text of the UPOV Convention, the prohibition on the patenting of plant varieties has been maintained in the EPC. In *Novartis/Transgenic Plant*,<sup>46</sup> the Enlarged Board of Appeal of the EPO provided further clarification of the ambit of the prohibition. In particular, the Board held that the exclusion only applies to claims specifically directed to a particular plant variety. This means that claims to plants will be allowed even if they encompass a plant variety, so long as they do not individually claim specific plant varieties.<sup>47</sup> Thus, a claim that embraces more than one variety of plant will be patentable, whereas a claim to a specific plant variety will not. Claims to most genetically-modified plants are therefore likely to be accepted since the technical feasibility of such inventions is typically not limited to specific plant varieties, but is capable of implementation in a number of different plant varieties.<sup>48</sup> The Board stated that this interpretation accords with the purpose of the exclusion. According to the Board, Article 53(b) ‘defines the borderline between patent protection and plant variety protection. The extent of exclusion for patents is the obverse of the availability of plant variety protection’.<sup>49</sup> Thus, inventions ineligible for protection under the plant breeder’s rights system were intended to be patentable under the EPC provided they fulfilled the other requirements of patentability.<sup>50</sup>

In summary, the position regarding the patentability of plants in Europe is as follows: the purpose of the exclusion is to prohibit the grant of patents for plant varieties that are capable of protection by plant breeder’s rights. A claim directed to a specific variety of plant will therefore not be patentable, however a claim that encompasses more than one variety will be patentable. Most genetically-modified plants will be patentable to the extent that the invention can be implemented in more than one variety of plant.

### **2.3.2 ‘Essentially Biological’ Processes**

In addition to prohibiting the granting of patents for plant and animal varieties, Article 53(b) of the EPC also prohibits patents from being granted in respect of ‘essentially biological processes’ for the production of plants or animals’. The scope of this provision has been considered by the EPO on a number of occasions (predominantly in relation to plants), however, its precise ambit remains unclear. In *Lubrizol/Hybrid Plants*,<sup>51</sup> the EPO held that the question of whether or not a process is ‘essentially biological’ had to be ‘judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved’. Human intervention was not, in itself, sufficient to bring the process outside the exclusion. Although the process claimed by the applicant in *Lubrizol* consisted entirely of selection and crossing steps, the Board held that it fell outside the exclusion because the arrangement of these steps as a whole represented a fundamental modification of known biological processes. Further, these steps had a decisive impact upon the desired breeding population.

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respect to a specific trait and therefore will never breed true, with the result that the subsequent generations of plants, consider as a whole population, were not stable and therefore could not be considered as a ‘variety’.

<sup>46</sup> G01/98 [2000] EPOR 303.

<sup>47</sup> *Novartis/Transgenic Plant* G01/98 [2000] EPOR 303, at p. 322. The decision thus overrules the earlier decision of the Technical Board of Appeal of the EPO in *Plant Genetic Systems/Glutamine Synthetase Inhibitors (Opposition by Greenpeace)* T356/93 [1995] EPOR 357, in which the Board held that claims that encompassed or included within their scope a plant variety could not be patented.

<sup>48</sup> *Ibid.*, at pp. 318, 319.

<sup>49</sup> *Ibid.*, at p. 319.

<sup>50</sup> *Ibid.*, at p. 317.

<sup>51</sup> T320/87 [1990] EPOR 173.

In *Plant Genetic Systems/Glutamine Synthetase Inhibitors (Opposition by Greenpeace)*,<sup>52</sup> the EPO held that a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result, does not fall within the exception. The method claimed in this case was a process for producing transgenic plants and seeds which are resistant to a particular class of herbicides (glutamine synthetase inhibitors). The EPO held that the process was patentable because the step of transforming the plant cells with a recombinant DNA sequence is an essential technical step that has a decisive effect upon the desired final result. Although the subsequent steps of regenerating and replicating the plants or seeds make use of natural machinery, the decisive step – the insertion of the relevant DNA sequence into the genome of the plant – could not occur without human intervention.

In *Novartis/Transgenic Plant*,<sup>53</sup> the Technical Board of Appeal of the EPO said that a decision about whether or not a process is ‘essentially biological’ involves a value judgment about the extent to which a process should be non-biological before it loses the status of ‘essentially biological’. The EPO said that there are three possible approaches to the interpretation of the provision:

- (1) Under the first approach, a process or method would be excluded if it includes an aspect or step that is biological. In other words, only those processes or methods consisting exclusively of non-biological steps would be patentable according to this approach;
- (2) The second approach, which is based on the *Lubrizol* decision, requires the decision-maker to weigh up the overall degree of human intervention in the process. Under this approach, the decision of whether or not a process or method is ‘essentially biological’ would be judged on the basis of the essence of the invention, taking into account the totality of human intervention and its impact on the result achieved.
- (3) According to the third option, the presence of a single artificial (or technical) element in the process or method would be sufficient to carry that process or method outside the exception.

However, the EPO did not indicate which approach it preferred. The subsequent introduction of the European Biotechnology Directive (discussed in further detail below) has further clouded the interpretation of the ‘essentially biological processes’ exclusion. Article 2(2) of the Directive, which is replicated in Rule 23b(5) of the EPC Implementing Regulations, provides that a process for the production of plants and animals is essentially biological if it consists *entirely* of natural phenomena such as crossing and selection. As the Technical Board of Appeal of the EPO noted recently in *Plant Bioscience/Broccoli*,<sup>54</sup> there is a conflict between this rule and previous decisions of the EPO. In particular, the rule contradicts the *Lubrizol* and *Plant Genetics Systems* decisions, which held that human intervention in a process or method will only carry a process or method outside the exclusion where it has a decisive impact on the final result and that a process consisting entirely of natural phenomena such as crossing and selection may fall outside the exception in these circumstances.

The patent application in *Plant Bioscience/Broccoli* illustrates the differences between the two approaches. The application relates to a method for the production of broccoli plants with elevated levels of anti-carcinogenic compounds (glucosinolates). The method involves several steps of crossing and selection, some of which are carried out with the assistance of molecular markers. Under Article 2(2) of the Biotechnology Directive, the method would be patentable

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<sup>52</sup> T356/93 [1995] EPOR 357.

<sup>53</sup> T1054/96 [1999] EPOR 357.

<sup>54</sup> (2007) 12 *Official Journal of the European Patent Office* 644.

because it does not consist entirely of natural phenomena. On the other hand, under the approach adopted in prior case law of the EPO the method would not be patentable because the use of molecular markers does not, in the Board's view and in light of the prior art, contribute 'anything beyond a trivial level to the claimed invention'. In view of this conflict, the Technical Board of Appeal decided to refer the case to the Enlarged Board of Appeal, the highest Board of Appeal in the EPO, to make a legal determination on the correct approach to be taken. However, the Board did provide some helpful insights into the history and the purpose of the provision. In particular, the Board explained that the drafters of the EPC regarded 'biological' as being opposition to 'technical' and that they deliberately chose the word 'essentially' in preference to the narrower 'purely', which appeared in an earlier draft of the EPC.<sup>55</sup> The Board also pointed out that the drafters of the EPC considered that plant breeding processes based on selection and hybridisation fell within the exclusion, as is the case under Article 2(2) of the Biotechnology Directive. However, the Board described this as a 'legal fiction' since 'the systematic crossing and selection as carried out in traditional plant breeding would not occur in nature without the intervention of man'.<sup>56</sup> The Board has therefore asked the Enlarged Board of Appeal to provide a legal determination on whether a process or method which contains a technical step that makes only a trivial contribution to the final outcome is excluded from patentability.

This referral has been consolidated with another referral relating to tomatoes produced by traditional breeding techniques. In *State of Israel/Tomatoes*<sup>57</sup> the application claimed a method of crossing *Lycopersicon esculentum* plants with *Lycopersicon* species to produce hybrids, and then re-crossing and selecting for reduced fruit water content by screening 'ripe fruit and wrinkling of the fruit skin' on the vine. Although the production of these plants involved the conventional techniques of crossing and selection unaided by technical means, nevertheless the applicant argued that the interspecies crossing required 'special intervention in order to reach a reliably fertile offspring and would not occur in nature since individuals belonging to separate species are generally not capable of interbreeding.' The applicant further argued that: on the vine screening after ripening was not a normal or natural criteria; leaving the fruit on the vine 'prepared the tomato fruit for being susceptible for selection'; and, selecting for an increased dry weight required the technical intervention of weighing. The Board considered that interspecies crossing and weighing did satisfy the threshold of human intervention to avoid the exclusion, although to be sure, they recognised that there was already a referral to the Enlarged Board of Appeal in *Plant Bioscience/Broccoli*, and so considered a range of further questions that might be referred.

The Enlarged Board's decision in these two cases, which is anticipated to finally bring some certainty to this issue, is eagerly awaited.

### **2.3.3 *Ordre Public and Morality***

Finally, the EPC prohibits the granting of patents the publication or exploitation of which would be contrary to public order or morality. The meaning of *ordre public* and 'morality' was considered by the EPO in *Plant Genetic Systems/ Glutamine Synthetase Inhibitors (Opposition by Greenpeace)*,<sup>58</sup> In that decision, the EPO held that the concept of *ordre public* covers the protection of public security and the physical integrity of individuals as part of society, as well as protection of the environment, whilst the concept of 'morality' refers to the totality of accepted norms of conduct inherent in European society.<sup>59</sup> In *Plant Genetic Systems*, Greenpeace opposed the grant of a patent

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<sup>55</sup> The earlier draft proposed that 'purely biological, horticultural or agricultural (agronomic) processes' shall not be patentable.

<sup>56</sup> *Plant Bioscience/Broccoli* (2007) 12 *Official Journal of the European Patent Office*, at pp. 660, 668.

<sup>57</sup> (2008) 11 *Official Journal of the European Patent Office* 523.

<sup>58</sup> T356/93 [1995] EPOR 357.

<sup>59</sup> *Plant Genetic Systems/ Glutamine Synthetase Inhibitors (Opposition by Greenpeace)* T356/93 [1995] EPOR 357, at p. 366.

for genetically-modified seeds and plants that were resistant to a particular class of herbicides, namely the glutamine synthetase inhibitors, on the ground that the exploitation of the patent would damage the environment, and thus was contrary to public order and/or morality. The Technical Board of Appeal of the EPO rejected Greenpeace's argument. The Board commenced by noting that plant biotechnology 'cannot be regarded as being more contrary to morality than traditional selective breeding because both traditional breeders and molecular biologists are guided by the same motivation, namely to change the property of a plant by introducing novel genetic material into it in order to obtain a new and, possibly, improved plant'.<sup>60</sup> The Board conceded that it would 'undoubtedly' be contrary to *ordre public* or morality to propose a misuse or destructive use of plant genetic engineering techniques, however it stated that a decision to revoke a patent on the grounds that the exploitation of the invention would seriously prejudice the environment would not be made without evidence to sufficiently substantiate the alleged threat to the environment. As Greenpeace had provided no such evidence its argument failed.

In practice, the exclusion has arisen mostly in relation to animals. In *Harvard/Onco-mouse*,<sup>61</sup> the EPO applied a cost/benefit approach to the question of whether the exploitation of a patent for a genetically-modified mouse that is predisposed to develop cancer was contrary to public order or morality. Weighing the relative benefits and costs associated with the intended use of the invention in cancer research, the EPO held that the potential benefits to be derived from such research outweighed the harm and suffering caused to the mice. The mouse was therefore patentable.<sup>62</sup>

In contrast, in 1991 the EPO rejected an application made by Upjohn in respect of a genetically-modified mouse disposed to develop alopecia (hair-loss) which was intended to be used in research aimed at discovering treatments for baldness. Applying the same cost/benefit approach that was applied in *Harvard/Onco-mouse*, the EPO decided that the harm likely to be suffered by the mice outweighed any potential benefit to be derived from research relating to hair growth, which, according to the EPO, is not connected with 'any serious threat to human beings'.<sup>63</sup> The EPO accordingly held that exploitation of the claimed invention would be contrary to public order or morality and was therefore unpatentable. Recently, an application by the University of Texas over dogs – beagles, in particular – whose immune systems had been rendered defective by radiation in order to mimic weakened human immune systems drew widespread criticism in Europe and North America. The dogs, which were intended to be used in HIV research (amongst other areas), were held by the EPO to be unpatentable, though not because of the public order or morality provision (which it did not consider). However, opponents of the patent have reserved the right to rely on the provision in any future EPO proceedings.

The EPO's approach in *Harvard/Onco-mouse* has now been superseded by Rule 23d(d) of the EPC Implementing Regulations.<sup>64</sup> Rule 23d(d) provides that European patents shall not be granted for biotechnological inventions that concern processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal. The rule also applies to animals resulting from such processes.

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<sup>60</sup> *Plant Genetic Systems/ Glutamine Synthetase Inhibitors (Opposition by Greenpeace)* T356/93 [1995] EPOR 357, at p. 369.

<sup>61</sup> T19/90 [1990] EPOR 501.

<sup>62</sup> The patent application was eventually accepted in 2004 when proceedings in the EPO were finally concluded.

<sup>63</sup> *Upjohn's Application (Hairless Mouse)* [1991] EP 89 913 146.0 (unreported), referred to in Warren-Jones, A., 'Vital Parameters for Patent Morality – A Question of Form', (2007) 2 *Journal of Intellectual Property Law and Practice* 12, 832 at p. 835, n. 16.

<sup>64</sup> Rule 23d(d) implements Article 6(2)(d) of the Biotechnology Directive.



### ***2.3.4 The European Biotechnology Directive***

The EPC has been supplemented by the introduction of the European Biotechnology Directive in 1998.<sup>65</sup> The Directive contains a set of minimum standards and principles of interpretation relating to the patenting of biotechnology inventions, which must be implemented in the national patent laws of member countries of the European Community. Though not legally required to do so, the EPO applies the provisions of the Biotechnology Directive to applications relating to biotechnology filed with EPO.<sup>66</sup> The Biotechnology Directive clarifies a number of issues relating to the patenting of biological material in Europe. Commercially, the most significant provisions in the Directive relate to the nature and scope of claims to DNA sequences, genes and the like. The Directive provides that an element, such as a DNA sequence, that is isolated from its surrounding environment by means of a technical process is patentable,<sup>67</sup> provided the patent application discloses the industrial application of the element.<sup>68</sup> The industrial application requirement will not be met unless the function of the DNA sequence is disclosed. For example, if the DNA sequence is used to produce a protein or part of a protein, the protein (or part thereof) that is produced, or the function performed by the protein, must be disclosed.<sup>69</sup>

In a significant extension of the scope of the rights conferred by a patent on a gene, the Directive also provides that the protection conferred by a patent on a product containing or consisting of genetic information (such as a gene) shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function.<sup>70</sup> Thus, a claim to a gene that has been incorporated into a plant or animal will extend to the plant or animal and to offspring of that plant or animal. Likewise, Article 8(1) of the Directive states that the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.<sup>71</sup> Thus, a claim to genetically-modified plant cells will extend to plants containing those cells.

These principles are subject to the limited exceptions contained in Articles 10 and 11. Article 10 clarifies that the reproduction of biological material for a purpose for which it was marketed does not constitute patent infringement. Thus, seed produced from legitimately purchased seed does not of itself constitute patent infringement. Article 11(1) also provides a limited authorisation for a farmer who purchases propagating material to use the product of his or her harvest for propagation or multiplication on his or her own farm, whilst Article 11(2) permits a farmer to use patented livestock for the purpose of pursuing his or her 'agricultural activity', provided that this does not involve the sale of livestock or is not otherwise done for the purpose of commercial reproduction.

The Directive also clarifies that a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the exclusion of plant varieties and is not therefore

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<sup>65</sup> The Directive is effective as of 1 September, 1999.

<sup>66</sup> Rule 23b(1) of the EPC Implementing Regulations provides that the Directive must be used as a supplementary means of interpretation of the EPC.

<sup>67</sup> Article 5(2).

<sup>68</sup> Article 5(3).

<sup>69</sup> Recitals 23 and 24.

<sup>70</sup> Article 9.

<sup>71</sup> 'Biological material' is defined in Article 2(1)(c) as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

excluded from patentability even if it comprises new varieties of plants.<sup>72</sup> Thus, genetically-modified plant varieties are in principle patentable.

## 2.4 Plants as Patentable Subject Matter in Australia

The patenting of inventions in Australia is governed by the *Patents Act 1990*. In Australia, two types of patent are available: standard and innovation patents. The innovation patent was introduced in 2001 as a second-tier form of protection for incremental innovations that are likely to have a short commercial life. Both the term of an innovation patent (eight years as opposed to twenty years for a standard patent) and the level of inventiveness (an ‘innovative’ step rather than an inventive step) necessary to obtain the grant of an innovation patent are less than that of a standard patent.

There are also important differences in the types of subject matter that are capable of being protected by each type of patent. In particular, whilst the subject matter capable of protection by each type of patent must consist of a ‘manner of new manufacture’,<sup>73</sup> plants (and animals), and the biological processes for the generation of plants (and animals), are not capable of protection by an innovation patent.<sup>74</sup> However, this does not apply to microbiological processes or the products thereof.<sup>75</sup> In respect of standard patents, the only limitation upon the type of subject matter that is capable of protection is that human beings, and the biological processes for their generation, are not capable of protection.<sup>76</sup> This limitation applies equally to innovation patents.

### 2.4.1 ‘Manner of Manufacture’

The law as to patentable subject matter in Australia is, and always has been, among the most liberal of any patent system. Along with Europe, Japan and the United States, Australia is one of only three countries in which patents may be obtained for new plant (and animal) varieties. Although no Australian court has directly considered the patentability of plants or animals, the High Court of Australia’s decision in *National Research Development Corporation v Commissioner of Patents*<sup>77</sup> (NRDC) has been widely interpreted as lending implicit support to the notion that plants are patentable.<sup>78</sup>

As noted above, the question of whether an invention constitutes patentable subject matter under Australian patent law depends on whether the invention can be classified as a ‘manner of manufacture’. In NRDC, the High Court of Australia emphasised that the words ‘manner of manufacture’ were not to be read literally. That is, the question is not ‘is this a manner (or kind) of manufacture?’. Instead, the phrase was to be given a meaning which gives effect to the underlying purpose of section 6 of the *Statute of Monopolies 1623*, the statute from which the phrase is drawn. In broad terms, the Court held that a product or process will be patentable if it consists of an ‘artificially created state of affairs’ that ‘offers some advantage which is material, in the sense that [it] belongs to a useful art as distinct from a fine art – that its value to the country is in the field of economic endeavour’.<sup>79</sup> Although the High Court did not further elaborate on

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<sup>72</sup> Recital 31.

<sup>73</sup> *Patents Act 1990*, subsections 18(1)(a); 18(1A)(a).

<sup>74</sup> *Patents Act 1990*, subsection 18(3).

<sup>75</sup> *Patents Act 1990*, subsection 18(4).

<sup>76</sup> *Patents Act 1990*, subsection 18(2). In addition, the Commissioner of Patents may refuse to accept an application for a standard patent in respect of an invention the use of which would be contrary to law: subsection 50(1)(a). However, this discretion has only rarely been exercised.

<sup>77</sup> (1959) 102 CLR 252.

<sup>78</sup> ‘The liberating effect of NRDC in opening up the range of patentable subject matter cannot’, Ricketson has argued, ‘be underestimated’: Ricketson, R., ‘The Patentability of Living Organisms’, in Galligan, D. J. (ed.), *Essays in Legal Theory: A Collaborative Work*, Melbourne: Melbourne University Press, 1984, pp. 85-113, at p. 95.

<sup>79</sup> (1959) 102 CLR 252, at p. 275.

what constitutes an ‘artificially created state of affairs’, in *Grant v Commissioner of Patents*,<sup>80</sup> the Full Court of the Federal Court of Australia held that the concept contemplates a ‘physical effect in the sense of a concrete effect or phenomenon or manifestation or transformation’.<sup>81</sup>

From the perspective of the patentability of plants, an important consequence of this open-ended, purpose-based approach to the question of patentable subject matter was to eliminate the then prevalent notion that agricultural and horticultural methods were not patentable subject matter. Prior to the High Court’s decision in *NRDC*, a number of cases had been decided in which applications directed to agricultural or horticultural methods had been refused for failing to disclose any manner of manufacture.<sup>82</sup> For example, in *Rau GmbH’s Application*,<sup>83</sup> an application pertaining to the selective cultivation of lupin seeds having both a higher oil content and lower alkaline content than normal, thus rendering them fit for commercial oil extraction, was rejected on the basis that:

Selective breeding of animals and cultivation of plants for the obtainment of improved stocks by rigorous selection of and breeding from the few individuals which are nearest the ideal has, as well known, been practised from the earliest times as a part of agricultural or horticultural development, as for example in the production of improved flowers or fruit with desired characteristics in the progeny, and the exercise of art or skill in these directions has not been regarded as coming within the term ‘manufacture’.<sup>84</sup>

So too in *RHF’s Application*,<sup>85</sup> Morton J expressed agreement with the examiner’s comment that ‘fruit and other crops, although the assistance of man may be invoked for their planting and cultivation, do not result from a process which is a ‘manner of manufacture’ as defined in the Acts’.

From decisions such as these emerged an ‘established [Patent] Office practice’ in the United Kingdom of denying protection for new varieties of plants or for new agricultural or horticultural methods on the basis that such did not consist in a ‘manner of manufacture’.<sup>86</sup> The High Court reviewed these decisions and their reasoning in *NRDC* and found that these cases not only provide ‘a classic illustration of thinking in terms of the everyday concept of manufacture instead of following the lines along which, over a long period, the courts have given

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<sup>80</sup> (2006) 234 ALR 230.

<sup>81</sup> *Ibid.*, at p. 237.

<sup>82</sup> It is not clear whether this practice also extended to the products of agricultural and horticultural processes, i.e. plants and plant varieties. In 1931, the Sargant Committee considered a proposal to extend the scope of patentable subject matter to scientific discoveries, thereby bringing within the remit of patent law a wider range of biological inventions, including new plant varieties. The proposal was rejected by the Sargant Committee on the basis that ‘biological developments involving invention are already capable of protection under the existing law’: Board of Trade, *Report of the Departmental Committee on the Patents and Designs Acts and Practice of the Patent Office*, Cmd. 3829, London: HMSO, 1931, at p. 61.

<sup>83</sup> (1935) 52 RPC 362.

<sup>84</sup> See also *Hamilton-Adams’ Application* (1918) 35 RPC 90 (process for rotating crops); *Standard Oil Development Co’s Application* (1951) 68 RPC 114 (method for the production of an improved tract of land by application of a selective herbicide); *Lenard’s Application* (1954) 71 RPC 190 (improved method of combating fungal disease in clove trees by method of pruning and spraying); *NV Philips Gloeilampenfabrieken’s Application* (1954) 71 RPC 192 (method of producing new form of Poinsettia by modification of climatic conditions); *Dow Chemical Co’s Application* [1956] RPC 247 (method of producing improved soil by application of seedicidal composition); *American Chemical Paint Co’s Application* [1958] RPC 47 (method of defoliating cotton prior to harvest so as to save cotton from contamination); *Virginia-Carolina Chemical Co’s Application* [1958] RPC 35 (method for eradicating nematodes from soil). Similar types of processes in relation to animals were also refused on this basis. See, for example, *Canterbury Agricultural College* [1958] RPC 85 (method of increasing wool yield of sheep by administration of certain substances).

<sup>85</sup> (1944) 61 RPC 49.

<sup>86</sup> As the Superintending Examiner noted in *Dow Chemical Co’s Application* [1956] RPC 247, ‘it has never been the practice of the Office to grant patents for methods of agriculture or for methods of cultivating the land’.

effect to the real purpose and operation of section 6 of the *Statute of Monopolies*,<sup>87</sup> the proposition for which the Patent Office alleged they stood ‘seems an example of a generalization not supported by the reasons leading to the conclusions in the particular instances from which the generalization is drawn’.<sup>88</sup> Consistent with the broad, open-ended, policy-based approach to the interpretation of ‘manner of manufacture’ emphasised earlier in its judgment, the Court concluded that there was nothing inherent in the nature of agricultural and horticultural processes which rendered them unfit for patent protection.<sup>89</sup>

As a majority of the High Court noted in *Grain Pool of Western Australia v Commonwealth of Australia*,<sup>90</sup> ‘the effect of the decision in *National Research Development Corporation* is to confirm that there is no intrinsic impediment to the patentability of plant varieties.’<sup>91</sup> Certainly, genetically-modified plants and animals are considered to be an ‘artificially created state of affairs’ and hence, patentable. Moreover, new plant varieties and animal breeds produced by conventional methods (such as crossing and selection) may also be patentable if the variety is artificial – that is, it is unlikely to occur in nature without human intervention – and the breeder has exercised control over the end result. Indeed, the first patent for a plant granted by the Australian Patent Office was for an orchid produced by conventional breeding methods.<sup>92</sup>

Whilst *NRDC* confirmed that there was no intrinsic impediment to the patentability of plant varieties in Australia, the first Australian plant patent was not granted until 1984.<sup>93</sup> There are a number of possible reasons for this anomaly. Most obviously (bearing in mind that most patents granted to date have been for genetically-modified plants), genetic transformation techniques were not introduced until the 1970s, whilst genetically modified plants were not released commercially before the 1980s. Genetically modified plants notwithstanding, the High Court’s decision in *NRDC* also left a number of issues unresolved. In particular, whilst *NRDC* confirmed that there was nothing in the nature of agricultural and horticultural *processes* which rendered them unsuitable for patent protection, it was doubted whether living organisms as such were patentable subject matter.<sup>94</sup> To date, no Australian court has ruled on this issue. However, in 1976 the Assistant Commissioner of Patents accepted that living organisms are patentable subject matter in *Ranks-Hovis McDougall Ltd’s Application*.<sup>95</sup> In that case, the examiner rejected an application for certain naturally-occurring and mutant strains of *Fusarium graminearum* on the basis that living organisms are not patentable subject matter. On appeal, the Assistant Commissioner reversed the examiner’s decision on the ground that the ‘objection that claim to a new microorganism, being something living, is not a manner of manufacture is based on too

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<sup>87</sup> (1959) 102 CLR 252, at pp. 278-9.

<sup>88</sup> (1959) 102 CLR 252, at p. 278.

<sup>89</sup> In a case decided the year previous, Lloyd-Jacob J, sitting as the Patents Appeal Tribunal, already appeared to reject this reasoning as unsound, noting that ‘[t]he increasing use of naturally occurring organisms for initiating or controlling or modifying manufacturing operations has wholly outmoded as a rule of thumb guide a restriction of patentability to inanimate matter’: *Virginia-Carolina Chemical Corp.’s Application* [1958] RPC 35, at p. 37.

<sup>90</sup> (2000) 202 CLR 479.

<sup>91</sup> *Ibid.*, at p. 502 per Gleeson CJ, Gaudron, McHugh, Gummow, Hayne and Callinan JJ. Earlier in their joint judgment (at p. 496) their Honours state that ‘it would be wrong to regard the legislative grant of monopoly rights in new plant varieties as being, in 1900, outside the ‘central type’ of the subject of patents of inventions.’

<sup>92</sup> Australian Patent No. 532235, ‘Cymbidium Orchid Cultivar’ (Adelaide Orchids Pty Ltd) (otherwise known as ‘Scott’s Sunrise Aurora’).

<sup>93</sup> *Ibid.*

<sup>94</sup> In addition, the High Court appeared to concur with the views expressed in *Lenard’s Application* (which related to a method pruning to reduce mortality from disease in clove trees) and *N.V. Philips Gloeilampenfabrieken’s Application* (which concerned a method for producing a new form of poinsettia), both of which ‘seem to depend on the view that the process in question was only one for altering the conditions of growth, so that the contemplated end result would not be a result of the process but would be ‘the inevitable result of that which is inherent in the plant.’

<sup>95</sup> (1976) 46 *Australian Official Journal of Patents, Trade Marks and Designs* 39, 3915 (21 October, 1976).

restricted a view of the meaning of manufacture in Section 6 of the *Statute of Monopolies*'. However, the Assistant Commissioner upheld the examiner's rejection of certain claims to naturally-occurring strains of the microorganism on the grounds that these claims both lacked novelty and did not consist of a manner of manufacture (being, at best, a discovery). On the other hand, the Assistant Commissioner accepted certain claims directed to mutant strains of the microorganism. The position in respect of these claims was, according to the Assistant Commissioner, different:

In respect of the invention claimed by claim 2, what has 'the inventor done'? What contribution has he made? He has discovered a naturally occurring microorganism and, by altering its conditions of growth, he has changed its morphological characteristics. If that is all he has done, he has made no useful contribution to the art. On the other hand, I think the situation is different if, in producing the variant by some man controlled microbiological process, he has produced a new microorganism which has improved or altered useful qualities.<sup>96</sup>

Finally, on 17 April 1980, almost two months to the day before the United States Supreme Court's decision in *Chakrabarty*, an Official Notice was published in the Australian Official Journal of Patents, Trade Marks and Designs which confirmed that:

The criteria to be met before an application concerned with living organisms will be accepted are precisely the same as those for any other application, ie no distinction is to be made solely on the basis that a claimed product or process is, or contains or uses, a living organism. Higher life forms will not be treated any differently from other life forms such as microorganisms.<sup>97</sup>

#### **2.4.2 Innovation Patents**

Subsection 18(3) of the *Patents Act 1990* (Cth) provides that for the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions. Microbiological processes and the products of such processes do not fall within the scope of this exclusion.<sup>98</sup>

According to IP Australia, the intent of the exclusion is 'in part' to avoid overlap between the Innovation Patent and Plant Breeder's Rights<sup>99</sup> Accordingly, the boundary of the exclusion corresponds with the non-exhaustive definition of 'plant' provided in the *Plant Breeder's Rights Act* – namely, all fungi and algae, not including bacteria, bacteroids, mycoplasmas, viruses, viroids and bacteriophages'. Consequently, 'for the purposes of the innovation patent, the above meaning of 'plant' under s 18(3) includes all fungae (including yeasts and moulds) and algae. Since they are not considered to be either plants or animals, claims to microorganisms including bacteria, protozoans, bacteroids, mycoplasmas, viroids, bacteriophages and viruses *per se* are not excluded under s 18(3) and are suitable subject matter for an innovation patent.<sup>100</sup>

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<sup>96</sup> *Ibid.*, at p. 3918.

<sup>97</sup> Australian Patent Office, 'Patent Applications Concerned with Living Organisms', (1980) 50 *Australian Official Journal of Patents, Trade Marks and Designs* 13 (17 April 1980), p. 1162.

<sup>98</sup> *Patents Act 1990* (Cth) ss. 18(4).

<sup>99</sup> The veracity of this proposition is uncertain, as the legislation, the extrinsic materials (such as the Explanatory memorandum) and the parliamentary debate do not address this matter, albeit the proposition has been made in subsequent reviews: see, for example, Advisory Council on Intellectual Property, *Patentable subject matter*, Issues Paper (2008) p. 29. See also Advisory Council on Intellectual Property, *Should Plant and Animal Subject Matter be Excluded from Protection by the Innovation Patent?* (2004) pp. 31-34. Notably, this distinction has been made in other jurisdictions, albeit in dealing with the overlap of 'plant variety' rather than 'plant': see *Plant Bioscience/Broccoli* T0083/05(2007) 12 *Official Journal of the European Patent Office* 644 at 653-654; *Novartis/Transgenic plant* G01/98 [2000] EPOR 303 at 310 and 316-318 (addressing the dual protection of plant varieties under the *Convention on the Grant of European Patents*, Art 53(b)).

<sup>100</sup> IP Australia, *Australian Patent Office: Manual of Practice and Procedures* (2009) [2.31.4.6]. Notably the actual meaning of 'microorganisms' as used by IP Australia is unclear as many organisms that might otherwise be considered 'plants'

Examples of subject matters that are not considered patentable by IP Australia include:

- genetically modified whole plants, plants produced by cross-breeding of one strain with another strain, or selection of a plant from a range of plants;
- genetically modified whole animals (including human beings), animals produced by cross breeding of one strain with another strain, or selection of an animal from a range of animals;
- seeds of plants, plant tissue cultures, or any matter that could give rise to a plant; and,
- animal embryos or fetuses, zygote, or any matter or group of cells, that could give rise to an animal.<sup>101</sup>

## 2.5 Conclusion

In summary, then, plants are patentable subject matter in the United States, Europe, and Australia. The extent to which conventional breeding processes for both plants are patentable in Europe is also uncertain. Further, plant varieties are patentable in Europe so long as the invention is not limited to a particular variety or breed.

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and 'animals' (and within the Kingdoms Animalia and Plantae) are small in size (in fact, microscopic) so that a size standard for the terms 'plant' and 'animal' seems inappropriate.

<sup>101</sup> IP Australia, *Australian Patent Office: Manual of Practice and Procedures* (2009) [2.31.4.6]. See also IP Australia, *The Budapest Treaty and Australian Patents* (2008) p. 5.

# 3 Inventive Step and Enablement

## 3.1 Introduction

Whilst the question of whether or not living organisms in general, and plants in particular, are patentable subject matter occupied the attention of the courts throughout much of the 20<sup>th</sup> century, doubts also existed about the extent to which plants were able to conform to a number of other criteria for patent protection – in particular, the inventive step and written description requirements. In the former case, the methods used to introduce new, or to improve existing, traits in plants varieties had long been practiced and were regarded as presenting few difficulties to those skilled in the art; in the latter case, the procedures involved in improving on, or introducing new traits into, plant varieties were intolerably difficult reduce to written form, and often could not be reliably reproduced.

As evidenced by the increasing number of patents that are being granted for new plant varieties in the United States, Europe and Australia, these criteria are no longer regarded as being as insuperable as they once were.<sup>102</sup> In both cases, these obstacles have been wholly or partially negated: in the case of the written description/enablement requirement, the adoption of a deposit regime for living organisms, following the negotiation of the *Budapest Treaty*, resolved many of the difficulties faced by plant breeders in seeking to comply with that requirement; and, in relation to the inventive step, by subtle transformations in both legal doctrine and the way in which the activities of plant breeders are conceived. In neither case has this process been uncontroversial or unproblematic, nor is it settled: in respect of both conventionally-bred and genetically-modified plants, considerable uncertainty continues to surround the way in which both patent offices and the courts are applying these criteria to plants, particularly those produced by conventional plant breeding methods. As Janis and Kesan have observed, whilst the threshold question of whether plants are patentable subject matter has now been resolved, ‘there is very little law explaining how these prerequisites should be applied to patents that claim conventionally bred plants.’<sup>103</sup>

In this section, we consider some of the issues that arise with respect to the application of these criteria to plants.

## 3.2 Plant Breeding and Inventive Step

The inventive step requirement has long been regarded as an almost insurmountable obstacle to the patenting of plants produced using conventional techniques, such as crossing and selection. There are several reasons for this. For one, there was a persistent perception that the activities of plant breeders are inherently non-technical, and instead are subject to happenstance or governed more by natural exigencies than the exertions of the breeder, with the end result being attributable more to the vagaries of Nature than to the actions of the breeder. As the Engholm Committee explained in its 1960 Report:

It has also been suggested that plant breeding is much less scientific and more dependent on chance than invention. We do not think that any plant breeder would seek to deny the importance of chance. But the breeder’s “eye for a good plant” plays a decisive role. As Pasteur says, fortune favours the prepared mind. Moreover the marked advances of recent years in crop quality are due, mainly, to developments in scientific

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<sup>102</sup> Byrne, N., *Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties*, London: Centre for Commercial Law Studies, 1991, p. 12.

<sup>103</sup> Janis, M. D., and Kesan, J. P., ‘Intellectual Property Protection for Plant Innovation: Unresolved Issues After *J.E.M. v Pioneer*’, (2002) 20 *Nature Biotechnology*, 1161, at p. 1162.

breeding methods, aided by the vast extension which has taken place in the whole scale of breeding operations. Of course, progress in the application of modern techniques has been markedly uneven in the different groups of plants. Chance plays a more important role in some groups than in others. But where modern breeding techniques are properly used by teams of skilled geneticists, cytologists, statisticians and other experts, *the broad results of crossing different plants are reasonably predictable. So, up to a point, are the chances of obtaining in due course any particular combination of desired characteristics. Developed on these lines, the plant breeding process seems to use to provide a good example of scientific planning for the attainment of foreseen ends.* As such it is broadly comparable with much large scale industrial research and invention. In neither field is chance eliminated or success assured (emphasis supplied).<sup>104</sup>

The question of whether or not conventional plant breeding is sufficiently ‘technical’ remains unresolved, as evidenced by the TBA’s recent referral of this question to the EBA.

The fact that the techniques that are used in the production of new plant varieties are well-established, and their use presents few difficulties to those skilled in the art, also informed the perception that no inventive step is involved in the production of new plant varieties using traditional breeding methods. Moreover, the varieties resulting from the use of such techniques often differ only slightly from other similar varieties – that is to say, conventional plant breeding is a largely incremental process.<sup>105</sup> Accordingly, over time a presumption developed that plants produced by conventional plant breeding methods lacked the necessary inventive step to support a patent.<sup>106</sup> Thus, as Lazenby observes in his 1986 report, ‘initiatives to develop breeders rights legislation separate from that of patents arose when plant breeders in various countries had their patent applications rejected for a variety of reasons, including: plant breeding did not meet the inventive step criterion, since nearly all the procedures were well known and obvious.’<sup>107</sup> In other words, the perception that plant varieties produced by conventional breeding methods are uninventive arose by implication: as the techniques themselves were obvious and uninventive, so too the plants derived from the use of those techniques must also be obvious.

However, by the early 1980’s ‘a general view’ had begun to emerge among plant breeders that this presumption was misplaced.<sup>108</sup> Yet the circumstances which gave rise to this change in attitude are far from clear. According to Van Overwalle, whilst European commentators acknowledged that ‘the inventive step in the field of plant breeding was not evident’, nevertheless many argued that the inventive step requirement was ‘insuperable for there was always the possibility that the application of a known process would result in a new goal or in a new special effect.’<sup>109</sup> According to Byrne, a key factor in the displacement of this presumption is that both

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<sup>104</sup> Committee on Transactions in Seeds, *Plant Breeders’ Rights: Report of the Select Committee in Seeds*, Cmnd. 1092, London: HMSO, 1960.

<sup>105</sup> Report of the Expert Panel on Breeding, *Clarification of Plant Breeding Issues under the Plant Breeders Rights Act 1994*, 2002, at p. 20: ‘The differences between the previous and subsequent variety can be large, small or very small, with the latter being the most common.’ The Report may be obtained from: <http://www.anbg.gov.au/breeders/plant-breeders-rights-act-report.pdf>.

<sup>106</sup> In essence, the presumption was regarded as the natural corollary of the acknowledgement that techniques themselves were obvious and uninventive: since the techniques used to produce plants are obvious, so too the plants derived from the use of these techniques must also be obvious.

<sup>107</sup> Lazenby, A., *Australia’s Plant Breeding Needs: A Report to the Minister for Primary Industry*, Canberra: AGPS, 1986, at p. 122. See also Crespi, R. S., *supra* n. 8, at p. 271: ‘Realistic commentators admit that most varieties of the kind specifically presented for plant variety protection will not qualify for patent protection because of the difficulty of showing that they entail an inventive step. It would also be difficult to describe the method of breeding in a way that would be repeatable. Therefore, the PVR should remain as the preferred option for legal protection for innovations at the level of specific varieties.’ Cf. Byrne, N., *supra* n. 102, at p. 10: ‘The [Patent] Office’s view ... was that, however inventive new plant varieties might be, they were not inventions within the meaning of the law.’

<sup>108</sup> Byrne, N., ‘Plant Breeder’s Rights’, in Lahore, J., Dwyer, J. W., and Dufty, A., *Patents, Trade Marks and Related Rights*, Sydney: Butterworths, 1996, at para. [29,030].

<sup>109</sup> Van Overwalle, G., ‘Patent Protection for Plants: A Comparison of American and European Approaches’, (1999) 39 *IDEA – The Journal of Law and Technology*, 143 at p. 153. Thus, according to Van Overwalle, ‘in Europe, the inventive-step requirement was not seen as posing any fundamental problem with regard to plant patents’: at p. 181.



the inventive step and written description requirements ‘were understood during the formative period of the UPOV system rather differently than they are seen today.’<sup>110</sup> Undoubtedly, the negation of the two most formidable obstacles to the patenting of plants – (lack of) patentable subject matter and the written description/enablement requirements – in the 1970s and 1980s would have been a source of encouragement to plant breeders desirous of making use of the patent system.<sup>111</sup> From there, it was a matter of overcoming the perception that plant breeding is an exercise that is inherently uninventive. In particular, plant breeders sought to convince the patent bureaucracy that whilst the techniques used in plant breeding were well established and routine, it did not necessarily follow that the improvement of, or the introduction of new traits into, existing varieties is without difficulty, or that the results of any given breeding program are predictable.<sup>112</sup> This approach is highlighted by Williams and Weber, who state that:

In the context of a plant, the typical obviousness rejection arises when the patent examiner is faced with a novel characteristic such as added colour or increased sugar content and finds that such characteristic would have been obvious to a skilled breeder to attempt to breed for the selected character trait using the known methods. The rebuttal generally consists of arguing that even if the phenotype was perhaps suggested, the underpinning genetics were unknown and, therefore, success could not have been predicted. For example, a character trait may have been a complex of alleles that were not readily marshalled into a single individual.<sup>113</sup>

Judging by the number of patents that have been granted in respect of plant varieties produced by conventional breeding methods, patent offices in the U.S., Europe and Australia responded favourably to these arguments. Despite this, relatively little is known about the way in which patent offices in these jurisdictions apply the inventive step requirement to plants. In the proceeding section, we review the few published decisions in which the application of the inventive step requirement to plants has been considered, and consider the criticisms of the approach taken by the USPTO and the EPO in these cases.

### 3.3 Nonobviousness and Plant Breeding: United States

The application of the inventive step requirement to conventionally-bred plant varieties has been considered by the USPTO and the Federal Court of Appeal for the Federal Circuit on several occasions.<sup>114</sup> The first published decision documenting the USPTO’s approach to the application of the nonobviousness requirement to conventionally-bred plant varieties is the Board of Patent

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<sup>110</sup> Byrne, N., *supra* n. 102, p. 12: ‘the UPOV system was established because, according to the thinking of the time, the requirements for the grant of a patent could not be met by the breeder of a new plant variety. In the light of current thinking, the criteria, particularly the rules on reproducibility and inventive step, set no insurmountable obstacles for the breeder of a new plant variety who wishes to patent it ...’

<sup>111</sup> That the U.S. Supreme Court did not identify nonobviousness as an impediment to the patenting of plants in *J.E.M. Ag-Supply Inc v Pioneer Hi-Bred* 534 U.S. 124 (2001) is instructive.

<sup>112</sup> In this regard, an analogy was drawn between the efforts of plant breeders and the empirical work conducted by industrial chemists. As the Engholm Committee observed in its 1960 Report:

‘The discovery of new chemicals and chemical processes seems to us to provide a specially close parallel between industrial research and modern plant breeding. In the chemical field, extensive use is made of the modern industrial technique of large scale systematic search, in selected areas where experience suggests that useful discoveries are most likely to be made. As in plant breeding, trial and error necessarily play an important part in the process of elimination. Much research effort produces negative results. In the development of pesticides, hundreds of different formulae may be tested and rejected for every one found worthy of attention for further study. *Neither the chemist nor the hybridist has any certain means of knowing in advance which particular combination will give the best results. Success can be foretold only in a broad sense.*’

Committee on Transactions in Seeds, *supra* n. 104, at pp. 25-6.

<sup>113</sup> Williams, S. B., and Weber, K. A., ‘Intellectual Property Protection and Plants’, in Barton, J. H., Qualset, C. O., Duvick, D. N., and Barnes, R. F. (ed.s), *Intellectual Property Rights Associated with Plants*, ASA Special Publication No. 52, American Society of Agronomy, 1989, pp. 91-107, at p. 99.

<sup>114</sup> The US Circuit Court of Appeals had previously struggled with the question of how to apply the nonobviousness requirement to plant patents in *Yoder Bros v California Plant Corp.* 537 F. 2d 1347 (1976).

Appeals and Interferences' decision in *Ex parte C* in 1992.<sup>115</sup> The application in that case was for a soybean variety that was developed by the applicant by crossing a commercial soybean with a known variety called "Pella". The Board upheld the examiner's rejection of the claims as obvious in light of the Pella variety and a Chinese soybean variety (the "prior art varieties"). In so doing, the Board rejected the applicant's arguments that the claimed variety was unobvious because it differed from the prior art varieties in pod colour and pubescence colour, provided greater oil yields than the prior art varieties, and was more resistant to *Phytophthora* root rot than the prior art varieties. The Board explained that, in order to make good these arguments, it was necessary for the applicant to demonstrate that the differences between the prior art varieties and the claimed variety were both unexpected and of practical significance. The Board noted that the claimed variety and the prior art varieties were both similar in colour and yield, and that it was well known that root rot resistance could be introduced into a plant by crossing it with varieties having resistance to root rot. This is precisely what the applicant had done; accordingly, the claims to the variety were held by the Board to be obvious.

On the other hand, in *Re Sigco Research*<sup>116</sup> the United States Court of Appeals found that claims directed to genetically stable, true-breeding sunflower lines, plants and seeds that produced oil with greater oxidative stability by virtue of an enhanced oleic acid content were nonobvious. The patent contained claims to seeds having an oleic acid content of approximately 80% or greater, relative to the fatty acid content of the seeds, and having a ratio of linoleic to oleic acid of less than about 0.09. The patent also contained claims to plants from which such seeds could be produced, and to a substantially uniform population of *Helianthus annuus* plants from which seeds having the prescribed oleic acid content and ratio can be produced.

The claimed invention was the product of a conventional plant breeding program using a known sunflower cultivar called 'Pervenets', which had been developed some years earlier in the Soviet Union. The applicant acknowledged that Pervenets was a promising starting point for the development of high oleic acid content sunflower seeds: the cultivar had displayed an increase of oleic acid content from 65% to 79% over other known sunflower cultivars, in conjunction with a decrease in linoleic acid content from 26% to 15%, compared with a 21% to 45% increase in the linoleic acid content of conventional sunflower seed. The Pervenets cultivar was therefore recognised as 'holding particular significance for a possible enhancement of oxidative stability in sunflower oils.'<sup>117</sup>

The claims were rejected as obvious by the USPTO in light of a number of articles, including: one written by the inventor (Fick) which disclosed that sunflower lines had been developed that contained individual plants having an oleic acid content of 80% to 90%; an article describing the development of the Pervenets variety, in which plants having an oleic acid content of 70%-75% had been obtained through the use of chemical mutagenesis (the Pukhalsky article); and, an article describing the use of conventional breeding techniques to obtain parental lines that are true-breeding for a particular trait (semi-dwarfism) that is controlled by a single, dominant gene (the Johnson article). Both the examiner and the Board of Appeals and Patent Interferences held that the invention was obvious because 'one having ordinary skill in the art of breeding sunflowers, and having knowledge of Pervenets' attributes and access to this variety, would have considered it obvious to utilize Pervenets as taught by Fick to achieve lines' having high oleic acid content 'which are true-breeding for this very desirable trait.' In other words, the USPTO took the view that those familiar with Pervenets would have expected that the acknowledged

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<sup>115</sup> 27 USPQ 2d 1491 (1992).

<sup>116</sup> 48 F. 3d 1238 (1995).

<sup>117</sup> Bent, S. A., Schwaab, R. L., Conlin, D. G., & Jeffrey, D. D., *Intellectual Property Rights in Biotechnology Worldwide*, New York: Stockton Press, 1987, at p. 194.

variability in the oleic acid content of the cultivar ‘would be amenable to standard breeding techniques aimed at enhancing the quantitative expression of a particular trait.’<sup>118</sup>

On appeal, the applicant emphasised the unpredictability of the genetic determinants involved in inheritance of the high oleic acid trait. In this regard, the applicant pointed out that the open-pollinated Pervenets cultivar was heterogeneous for oleic acid content, with individual plants yielding widely different levels of oleic acid, and the high oleic acid trait was not reproducibly expressed over successive generations. In light of this variability, the applicant urged that it could not have been predicted at the commencement of the breeding program that there was at least one partially dominant high oleic acid determinant in Pervenets, and that conventional breeding techniques would enable the production of a sunflower plant yielding seed with an oleic acid content of approximately 80% or greater.<sup>119</sup> The applicant also contended that even for those Pervenets sunflower plants which did produce high oleic acid content seed, corresponding linoleic acid concentrations could be substantial, ranging as high as 26% of greater. Consequently, the applicant argued that the skilled worker would not have considered it obvious that seeds having a high oleic acid content, in combination with a linoleic to oleic acid ratio of less than 0.09, could be obtained from the use of Pervenets cultivars in a conventional breeding program.

These arguments were accepted by the Federal Court of Appeals. According to the Court, the USPTO failed to discharge the burden establishing a *prima facie* case that a person skilled in the art would be led to combine the teachings of the prior art. Following the Federal Court of Appeals’ decision in *In re Dow Chemical Co.*,<sup>120</sup> the court held that there must be some suggestion in the prior art that conventional plant breeding techniques ‘such as those used in Johnson’ could be used ‘to arrive at sunflower plants true breeding for the trait of at least 80 percent oleic acid content.’<sup>121</sup> Applying this reasoning, the Court stated that none of the prior art references suggested that a line with high oleic acid could be made true breeding. Moreover, the Court found that none of the prior art references suggested that inbreeding would be successful, ‘particularly when the Russians, who were leaders in breeding sunflowers for altered fatty acid composition, continued to use chemical mutagenesis and cross-pollination. Rather the Russian references suggest that inbreeding, although otherwise obvious to try, would not succeed with Pervenets.’<sup>122</sup> Instead, the Court accepted the applicant’s argument that, given the ‘variability of high oleic acid content in the Pervenets starting variety’,<sup>123</sup> ‘success was unpredictable in establishing true breeding for the high oleic acid trait.’<sup>124</sup>

More recently, in *In re Pod-Ners LLC*,<sup>125</sup> the Federal Court of Appeals rejected a controversial application claiming yellow beans, known as ‘Enola’ beans, along with plants produced from such beans, and methods of producing the plants by crossing parent plants. The applicant had purchased in Mexico a package of dry beans, which contained beans of various colours and varieties, including yellow beans. The applicant returned with the beans to the United States and selectively propagated plants produced from the yellow beans over three growing seasons.

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<sup>118</sup> *Ibid.*

<sup>119</sup> *Ibid.*, at pp. 194-5.

<sup>120</sup> 837 F. 2d 469 (1988).

<sup>121</sup> In *Dow Chemical*, the Court stated that ‘the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art ... There must be a reason or suggestion in the art for selecting the procedure used ...’ (internal references omitted).

<sup>122</sup> 48 F. 3d 1238 (1995), at p. 2.

<sup>123</sup> Bent, S. A., et. al., *supra* n. 117, at p. 195.

<sup>124</sup> 48 F. 3d 1238 (1995), at p. 2.

<sup>125</sup> *In re Pod-Ners LLC* 337 Fed.Appx. 901 (2009).

Eliciting claims of bio-piracy, the applicant then filed a patent application, including claims to beans with a yellow coat (defined with reference to a range of shades of yellow on a particular colour chart), plants produced from such beans, and a method for crossing parent plants, at least one of which was derived from the yellow beans contained in the package that the applicant purchased in Mexico.

The application was rejected by both the examiner and the Board of Appeals and Patent Interferences as obvious in light of a well-known yellow bean, 'Azufrado Peruano 87', which had been previously disclosed in an article. The examiner and the Board accepted that in terms of both their phenotype and genotype, the beans and plants of the claimed cultivar and Azufrado Peruano 87 were substantially the same. The Board's decision was then affirmed on appeal by the Federal Court of Appeals. The Court observed that in selecting and reproducing the claimed beans, the applicant did not attempt to produce beans of the particular narrow range of yellow that was specified in the claims, but was merely attempting to reproduce the yellow beans he had acquired in Mexico, with a view to improving upon them. Furthermore, the Court held that, in so doing, the applicant did not devise or apply any new or unexpected techniques in reproducing the beans, but simply followed 'normal and well-established agricultural methods and techniques'. Accordingly, the Court held that the claimed 'invention' was obvious, if not anticipated.<sup>126</sup>

Surprisingly, given the preponderance of claims to genetically-modified plants, relatively little case law exists regarding the application of the nonobviousness requirement to genetically-modified plants. However, the Federal Court of Appeals recently had the opportunity to consider such claims in *Syngenta Seeds Inc v Monsanto Co.*<sup>127</sup> The patents claimed a transgenic corn plant that produces the *Bacillus thuringiensis* (Bt) protein, 'wherein the foreign DNA nucleic acid coding sequence has a G+C [guanine + cytosine] content of at least about 60%'. Bt is a bacterium that produces a protein which is toxic to certain insects, and a number of different plant varieties had previously been successfully transformed with the Bt gene which encodes this protein. However, the Bt genes were under-expressed when inserted into the corn plant genome. The patentee claimed to have discovered that the expression of the Bt protein could be improved by altering the percentage of guanine and cytosine codons in the Bt gene from about 38% to 65%, since corn plant genomes tend to have a high concentration of G+C codons.

The patentee appealed from the District Court's finding that the patent was infringed, but invalid on the ground that the claimed plants were obvious. The Federal Court of Appeals upheld the District Court's decision that the claimed plants were obvious in light of a published patent application which disclosed that Bt expression is improved by selecting codons that are preferred by the native plant, and that, in contrast to plant genes, which ordinarily display a bias towards G+C codons, Bt genes have a high proportion of codons that are rich in adenine and thymine. The patentee also acknowledged that it was well established at the time it commenced its research that the coding regions of corn genes tend to be high in G+C. The Court rejected the patentee's arguments that altering the proportion of G+C codons in the Bt gene to at least 60% had been an *unexpected* success, and that there was no suggestion in the prior art that a Bt gene with this proportion of G+C codons would produce exceptionally good results in corn plants. According to the Court, the prior patent 'plainly' suggested that 'some increased efficiency of expression could be achieved by producing a synthetic Bt gene with a coding region consisting

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<sup>126</sup> However, the Court did appear to accept that the *prima facie* obviousness of the claims might have been rebutted by so-called 'secondary evidence' of non-obviousness, such as evidence that 'the particular shades of yellow resulted in substantial sales of the Enola beans, that there was a long [felt] need for beans of that colour that others were unable to supply, or that others copied the Enola bean.'

<sup>127</sup> 231 Fed. Appx. 954 (2007). The decision is yet another non-precedential decision of the Federal Court of Appeals.

entirely of plant-preferred codons.’ In the case of corn, such a gene would ‘necessarily have a G+C content of more than 60 percent.’<sup>128</sup> Moreover, the prior patent suggested that there was a reasonable expectation of success that increasing the proportion of G+C codons in the Bt gene would result in a significantly improved level of expression of the Bt protein. Accordingly, the claims were obvious.

### 3.4 Inventive Step and Plant Breeding: Europe

As noted in section 2.3 above, the patent law of a majority of European countries is based on the provisions of the *European Patent Convention*. Whilst the EPC sets out the basic criteria of validity for European patents, these criteria may be interpreted differently by each of the member states. The inventive step requirement is one criterion that is subject to differing interpretations amongst individual member states. For example, whilst the European Patent Office (“EPO”) employs the problem-solution test when assessing the presence or absence of an inventive step, British courts are more inclined to apply the approach formulated by the English Court of Appeal in *Windsurfing International Inc v Tabur Marine (GB) Ltd.*<sup>129</sup> In this section we shall focus on the EPO’s approach to the assessment of inventive step for two reasons. First, there is a dearth of case law in individual member states considering the application of the inventive step requirement to plants, whereas the EPO has interpreted the inventive step requirement on a number of occasions. Secondly, whilst individual member states of the EPC are at liberty to arrive at their own interpretation of the criteria of validity, an underlying philosophy of the EPC is for member states to aspire to comity with the EPO’s decisions where possible.<sup>130</sup>

The Enlarged Board of Appeal of EPO recently had the opportunity to consider the application of the inventive step requirement to plants produced by traditional breeding methods in *Plant Bioscience/Broccoli*.<sup>131</sup> As noted above in Section 2.3.2, the application concerns a broccoli plant with elevated levels of glucosinolates that has been produced using conventional breeding methods, aided by marker-assisted selection.<sup>132</sup> The application includes claims to broccoli plants and edible portions thereof, seeds, and lines, with elevated levels of 4-methylsulfinylbutyl glucosinolates (“4-MSB”), or 3-methylsulfinylpropyl glucosinolates (“3-MSP”), or both. The application also contains claims to methods of producing *Brassica oleracea* with elevated levels of 4-MSB or 3-MSP consisting of: crossing wild broccoli species selected from the group consisting of *Brassica villosa* and *Brassica drepanensis* with broccoli double haploid breeding lines; selecting hybrids with elevated levels of 4-MSB or 3-MSP; backcrossing and selecting plants with genes encoding the expression of elevated levels of 4-MSB or 3-MSP; and, selecting a broccoli line with elevated levels of 4-MSB or 3-MSP, that are capable of causing a strong induction of phase II enzymes. Molecular markers are used to select hybrids and plants with elevated levels of 4-MSB or 3-MSP.

At the priority date of the patent all of the materials and techniques that were necessary to reproduce the claimed method – including seeds of both *B. villosa* and *B. drepanensis*, the techniques to obtain double haploid lines of broccoli, methods of backcrossing, the selection of hybrids with elevated glucosinolates levels, and the design of molecular markers that segregate

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<sup>128</sup> *Ibid.*, at p. 958.

<sup>129</sup> [1985] RPC 59. The underlying principle of the problem-solution approach is that the invention is seen as the solution to the technical problem of getting from the closest prior art to the claimed result.

<sup>130</sup> See Llewelyn, M., and Adcock, M., *European Plant Intellectual Property*, Oxford: Hart Publishing, 2006, at p. 260: ‘The nature of the European Patent Organisation is such that the EPO cannot compel national patent offices (or courts) to interpret or apply these substantive provisions in a particular way. Instead, it is left to national granting offices (and courts) to decide upon appropriate local practice.’

<sup>131</sup> T83/05 [2008] EPOR 145.

<sup>132</sup> Glucosinolates are precursors to isothiocyanates, which are proteins known to exhibit anti-carcinogenic properties.

with a desired trait – were publicly available or generally known in the art, and the Board accepted that the implementation of these techniques ‘would not cause any problem to the skilled person.’<sup>133</sup> Despite this, the TBA found that the inventive was not obvious.

The opponent claimed that the primary claims lacked inventive step in light of the closest piece of prior art, which disclosed that levels of 4-MSB had been increased tenfold in two new broccoli lines that were produced from crosses between a commercial cultivar and two infertile species of wild *Brassica*. As this piece of prior art provided no information on which wild *Brassica* species had been used, the EBA characterised the technical problem to be solved as ‘the identification of wild *Brassica* species which can be used to achieve the desired effect.’<sup>134</sup> The decisive question, according to the Board, was thus ‘whether starting from this closest prior art, it would have been obvious for a skilled person to select wild *Brassica* species *B. villosa* or *B. drepanensis* for crosses with a broccoli line in order to considerably increase its 4-MSB GSL level.’ In this connection, the opponent referred to a prior publication which provided a genetic analysis of a backcross population between two wild species, *B. drepanensis* and *B. atlantica*. Although the backcross population contained plants with considerably higher levels of 3-MSP than either of the parents, the article stated that an allele that is necessary for the production of 4-MSB is absent from the genome of *B. drepanensis*. Despite this, the article concluded that it was possible to optimise the level of 4-MSB in cruciferous vegetables and salad crops through a combination of a null allele at the *Gsl-alk* locus and a functional allele at the *Gsl-elong* locus.<sup>135</sup> The article also suggested that the use of marker-assisted selection to introduce correct alleles into *Brassica* crops from either wild or cultivated forms of *Brassica oleracea* provided one strategy by which this result could be achieved.

The EBA rejected the opponent’s argument that the claims were obvious in light of this disclosure. Not only does *B. drepanensis* not produce 4-MSB, but the prior publication addressed the question of changing the types of glucosinolates produced, as opposed to the technical problem to which the applicant’s invention provided a solution – namely, how to increase the level of 4-MSB in a crop which already contains the correct combination of alleles to produce it. Moreover, the prior art also disclosed that *B. villosa* and *B. drepanensis* are closely related; therefore, a skilled person would have expected similar glucosinolates profiles for both of these species, and would not have selected *B. villosa* as suitable to solve the problem posed. Therefore, the claims did not lack inventive step in light of this disclosure.

The EPA also rejected the opponent’s argument that certain other claims relating to broccoli plants having elevated levels of 3-MSP and/or 4-MSB between 10 and 100 µmoles per gram of dry weight were obvious in light of a broccoli cultivar (‘Royal Purple’) which contained 11.2 and 88.3 µmoles per gram of fresh weight of 3-MSP and 4-MSB respectively (this corresponds to a combined weight of 9.95 µmoles per gram of dry weight). The opponent argued that there was no inventive step involved in increasing the level of glucosinolates by merely 0.05 µmol/g over that contained in Royal Purple. However, this argument was rejected by the Board: ‘the fact that a plant’s level of 3-MSP GSL + 4-MSB GSL disclosed in the prior art approaches that of a claimed plant, does not mean that the latter is obvious. The relevant question is whether or not the claimed plant *follows* from the prior art in an obvious way.’<sup>136</sup> In this regard, the Board noted that none of the prior art *suggested* that the level of 3-MSP in plants could be increased by crossing broccoli double haploid breeding lines with wild *Brassica* species, and, given the

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<sup>133</sup> T83/05 [2008] EPOR 145, at p. 153.

<sup>134</sup> *Ibid.*, at p. 155.

<sup>135</sup> The *Gsl-elong* allele is necessary for the production of 4-MSB, while the *Gsl-alk* allele is necessary for the conversion of both 4-MSB and 3-MSP to phase II enzymes.

<sup>136</sup> T83/05 [2008] EPOR 145, at p. 158.

previously published genetic analysis of the backcross population between *B. drepanensis* and *B. atlantica*, considered that a skilled person would not have expected from the prior art that such an increase could be achieved in broccoli by crossing with *B. villosa* and *B. drepanensis*.

In respect of claims directed to genetically-modified plants, the EPO has consistently framed the question of whether or not the claimed subject matter contains an inventive step in terms of whether or not the skilled worker, starting from the closest piece of prior art, has a reasonable expectation of success in solving the objective technical problem. For example, in *Mycogen/Modifying plant cells*,<sup>137</sup> the TBA deemed that claims to methods of genetically modifying dicotyledonous plant cells, involving the transfer of a phaseolin gene, and to transformed dicotyledonous plant cells, were not obvious in view of numerous uncertainties and difficulties associated with the technical field at the priority date.<sup>138</sup> Before the priority date, numerous attempts had been made to obtain expression of foreign genes in plant cells. These attempts were unsuccessful because the control (i.e. promoter) sequences of these genes were not recognised by the plant machinery. A transcript of an oral disclosure made before the priority date observed that it had not yet been demonstrated whether or not expression of foreign genes could be obtained by placing them under the control of a promoter that is derived from a plant, and noted that experiments to test this hypothesis were yet to be completed. Subsequently, the patentee succeeded in obtaining expression of phaseolin in dicotyledonous plants by performing the procedure foreshadowed in the prior disclosure, i.e. by transferring to the genome of a dicotyledonous plant cell a phaseolin gene that was placed under the control of a promoter sequence derived from a plant.

Although the experiments performed by the patentee had been ‘anticipated’ by the prior disclosure, and were therefore obvious to try, the TBA held that, before starting the experiments, the skilled worker would have had no reasonable expectation that disclosed methods would be successful in producing detectable levels of phaseolin in a dicotyledonous plant cell: not only was the art of genetically modifying plant cells so as to achieve detectable levels of expression of a transferred foreign gene yet to be routinely established, there had also been no prior disclosure of the expression of phaseolin in recombinant organisms, or of foreign genes in plants when an endogenous promoter was included. Accordingly, the skilled worker was not in a position to predict that the experiments foreshadowed in the prior disclosure would be successful.

A similar result was reached in *Monsanto/Insect resistant tomato plants*.<sup>139</sup> The patent contained claims to both methods of producing genetically transformed tomato plants which exhibit insecticidal activity toward *Lepidopteran* larvae, and to transformed plant cells which exhibit such insecticidal activity. The TBA found that the claims were not obvious, notwithstanding the fact that the transformation of a tomato plant according to the claimed methods was technically feasible at the priority date, and that tobacco plants which exhibited insecticidal activity toward *Lepidopteran* larvae had previously been produced by transferring to their genome DNA sequences which encoded a *Bacillus thuringiensis* (*Bt*) toxin. The decisive factor was the fact that previous attempts at achieving the desired insecticidal effect on *Lepidopteran* larvae had succeeded only when truncated DNA sequences which encoded a *Bt* toxin had been used. In contrast, the claimed invention employed a full length DNA sequence that encoded a *Bt* toxin. As previous attempts to transform tobacco plants with full length DNA sequences encoding *Bt* toxins had exhibited no significant effect on the mortality of *Lepidopteran* larvae, the TBA thought that the skilled person would not reasonably expect that transforming a tomato plant with a full length DNA sequence would achieve the desired insecticidal effect.

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<sup>137</sup> T694/92 [1998] EPOR 114.

<sup>138</sup> Phaseolins are storage proteins.

<sup>139</sup> T425/96 [2002] EPOR 45.

On the other hand, similar reasoning was employed in *Monsanto/Somatic Changes* to find the claimed invention obvious.<sup>140</sup> The patent included claims to methods of effecting somatic changes in higher plants by introducing into a plant a DNA sequence encoding an RNA sequence that is capable binding to a given target pathogenic RNA strand ('anti-sense' RNA), as well as claims to plants and seeds that are transformed according to these methods. The TBA held that the claims were obvious in light of a prior publication which suggested that the use of anti-sense RNA in plants was a promising means of providing protection against plant viruses. Although this technique had previously only been employed in bacterial and mammalian cells, the TBA accepted that there was sufficient knowledge about the elements and techniques which could be used in order to successfully achieve the insertion and expression in plants of foreign generic information, and that nothing in the prior art indicated that an anti-sense RNA strand would have been particularly unstable in plants or that an inserted DNA sequence encoding an anti-sense RNA would not have been transcribed into an RNA strand. The TBA stated that in the absence of real difficulties which would be encountered, the skilled person, when following the route indicated by the prior art, would have had either some expectation of success, or, at worst, no particular expectations of any sort, but merely the curiosity to see whether a result could be achieved. However, the latter situation, according to the TBA, does not equate with a reasonable expectation of success.<sup>141</sup>

### 3.5 Inventive Step and Plant Breeding: Australia

There are few Australian decisions concerning the application of the inventive step to plant breeding. However, a recent decision of a Deputy Commissioner of Patents involving genetically-modified wheat is instructive, not only in relation to the Australian Patent Office's approach to the assessment of inventive step for genetically-modified plants, but also in relation to its interpretation of the inventive step requirement more generally. The application in *Commonwealth Scientific and Industrial Research Organisation v Monsanto Technology LLC*<sup>142</sup> was directed to methods of producing stably-transformed fertile wheat using *Agrobacterium*-mediated transformation.<sup>143</sup> The application was opposed by CSIRO on a number of grounds, including lack of inventive step. In this regard, CSIRO argued that the alleged invention was obvious in light of the common general knowledge alone, or together with a number of other prior art documents. The Deputy Commissioner rejected CSIRO's argument that the invention was obvious having regard to the common general knowledge of the skilled worker involved in monocot plant transformation. In so doing, the Deputy Commissioner applied the "problem-solution" approach to the assessment of inventive step, an approach which, so far as Australian authority is concerned, he identified as having originated with Aicken J's well-known judgment in *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262:

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<sup>140</sup> T333/97 [2003] EPOR 326.

<sup>141</sup> *Ibid.*, at p. 334. The TBA also commented that 'in cases where the prior art provides suggestions or incentives to do something and thus it may seem obvious for the skilled person to follow the indicated path, the question may arise whether the said skilled person, based on a scientific evaluation of the facts at hand, would thereby have had a "reasonable expectation of success". Generally speaking, the more unexplored a technical field of research is, the more difficult is the making of predictions about the successful conclusion of a given endeavour and, consequently, the lower the expectation of success' (at p. 332). However, the TBA noted that 'any allegation of factors putting in jeopardy the reasonable expectation of success must be based upon technical facts ...'

<sup>142</sup> [2007] APO 15.

<sup>143</sup> *Agrobacterium*-mediated transformation is the most widely-used technique for introducing foreign or endogenous DNA into the genome of a plant. The technique utilises *Agrobacterium tumefaciens*, a common soil bacterium that naturally inserts its genes into plants and uses the machinery of plants to express those genes in the form of compounds that the bacterium uses as nutrients. *A. tumefaciens* has the exceptional ability to transfer a particular DNA segment into the nucleus of infected cells where it is then stably integrated into the host genome and transcribed.



The test is whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not.

Curiously, the Deputy Commissioner regarded the High Court of Australia as having ‘expanded’ on the problem-solution approach in its decision in *Aktiebolaget Hässle v Alphapharm Pty Ltd*,<sup>144</sup> in particular the majority’s identification of the correct ‘test’ for inventive step as:

Would the notional research group at the relevant date, in all the circumstances, which include a knowledge of the relevant prior art ... directly be led as a matter of course to try [a particular thing] in the expectation that it might well produce a useful result? (Deputy Commissioner’s paraphrase)<sup>145</sup>

According to the Deputy Commissioner, the combined effect of these decisions is that in order for an alleged invention to be regarded as obvious, ‘there must be a motivation for the skilled person to apply what is disclosed in a relevant prior art document or what is common general knowledge in the art with the expectation that it will produce the claimed result.’<sup>146</sup>

In respect of CSIRO’s argument that each of the steps comprising the applicant’s method for producing transgenic wheat was part of the common general knowledge at the priority date of the application, the Deputy Commissioner stated that even if this was in fact the case, it did not necessarily follow that it would have been obvious to the skilled person to combine these steps to produce transgenic cotton. In particular, the Deputy Commissioner observed that although *Agrobacterium*-mediated transformation of many dicot species was routinely practised at the priority date of the application, it was still widely accepted well into the 1990s that monocots were ‘intractable’ to *Agrobacterium*-mediated transformation. This was despite the fact that a paper published two years before the priority date of the application, which was described as having ‘changed the whole ball game’ for monocot transformation, detailed the transformation of rice using *Agrobacterium*, and confirmed that the methods used in the transformation of rice are similar to those used in respect of dicotyledons. Notwithstanding this revelation, which was accepted as forming part of the common general knowledge, the Deputy Commissioner accepted that doubts remained in relation to the sorts of modifications which would be required in applying dicotyledons methods to monocots – in particular, in relation to appropriate *Agrobacterium* vectors, suitable target tissues and inoculation and co-culture procedures.<sup>147</sup> Accordingly, the Deputy Commissioner was not satisfied that ‘the skilled person would have expected that *Agrobacterium*-mediated transformation methods that were routine in dicotyledons could be married with standard tissue culture and plant regeneration methods for wheat to produce stable, transgenic wheat.’<sup>148</sup> Accordingly, the claims were not obvious in light of the common general knowledge in the field.

The Deputy Commissioner also rejected CSIRO’s argument that the alleged invention was obvious in light of a number of prior publications. The closest pieces of prior art included: a

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<sup>144</sup> (2002) 212 CLR 411.

<sup>145</sup> The Deputy Commissioner’s reasoning is curious because the High Court has cautioned against the use of the problem-solution approach when assessing the presence or absence of an inventive step: see *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No. 2)* (2007) 235 ALR 202. It should also be noted that the High Court stated that when assessing the relevance of prior art information to the question of whether or not the invention is obvious, only prior art information that is addressed to the particular technical problem faced by the applicant/patentee can be considered. Cf. *KSR International Co v Teleflex, Inc* 550 U.S. 398 (2007).

<sup>146</sup> [2007] APO 15, at para. 93.

<sup>147</sup> It is notable that the applicant’s research confirmed that standard vectors, tissues and inoculation procedures are effective in wheat.

<sup>148</sup> [2007] APO 15, at para. 99.

patent disclosing *Agrobacterium*-mediated transformation of wheat; and, two patents disclosing *Agrobacterium*-mediated transformation of corn and rice using callus tissue and immature embryos.

In respect of the first piece of prior art, the Deputy Commissioner noted that the patent disclosed the use of targeted inoculation of wounded wheat seedlings. In contrast, the method described in the applicant's specification utilised cultured embryonic tissue. In the Deputy Commissioner's view, the skilled worker would regard this as a fundamental difference: they would appreciate that in an 'unpredictable art' such as plant transformation success with a specific type of tissue in a particular plant does not necessarily predict success with different tissue in the same plant.<sup>149</sup> As such, a skilled reader of the prior patent would limit him or herself to the fresh, wounded tissue disclosed in that specification, rather than the embryonic tissue utilised in the applicant's methods.

In relation to the second pieces of prior art, although the prior patents disclosed the use of embryonic tissue in the transformation of rice and maize, the Deputy Commissioner again emphasised that there was an expectation at the priority date of the application that modifications would be required before methods that had been successful in one cereal could be successfully applied to another. However, the scope and the nature of these modifications was unclear. The fact that most wheat cultivars have a complex hexaploid genome, unlike the diploid genomes of rice and maize, did little to assuage this uncertainty. In these circumstances, the Deputy Commissioner was not satisfied that the disclosures in the prior patents would have motivated the skilled person to try the same or similar protocols described therein in wheat with an expectation that stable transgenic wheat would result, notwithstanding that the applicant's work, and the work of others after the priority date of the application, revealed that in many cases only minor modifications were required and that these modifications were of a routine nature.<sup>150</sup>

According to the Deputy Commissioner, although the successful transformation of rice and maize had raised 'raised expectations in the art that other cereals such as wheat could be transformed by *Agrobacterium*', he was not satisfied that the skilled worker would consider that 'any of these citations provided a method that could be routinely applied or adapted to a range of cereals extending beyond the specific cereal disclosed in the citation.'<sup>151</sup>

### 3.6 Conclusion

It is difficult to divine a consistent approach to the assessment of inventive step across these three jurisdictions. As one commentator has observed, 'the lack of examples of attempts to patent plant varieties of the typical kind for which PVR are granted has tended to give this debate an academic rather than practical character.'<sup>152</sup> However, a number of general observations can be made. First, it is clear that the fact that the techniques used in the production of conventionally-bred plants are established and within the competency of the ordinary skilled worker does not necessarily render the resulting plants obvious. In both *Plant Bioscience/Broccoli* and *CSIRO v Monsanto*, each of the steps comprising the respective applicant's breeding methods were well known, and their implementation would not have caused any problem to the skilled worker. Despite this, in neither case were the claimed plants obvious: in the former case, because the prior art provided no indication about which wild *Brassica* species could be used to obtain increased levels of glucosinolates; in the latter case, because of

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<sup>149</sup> Ibid., at para. 112.

<sup>150</sup> Ibid., at para. 116.

<sup>151</sup> Ibid., at para. 118.

<sup>152</sup> Crespi, R. S., *supra* n. 8, at p. 271.

uncertainties which existed in the art at the priority date in relation to the viability in monocot plant varieties of techniques that had been successful in the transformation of dicotyledons.

Second, in respect of genetically-modified plants, the patent offices of each of the three jurisdictions approach the question of obviousness by asking whether, based upon the prior art and the common general knowledge in the field, the skilled worker had a reasonable expectation of success of producing the claimed plant. Finally, it is more difficult to discern a coherent approach to the assessment of inventive step in relation to conventionally-bred plants, perhaps for the reason that the question of obviousness has seldom arisen in this context. In the one case in which the question arisen in Europe, the EPO adopted a similar approach to that which it has applied to genetically-modified plants, *viz.* whether the claimed plant follows from the prior art in an obvious way, i.e. whether the claimed plant is suggested by the prior art. On the other hand, in the United States, the jurisdiction in which the question has most frequently arisen, both the USPTO and the Federal Court of Appeals for the Federal Circuit have frequently approached the question by asking whether the prior provided some teaching, suggestion or motivation to produce the claimed plant, and, if so, whether success was unexpected or unpredictable.

A number of academics and practitioners have criticised this approach on the basis that it, in effect, creates a presumption that plants produced by conventional breeding techniques are nonobvious because ‘they are unpredictable in the sum of all their [phenotypic] characteristics.’<sup>153</sup> That is, even if a given trait is obvious to select for, the underpinning genetics may be unknown and, therefore success cannot be predicted in advance.<sup>154</sup> As Huib Ghijsen, the IP and Germplasm Protection Manager for Bayer BioScience, explains, ‘The inventive step in conventional plant breeding as compared to the prior art is limited to the shaping of a new variety out of the “melting pot” of genetic resources, comprising a new and unique combination of known characteristics. After crossing the invention with other plants of a different genetic make-up, this unique combination of known characteristics breaks down or “melts” into an unlimited number of new, unpredictable combinations as expressed in the F<sub>2</sub> generation.’ The corollary of this reasoning, according to Ghijsen, is that utility patents on plant varieties are routinely granted by the USPTO on the basis that ‘each variety is the unexpected (non-obvious) result of a known breeding process.’<sup>155</sup> The non-obvious requirement is therefore met ‘by implication’. As a result, utility patents are available whenever the particular combination of characteristics represented in the variety is unique – i.e. novel. Therefore, there is no meaningful distinction between novelty and inventive step, or, indeed, between inventive step under the utility patents statute and distinctiveness under the PVP Act. This view is supported by Barbara Johnson, who suggests that ‘as a practical matter, if there are unusual and desirable novel morphological innovations in a plant, nonobviousness can usually be assumed.’<sup>156</sup> Nicholas Seay has ventured even further, commenting that ‘at present, it is difficult to envision a new plant variety which would be obvious under Section 103.’<sup>157</sup>

Whilst Ghijsen accepts that the unpredictable nature of conventional plant breeding may provide evidence of an inventive step, William Lesser has argued that the USPTO’s approach to the assessment of nonobviousness should be completely revised. Like Ghijsen, Lesser has argued that the inevitable consequence of the USPTO’s emphasis on the unpredictability of the genetic

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<sup>153</sup> Kock, M. A., ‘Effects of Patents on Enabling Technologies and Plant Breeding’, [2005/2006] 2 *Bio-science Law Review*, 60.

<sup>154</sup> Van Overwalle, G., *supra* n. 109, at p. 181.

<sup>155</sup> Ghijsen, H., ‘Access to Germplasm for Further Breeding in the Case of Patents and After-sale Conditions’, [2005/2006] 2 *Bio-science Law Review*, 87 at p. 88.

<sup>156</sup> Johnson, B. E., ‘Utility Plant Patents: A Practical Introduction’, (2002) 21 *Biotechnology Law Report*, 435 at p. 436.

<sup>157</sup> Seay, N., ‘Protecting the Seeds of Innovation: Patenting Plants’, (1989) 16 *AIPLA Quarterly Journal*, 418 at p. 435.

make-up of plants produced by conventional breeding techniques is that nonobviousness for plants produced by these methods can be presumed:

For plant varieties the elements – germplasm – may be familiar, at least to the breeders of a firm, and the breeding method may be obvious, but given the probabilistic aspect of heredity, a particular outcome is anything but predictable ... The probabilistic nature means that references to ‘predictable’ results for establishing obviousness in the Patent Examiner’s Manual do not apply; even a ‘reasonable expectation of success’ is questionable.<sup>158</sup>

This has resulted in what Lesser describes as ‘protection creep’, a process whereby patents are increasingly becoming the predominant form of protection for plant varieties in the United States due to the lack of a meaningful nonobviousness standard. According to Lesser, this situation is compounded by the fact that utility patents are being granted for plant varieties which exhibit insubstantial ‘improvements’ in physiological or morphological traits, the benefits of which do not outweigh the social costs associated with the greater degree of protection afforded by utility patents relative to other forms of protection. In Lesser’s view, this is inconsistent with the approach to obviousness applied in other technical fields:

It is unlikely that the proverbial ‘better mousetrap’ would be considered a nonobvious advancement if chrome plated, even if the plating process turned out to be a complex and unpredictable process to master, involving both skill and investment. Yet by granting a patent for a corn variety with non-significant physiological and morphological characteristics that is essentially what the PTO does.’<sup>159</sup> [N.B. this is based on Lesser’s observation that utility patent applications for major crops typically include comparisons (i.e. performance data) with “selected hybrids of commercial value”, which are of dubious import. From this observation follows the contention that intellectual property protection levels under utility patents ‘for corn – among other crops – are too high for the breeding advances granted protection.<sup>160</sup>]

Lesser’s argument here seems to be that utility patents are being granted for breeding advances that would qualify for protection under the PVPA or the PPA (save for yield, which is not a differentiation characteristic for plant patents),<sup>161</sup> and that, given the greater scope of protection and fewer exceptions afforded by utility patents, utility patents should only be available for significant physiological or morphological improvements. Only then is the greater degree of protection conferred by a utility patent, and the concomitant costs associated with this form of protection, justified.

To this end, Lesser advocates the adoption of ‘functional nonobviousness standards’ for plants:

The current PTO interpretation that all breeding is a probabilistic undertaking requiring skill and resources so that any resulting distinctiveness in a variety is nonobvious is not meaningful, leading as it does to no substantive nonobviousness standard. What is needed is limiting relevant nonobviousness only to certain plant characteristics, those with some practical significance ... Proposed here is the designation of a limited number of plant characteristics, all of practical agronomic importance, which must be achieved to establish nonobviousness. When possible, standards should be statistical with reference to an identified standard, such as a particular reference variety.<sup>162</sup>

In turn, these new criteria would require the development of trial procedures ‘with reference varieties identified so that the comparative performance numbers are meaningful.’<sup>163</sup> In other words, nonobviousness would be assessed in a similar fashion to the way in which the DUS criteria for plant breeder’s rights are assessed.

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<sup>158</sup> Lesser, W., *supra* n. 17, at pp. 252, 260.

<sup>159</sup> *Ibid.*, at p. 269.

<sup>160</sup> *Ibid.*, at p. 268.

<sup>161</sup> *Ibid.*, at p. 258.

<sup>162</sup> *Ibid.*, at p. 271, 272.

<sup>163</sup> *Ibid.*, at p. 271.

The problem with this approach, which is acknowledged by Lesser, is that patent law in general has abandoned any pretence to judge the commercial or functional value of inventions, its only concern being to ensure that the invention has some practical use in the sense of providing to the public ‘a useful choice’. Whilst the emergence of genetic engineering, and the ethical concerns associated therewith, has brought to light the limitations of patent law’s abstinence from judgment,<sup>164</sup> as Lesser notes, in passing the PPA in 1930, the U. S. Senate deliberately refrained from introducing criteria relating to the practical or market value of plants.<sup>165</sup> Moreover, the adoption of specific nonobviousness criteria for plants would also inevitably raise claims that it contravenes the supposed technological agnosticism of the patent system, which is enshrined in Art. 27.1 of the TRIPs Agreement. Finally, the prospect of dual protection for plant varieties is explicitly recognised in the 1990 revision of UPOV.<sup>166</sup>

Lesser’s proposals for reform are also undermined by his concession that ‘this conclusion [that claims limited to an exact assemblage of traits will be nonobvious] may not apply in future years as genetic mapping and other breeding techniques might evolve to the point where combining particular traits becomes predictable and therefore obvious. But that stage has not been reached at the present and is not likely to be reached in the immediate, foreseeable future.’<sup>167</sup>

Other commentators have argued that a more rigorous and expansive approach to the assessment of inventive step is needed, which attributes greater emphasis to all of the surrounding factors, not only the unpredictability of plant traits resulting from conventional breeding processes. For example, Pierre Roger has argued that:

... the actual acquisition of these [phenotypical] characteristics is not in itself an innovatory measure, as it involves transferring a particular trait from a related wild species to the genetic background of our cultivated species. These are the very foundations of the breeder’s trade, but was the recommended crossbreeding easy or not? Was there a reasonable expectation of success at the time it was carried out? Did unexpected technical problems have to be resolved in order to make this transfer successfully? The real validity of these patents will be strengthened by whether these questions receive an appropriate response.<sup>168</sup>

Moreover, as Adcock and Llewelyn remind us, the USPTO’s interpretation of the obviousness requirement in the context of conventionally-bred plants ‘has yet to be tested in the courts.’<sup>169</sup> On the two occasions that the Federal Court of Appeals has considered the obviousness requirement in relation to conventionally-bred plants, it has issued ‘non-precedential decisions’, which means that they cannot be employed as precedent in future cases. Despite this, it appears that the reasoning articulated in those cases has been adopted by the USPTO in its assessment of the obviousness of claims to conventionally-bred plants.

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<sup>164</sup> Of course, many advocates of such technology would argue that ethical considerations have no place in the assessment of patentability in the first place.

<sup>165</sup> Lesser, W., *supra* n. 17, at p. 269. In its report, the Senate stated that it is ‘immaterial whether in the judgment of the Patent Office the new characteristics are inferior or superior to those of existing varieties.’

<sup>166</sup> Yet Lesser points out that his proposal is ‘far from unique’: ‘breeders routinely follow these practices when developing new varieties: *Ibid.*, at p. 272.

<sup>167</sup> *Ibid.*, at p. 261.

<sup>168</sup> Roger, P., ‘A European Professional View on Intellectual Property for Plant-related Innovations’, (2005/2006) 8 *Bio-Science Law Review* 2, 97 at p. 100.

<sup>169</sup> Llewelyn, M., & Adcock, M., *supra* n. 130, at p. 88, n. 37. Llewelyn and Adcock refer to US patent 6,222,101, granted to Pioneer Hi-bred over a canola variety that has been traditionally bred to have low levels of erucic acid. According to Llewelyn and Adcock the USPTO found that the variety was non-obvious on the basis that the combination of phenotypic features of which the variety is comprised was ‘unpredictable’.

However, the USPTO may well be compelled to alter its approach to the assessment of inventive step in light of the United States Supreme Court's decision in *K.S.R. International Co v Teleflex Inc.*<sup>170</sup> In that case, the Supreme Court criticised the underlying reasoning in decisions such as *In re Sigco* – namely, that there must be some teaching, suggestion or motivation to combine or modify the teachings of the prior art to produce the claimed invention – as too 'narrow' and 'formalistic'. Instead, the Supreme Court advocated an 'expansive and flexible' approach to the assessment of nonobviousness, which takes into account the 'diversity of inventive pursuits and of modern technology'. Similar criticisms can be made of both the USPTO's and the Federal Circuit Court of Appeals' over-reliance upon the unpredictability of the genetic composition of plants produced by traditional plant breeding methods.

According to Ghijsen, a change in approach by the USPTO to the assessment of obviousness in the context of conventionally-bred plants can already be discerned. Writing before the U.S. Supreme Court's decision in *KSR*, he commented that '[t]he USPTO now asks a number of quite extensive questions of the applicants concerned on the original breeding parents of the variety in question, their lineage back to public varieties, details concerning public availability of parents and progeny, and method steps of producing the invention.' However, Ghijsen concedes that it is 'unclear what the outcome and impact of this *new development* will be on the claims as ultimately to be issued'.<sup>171</sup> Also uncertain is whether these questions will be asked 'on a routine basis for all plant variety patent applications, thus possibly raising the patent requirements for such inventions.' However, this does signal, according to Ghijsen, 'a more critical attitude of at least some USPTO examiners.'<sup>172</sup> What does seem clear is that it seems likely that, as Janis and Kesan predicted almost a decade ago, 'the reach of the non-obviousness doctrine may well be tested in connection with claims' to plants developed by way of conventional breeding methods.<sup>173</sup>

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<sup>170</sup> 550 U.S. 398 (2007).

<sup>171</sup> Ghijsen, H., *supra* n. 155, at p. 89 (emphasis supplied).

<sup>172</sup> *Ibid.*

<sup>173</sup> Janis, M. D., and Kesan, J. P., *supra* n. 103, at p. 1162.

# 4 Sufficiency and Enablement

## 4.1 Introduction

In addition to complying with the so-called ‘external’ requirements of validity – i.e. patentable subject matter, novelty, inventive step, and industrial applicability/utility – an applicant for a patent must also satisfy the ‘internal requirements of validity’. As this label suggests, the internal requirements pertain to the form and content of patent specifications. The most important of the internal requirements are to:

- describe the invention fully, including the best mode of performing (i.e. making and using) the invention (the ‘written description’/‘disclosure’ and ‘best mode’ requirements, respectively);<sup>174</sup>
- disclose in sufficient detail how to reproduce the invention (the ‘enablement’ requirement);<sup>175</sup> and,
- include claims which define in clear and succinct terms the invention for which protection is sought.

Each of the jurisdictions considered in this Discussion Paper also impose a further requirement – namely, that the claims must be supported by, or ‘fairly based’ on, the material disclosed in the specification.<sup>176</sup> This requirement is enforced differently in each jurisdiction. In the United States, this requirement is treated as inherent aspect of the enablement requirement. According to this interpretation, a claim will not be valid unless the specification enables a person of ordinary skill in the art to produce everything encompassed within the scope of the claim.<sup>177</sup>

In Europe, a similar interpretation has been adopted, but is in practice applied differently. Prior to a patent being granted, a claim which includes within its scope material which the specification does not enable a skilled worker to produce would be rejected under Art. 84 of the EPC, which states that the claims shall be clear and concise and supported by the description. However, a patent, once granted, cannot be revoked for failure to comply with this provision because lack of support is not a ground of revocation. Notwithstanding this deficiency, the EPO and the courts of a variety of jurisdictions have imported this principle into their interpretation of Art. 83, which states that the application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Both the EPO and the House of Lords have interpreted this provision as imposing a requirement upon an applicant to disclose the invention in a manner sufficiently clear and complete for it to be carried out *across the entire width of the claim* by a person skilled in the art.<sup>178</sup> Thus, whilst the manner in which this principle is

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<sup>174</sup> In Australia, see *Patents Act 1990*, s. 40(2)(a); in the United States, see §112; in Europe, see EPC, Art. 83.

<sup>175</sup> In Australia, see *Patents Act 1990*, s. 40(2)(a); in the United States, see §112; in Europe, see EPC, Art. 83.

<sup>176</sup> In Australia, see *Patents Act 1990*, s. 40(3); in Europe, see EPC, Art. 84. In the United States, this requirement does not have a distinct statutory basis, but is treated as an implicit requirement of §112.

<sup>177</sup> See, for example, *In re Vaack* 947 F. 2d 488 (1991): ‘there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed’; *Amgen Inc v Chugai Pharmaceuticals Ltd* 927 F. 2d 1200 (1991): ‘It is not necessary that a patent applicant test all of the embodiments of his invention; what is necessary is that he provides a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims’; *National Recovery Technologies Inc v Magnetic Separation Systems Inc* 49 USPQ 2d 1671 (1999): ‘The enablement requirement requires that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement’; *Liebel-Flarsheim Co v Medrad Inc* 481 F. 3d 1371 (2007).

<sup>178</sup> In the United Kingdom, see *Biogen Inc v Medeva Plc* [1997] RPC 1; for the position under the EPC, see *Exxon/Fuel*

applied in Europe differs from the way in which it is applied in the United States, the result is much the same.

In Australia, the requirement that the claims must be supported by matter disclosed in the specification is interpreted rather differently. Unlike the United States and Europe, the requirement of support, or ‘fair basis’ in the colloquial vernacular, is conceptually segregated from the enablement requirement.<sup>179</sup> In addition to the written description and enablement requirements, ss. 40(3) of the *Patents Act 1990* mandates that the claim or claims must be fairly based on the matter described in the specification. The Australian High Court has interpreted this provision in a narrow and formulaic fashion, in effect requiring only that the language used in the claims be no wider than the language used by the applicant to describe his or her invention.<sup>180</sup> In other words, Australian patent law contains a requirement of ‘textual support’ (as opposed to technical support) only.<sup>181</sup>

The High Court has also interpreted the enablement requirement in an extremely narrow manner. In contrast to the position in Europe and the United States, the High Court has consistently held that the specification will be sufficient provided it enables the skilled worker to produce *something* falling within the scope of each claim.<sup>182</sup> In other words, an applicant may include within the scope of a claim subject matter which the specification does not enable the skilled worker to make and/or use. The High Court’s interpretation therefore potentially enables an applicant to claim protection for more than s/he has disclosed and enabled. This is the principal point of departure from the U.S. and European interpretation of the enablement requirement, which requires that everything encompassed within the scope of a claim be fully enabled by the specification.

The High Court’s interpretation of the fair basis and enablement requirements has been extensively criticised, including by IP Australia, which has questioned whether the Court’s interpretation ‘strikes the right balance between protection for the inventor and disclosure for the public, and whether an invention may be afforded substantially broader protection in Australia than could be obtained in other jurisdictions.’<sup>183</sup> These issues will not be addressed in this Discussion Paper, although we concur in the view that this interpretation is at odds with the underlying rationale of the patent system. However, it should also be mentioned that the High Court has not had the opportunity to consider the application of these principles to biotechnological or plant-based subject matter. Indeed, one of the remarkable features of Australian patent law is that a higher court has not had occasion to consider the principles of patentability in the context of a biotechnological invention.<sup>184</sup> It may well be that Australian courts might be compelled to reconsider the application of the enablement and fair basis requirements when they are finally forced to do so.

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*Oils*, T409/91 [1994] EPOR 149; *Unilever/Hexagonal Liquid Crystal Gel*, T435/91 [1995] EPOR 314.

<sup>179</sup> In *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274, the High Court emphasised that each of the requirements of validity ‘are, and must be kept, conceptually distinct.’

<sup>180</sup> *Ibid.*

<sup>181</sup> In *Lockwood*, the Court stressed that in considering fair basis, one looks to the specification to see what *the inventor has himself said* is his invention, not to what the inventor has ‘really’ or ‘truly’ invented – that question is only relevant to novelty and obviousness: ‘In assessing whether the invention claimed by a patentee is fully described or fairly based, it is necessary to take into account...*only* what is said about it in the specification...’

<sup>182</sup> *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 177 CLR 1. In *Lockwood*, the Court emphasised that this is ‘an important aspect of Australian patent law’.

<sup>183</sup> IP Australia, *Getting the Balance Right: Toward a Stronger and More Efficient IP Rights System*, Consultation Paper, March 2009.

<sup>184</sup> A notable exception is *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (1998) 156 ALR 30.



## 4.2 Enablement

The difficulty of reconciling the written description and enablement requirements with the basic unpredictability and complexity of biological systems has long been recognised.<sup>185</sup> One of the enduring issues confronting plant breeders desirous of utilising the patent system is whether a plant variety can be disclosed in such a way that the variety can be reproduced without prolonged investigation or experimentation by the skilled person. Indeed, the enablement requirement has been described as ‘the major patentability issue for plant varieties produced by traditional plant breeding techniques.’<sup>186</sup> The reasons for this are several. From the late eighteenth century onwards, the primary means by which an applicant for a patent disclosed his or her invention to the public was by filing a written description of the invention along with the patent request.<sup>187</sup> Whereas descriptions of mechanical and chemical inventions could readily be supplemented with drawings or formulae depicting the physical structure or composition of the invention, plants are far less amenable to written representation. Moreover, it was considered ‘nearly impossible’ to provide a step-by-step description of the breeding method by which a plant was produced which was capable of being repeated by the skilled person.<sup>188</sup> Even if it was possible for an applicant to accurately describe the breeding method used in the production of the new variety, given variability in the distribution of traits among the progeny of sexually-produced plant varieties, the skilled worker seeking to implement the disclosure might still be required to undertake extensive experiments in order to *consistently* replicate the results obtained by the breeder.<sup>189</sup> Whilst it has long been accepted that a description of an invention may satisfy the disclosure requirement, notwithstanding the fact that the skilled worker is required to undertake further experiments or investigations before the disclosure can be implemented, it was

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<sup>185</sup> Fritze, D., & Weihs, V., ‘Deposition of Biological Material for Patent Protection in Biotechnology’, (2001) 57 *Applied Microbiology and Biotechnology*, 443.

<sup>186</sup> Stearne, P.A. and Hughes, E.J., ‘Intellectual Property Regimes of Plant Patent Protection’, in Bray, R.A., Wood, I.M. & Fletcher, R.J. (ed.s), *New Crops, New Products. New Opportunities for Australian Agriculture, Volume 1: Principles and Case Studies*, Proceedings of the First Australian New Crops Conference, Canberra: Rural Industries Research and Development Corporation, 1997. In the wake of the U. S. Supreme Court’s decision in *Diamond v Chakrabarty*, many of the APLA’s Plant Variety Protection Committee inclined to the view that plants, whether asexually or sexually reproduced, were patentable; the main area of concern in attempting to obtain utility patent protection for plants ‘is meeting the requirement of 35 U.S.C. 112’: Cooper, I. V., *Biotechnology and the Law*, Vol. 1, New York: West, 2009 Revision, at p. 9-1.

<sup>187</sup> The requirement of a written description is a departure from previous practice, whereby the patentee undertook to personally instruct apprentices in the use of the technology.

<sup>188</sup> Van Overwalle, G., *supra* n. 109, at p. 192. Thus, in *J.E.M. Ag Supply Inc v Pioneer Hi-Bred International Inc* 534 US 124 (2001), a majority of the United States Supreme Court explained that the *Plant Patent Act* was introduced in 1930 because at the time Congress believed both that plants were not patentable subject matter and could not, in practice, meet ‘the stringent disclosure requirement.’ The majority went on to say that ‘advances in biological knowledge and breeding expertise have allowed breeders to satisfy §101’s demanding description requirement.’ See also *Diamond v Chakrabarty* 447 US 313, at pp. 311-2; *In re Wands* 858 F. 2d. 731 (1988), at pp. 735-6 (‘where an invention depends on the use of living materials ... it may be impossible to enable the public to make the invention (i.e. to obtain these living materials) solely by means of written disclosure’); and, *In re Lundak* 773 F. 2d. 1216 (1985), at p. 1220 (‘when an invention relates to a new biological material, the material may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification’).

<sup>189</sup> In *Rote Taube* (‘Red Dove’) (1970) 1 IIC 136, the German Federal Supreme Court held that a patent disclosure was complete only if the person skilled in the art ‘can work according to [the applicant’s] teaching an arbitrary number of times with consistent success.’ In so doing, the Court upheld the German Patent Office’s presumption that a claimed breeding procedure will not satisfy the enablement requirement unless the procedure ensures ‘a genetically identical repetition’ of the breeding method or ‘the same genetic results ... with a high degree of certainty’ (at pp. 141-2). According to Bent et. al., the impact this decision was ‘substantial and immediate’, and had the effect of ‘sanctioning a presumption against actual repeatability when *any* living-matter invention was claimed’: Bent, S., et. al., *supra* n. 117, at p. 223. The Court subsequently resiled from the position that ‘the deposit and release of a reproducible sample of [a] new organism was not sufficient for the requirement of reproducibility’: *Tollwutvirus* (‘Rabies Virus’) (1987) GRUR 231. The Court held instead that it is sufficient ‘if the public is provided with a new cultivated organism which can be multiplied by conventional biological means’ – that is, by depositing the organism so that ‘an interested third party is ... in a position to obtain [the claimed organism] ...’

feared that the degree of experimentation that would be required to implement a *written* description of the breeding method would be unreasonable. These problems are further exacerbated by the fact that the parent plants may not be publicly available, and may perform in some environmental conditions, but not in others.

However, these problems were by no means unique to plants. The discovery of penicillin and the commencement of large-scale antibiotic production in the post-war period created similar problems for the pharmaceutical industry, and set in train a series of events which would eventually sweep away many, if not all, of these objections. Doubtful of whether the description of the way in which he had discovered the antibiotic chorotetracycline would satisfy the written description requirement, in 1949 an applicant for a U.S. patent took the unprecedented step of depositing the micro-organism which produced chorotetracycline with the U.S. Department of Agriculture's Northern Regional Research Laboratory.<sup>190</sup> Following this precedent, the USPTO initiated a practice of requiring all applicants filing claims to micro-organisms, which were not known or publicly available, to deposit a culture of the micro-organism with a depository to which the public had free access as of the filing date of the application.<sup>191</sup> By the end of the 1950s, patent offices in a number of jurisdictions had instituted similar protocols for the deposit of micro-organisms.<sup>192</sup> The deposit regime therefore enabled the written description requirement to be satisfied 'in surrogate form.'<sup>193</sup>

Although the depositing of micro-organisms with culture collections was common by the 1970s, the deposit procedures adopted in each jurisdiction varied widely, particularly in regard to the questions of whether, when and under what conditions the public should be granted access to the deposited material.<sup>194</sup> Further, in addition to the specific bureaucratic requirements that existed in each country, individual deposits were requested in each country in which protection was sought. The diplomatic conference at which the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* was adopted was convened to address these questions and to attempt to harmonise procedures relating to the circumstances in which a deposit must be made, and when and how the deposited materials can be accessed.<sup>195</sup> The diplomatic conference was unable to reach agreement on all of these issues – most notably, the timing of the requirement to make the deposit, and the timing of, and conditions for, the furnishing of samples to third parties – however, consensus was reached on a number of crucial aspects of the procedure for deposit.<sup>196</sup> In particular, the *Treaty* eliminates the need to deposit materials in each country in which protection is sought. Instead, each contracting State that allows or requires the deposit of micro-organisms for the purpose of patent procedure must recognise a deposit of a micro-organism made with any 'international depository authority'

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<sup>190</sup> Straus, J., & Moufang, R., *Deposit and Release of Biological Material for the Purposes of Patent Procedure* (trans. Rich, A.), Baden-Baden: Nomos Verlagsgesellschaft, 1990, at p. 13.

<sup>191</sup> Meyer, V. H., 'Problems and Issues in Depositing Microorganisms for Patent Purposes', (1983) *65 Journal of the Patent Office Society*, 455. The USPTO's procedure was subsequently ratified by the Court of Customs and Patent Appeals in *In re Argoudelis* 434 F. 2d 1390 (1970). However, the Court rejected the USPTO's policy that the deposit must be made available to the public by the filing date; whilst the deposit must be made available to the USPTO for examination purposes, the Court held that there is no obligation to make the deposit available to the public prior to the grant of the patent.

<sup>192</sup> In particular, patent offices in the United States, the Federal Republic of Germany, the Netherlands, and Switzerland. See Straus, J., & Moufang, R., *supra* n. 190, at p. 13.

<sup>193</sup> *Enzo Biochem Inc. v Gen-Probe Inc.*, 296 F. 3d 1316 (2002), at p. 1326.

<sup>194</sup> Straus, J., & Moufang, R., *supra* n. 190, at p. 41.

<sup>195</sup> The Treaty entered into force on 9 August, 1980. As of 7 May 2010, 72 countries have ratified the *Treaty*, including Australia.

<sup>196</sup> The procedure governing applications for access to, and the release of, deposited samples in Australia is outlined in IP Australia, *Australian Patents for Plants*, 1998, available from: <http://www.ipaustralia.gov.au/pdfs/patents/specific/Australian%20Patents%20for%20Plants.pdf>.

(‘IDA’) – a recognised institution capable of handling and preserving micro-organisms and other biological materials – regardless of where the authority is located.<sup>197</sup>

Although, as its title suggests, the *Treaty* was originally designed to address issues relating to the description and enablement of micro-organisms, the deposit regime that was introduced by the *Treaty* has, over time, been adapted to other biological materials, including plants and plant genetic materials. One reason for this is that the *Treaty* itself contains no definition of the term ‘micro-organism’. The reasons for this omission uncertain, however it has been suggested that the term was deliberately left undefined in order to accommodate other biological materials that might in the future encounter the same problems of description and enablement that are associated with micro-organisms.<sup>198</sup> In practice, this means that term ‘microorganism’ is interpreted in a broad sense, covering biological material the deposit of which is necessary for the purposes of disclosure, including plants and plant genetic material, such as seeds, plant tissue culture, and cell and protoplast culture. Since the *Treaty* came into effect, IDA’s have accepted deposits for biological materials which do not fall within a literal interpretation of ‘microorganism’, and it has been suggested that the subject matter capable of deposit ‘appears only limited by what a particular IDA is prepared to accept as a deposit under the *Treaty*.’<sup>199</sup> According to WIPO, ‘whether an entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it.’<sup>200</sup>

The fact that the *Treaty* is predicated upon a voluntary scheme initiated by applicants lends some support to this interpretation. Despite this, regulations have been introduced in a number of jurisdictions which specifically sanction the use of deposits for claims to plants and other biological materials. In the United States, the USPTO’s Board of Patent Appeals and Interferences officially sanctioned the use of the deposit system for plants in 1992 in the decision of *Ex parte C*.<sup>201</sup> Thus, ‘thanks to a legal innovation – the patent deposit – it is now possible to disclose a new variety of plant in a manner which fully complies with the present disclosure requirement, Section 112.’<sup>202</sup> In 1990, the USPTO implemented regulations that confirm the Board’s decision in *Ex parte C*. The regulations, which apply to ‘biological material’ generally, provide that where an invention is, or relies on, a biological material – being material that is capable of self-replication either directly or indirectly – the disclosure *may* include a reference to a deposit of such biological material.<sup>203</sup> As the regulations make plain, use of the deposit facility is not mandatory. In general, a deposit must only be made when ‘words alone cannot sufficiently describe how to make and use the invention in a reproducible manner’,<sup>204</sup> and the claimed material is not known and readily available to the public, or cannot be derived from readily available starting materials through routine screening that does not involve undue experimentation.<sup>205</sup> However, if the examiner forms the view that a deposit is needed, but it has

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<sup>197</sup> As of 1 March 2010, there were 38 such depositories, including two in Australia: The National Measurement Institute and the Lady Mary Fairfax Cellbank Australia. The type of biological material accepted by each depository varies widely. For example, neither of the Australian depository authorities accepts the deposit of plants or plant genetic materials. There are only four IDAs anywhere in the world that accept deposits of seeds.

<sup>198</sup> World Intellectual Property Organisation, *Guide to the Deposit of Microorganisms Under the Budapest Treaty*, Geneva: WIPO, 2006, at p. 4. The Guide is available from: <http://www.wipo.int/treaties/en/registration/budapest/guide/index.html>.

<sup>199</sup> IP Australia, *supra* n. 101.

<sup>200</sup> World Intellectual Property Organisation, *supra* n. 198.

<sup>201</sup> 27 USPQ 2d 1491 (1992).

<sup>202</sup> Cooper, I. P., *supra* n. 186, at p. 9-4.

<sup>203</sup> ‘Deposit of Biological Material’, 37 CFR 1, §1.801. ‘Biological material’ includes bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds.

<sup>204</sup> United States Patent and Trademark Office, *Manual of Patent Examining Procedure*, 2402.

<sup>205</sup> *In re Wands*, F. 2d 731 (1988), at p. 736.

not been made, s/he may reject the application under §112.<sup>206</sup> Where a deposit is made or is deemed necessary by the examiner, the specification must also contain, amongst other things, a description of the deposited biological material sufficient to specifically identify it and to permit examination.<sup>207</sup> With one exception, there is no requirement for a minimum number of materials to be deposited. However, where the invention consists of, or involves, a plant that is reproduced by seed, a minimum of 2500 seeds must be deposited with an IDA.<sup>208</sup> Significantly, U.S. patent applicants must only make the deposited material available to the public as of the date on which the patent is granted;<sup>209</sup> in contrast, most other jurisdictions, including Europe, require that the deposited material be made available to the public as of the day on which an application is published.<sup>210</sup>

In Europe, Rule 31(1) of the EPC Implementing Regulations provides that an application for an invention which ‘involves the use of or concerns’ biological material that is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, will be considered insufficient unless the biological material has been deposited with a recognised depositary institution no later than the filing date of the application.<sup>211</sup> In addition, the application must contain a disclosure of ‘such relevant information’ as is available to the applicant regarding the morphological and biochemical characteristics of the biological material deposited, and the proposed taxonomic description.<sup>212</sup>

In Australia, the provisions of both the *Patents Act 1990* and the *Patents Regulations 1991* are silent on this issue. Australia is, however, a signatory of the *Treaty*, which came into force in Australia on 7 July, 1987. The provisions of the *Treaty* are implemented by sections 6 and 41-2 of the *Patents Act 1990*, and in Part 2 of Chapter 3 of the *Patents Regulations 1991*. Whilst these provisions apply only to micro-organisms,<sup>213</sup> IP Australia adopts the position that the procedure established for the deposit of micro-organisms may also be relied on in relation to claims to plants. The same position obtains in a number of other countries.

Although the policy of allowing deposits of plant cells and plant reproductive material has not received judicial or legislative fiat, the introduction of the deposit system has been lauded for removing ‘the most critical impediment to patenting plants: repetition of the process of

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<sup>206</sup> 37 CFR 1, §1.809. However, the applicant is given the option of making good on this deficiency by making a deposit of the biological material, or by providing a written undertaking that s/he will do so.

<sup>207</sup> *Ibid.*.

<sup>208</sup> United States Patent and Trademark Office, *Manual of Patent Examining Procedure*, 2403. The same position obtains under the PVP. The applicant will be given the opportunity to request that a lesser number of seeds be deposited, however the quantity of seeds deposited must be sufficient to satisfy demand for samples once the patent is granted.

<sup>209</sup> *In re Argoudelis* 434 F. 2d 1390 (1970), at p. 1393: ‘It is not necessary that the general public have access to the culture prior to the issuance of the patent.’

<sup>210</sup> Rule 28(3) of the EPC Implementing Regulations.

<sup>211</sup> See also Art. 13(1) of the European Biotechnology Directive. ‘Biological material’ is any material containing genetic information and capable of reproducing itself or being reproduced in a biological system: r. 26(3); European Biotechnology Directive, Art. 2(1)(a).

<sup>212</sup> Rule 31(1)(b)/Art. 13(1)(b). Both the Implementing Rules and the Directive fail to specify what the ‘relevant information’ consists of; however, the Guidelines for Examination state that the relevant information is the morphological and biochemical characteristics of the biological material, and the proposed taxonomic description: *Guidelines for Examination in the European Patent Office*, Part C, II-12. The Guidelines may be obtained from [http://documents.epo.org/projects/babylon/eponet.nsf/0/7FFC755AD943703DC12576F00054CACC/\\$File/guidelines\\_2010\\_general\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/7FFC755AD943703DC12576F00054CACC/$File/guidelines_2010_general_en.pdf). Rule 33/Art. 13 also sets forth conditions for access to, and supply of, deposited samples.

<sup>213</sup> Section 41(1) of the Act provides that ‘to the extent that an invention is a micro-organism, the complete specification is to be taken to comply with paragraph 40(2)(a), so far as it requires a description of the micro-organism, if the deposit requirements are satisfied in relation to the micro-organism.’

making.’<sup>214</sup> However, this view is not universally accepted. One objection that has been articulated is that a deposit of heterozygous biological material, such as sexually reproduced plant seed, cannot be regarded as sufficient to fully describe (i.e. enable) such materials because it is not possible to consistently reproduce the results obtained by the breeder using the deposited sample:

... each deposited seed has a unique genetic composition that is essentially different to its parents and different to the other progeny ... where the deposited material is a heterozygous biological material resulting from sexual reproduction the deposited materials may not exhibit the desired characters and where those characters are exhibited they may not be expressed in the best genetic background.<sup>215</sup>

In other words, it may not be possible to reproduce from the deposited material the same results that were obtained by the breeder to the same degree, and it is unlikely that the plants produced from deposited seeds will represent the best mode of performing the invention.

To date, no court has directly addressed these concerns. However, in *Ex parte C*,<sup>216</sup> the USPTO’s Board of Patent Appeals and Interferences accepted that some degree of variation among the progeny of deposited seed was acceptable:

We see little difference between the concept of screening a microorganism to develop a desired strain, which was before the court in *Argoudelis*, and the concept of screening plants to develop a desired variety which is before us now. Appellant has disclosed the parent varieties crossed and provided a general description of the selection process. An exacting description relating to how to select for the desired plant could only detail an experimental screening program which would not necessarily result in the exact same plant being obtained but, rather, would result in one which, though different, would have virtually the same characteristics. We are in agreement with appellant that upon deposit of the seeds in the ATCC the specification satisfies the enablement and best mode requirements of 35 U.S.C. §112.<sup>217</sup>

Likewise, IP Australia takes the view that a specification is not insufficient simply because the results obtained by the applicant cannot be precisely replicated from deposited seed: ‘the issue when considering repeatability is not the numerical probability of achieving the specified result, but whether the result can be reproduced to a practical level acceptable to the person skilled in that particular technology.’<sup>218</sup> While IP Australia has not attempted to define what constitutes a ‘practical level’ of reproducibility, it has illustrated what it regards as an unacceptable level of repeatability. In a case involving the ‘Scarlett Queen Elizabeth’ rose, the method of production was a chance genetic mutation. It has been estimated that the chance of such a variety occurring is 1 in 100,000,000. IP Australia would consider this process essentially unrepeatable and would not grant the patent.<sup>219</sup> This is in line with the Technical Board of Appeal of the EPO’s decision in *Pioneer/Oilseed Brassica*,<sup>220</sup> in which a conventional plant breeding program which yielded only three lines with the claimed traits out of 700 backcrosses was not considered to be enabling.<sup>221</sup>

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<sup>214</sup> Van Overwalle, G., *supra* n. 109, at p. 187.

<sup>215</sup> Lawson, C., ‘Depositing Seeds to Comply with the *Patents Act 1990* (Cth) – The Adequacy of Definition and Description’, (2004) 23(1) *University of Tasmania Law Review*, 70 at pp. 76, 84.

<sup>216</sup> 27 USPQ 2d 1491 (1992).

<sup>217</sup> See also *Amgen Inc v Chugai Pharmaceutical Co* 927 F. 2d. 1200 (1991), at p. 1212: ‘we have long held that the issue is whether the disclosure is “adequate,” not that an exact duplication is necessary ... What is required is an adequate disclosure of the best mode, not a guarantee that every aspect of the specification be precisely and universally reproducible’; Moufang, R., ‘Protection for Plant Breeding and Plant Varieties – A Frontier of Patent Law’, (1992) 23 *International Review of Industrial Property and Copyright Law*, 328 at p. 341.

<sup>218</sup> IP Australia, *supra* n. 196.

<sup>219</sup> *Ibid.*

<sup>220</sup> T1026/02 [2004] EPOR 421.

<sup>221</sup> Although the case was concerned with whether a prior publication which disclosed the breeding program constituted an enabling disclosure which deprived the claimed plants of novelty, the TBA confirmed that ‘the

The TBA held that where the claimed plant traits – here, a Brassica line comprising a homozygous fertility restorer gene for ogura cytoplasmatic male sterility and low glucosinolate content – are the result of a fortuitous event (in this case, meiotic crossing over events), the disclosure will not be regarded as enabling ‘in the absence of evidence that such chance events occur and can be indentified *frequently enough* to guarantee success’ (emphasis added).<sup>222</sup> However, like IP Australia, the TBA did not elaborate on what level of frequency might be required.

Whilst the legal position is far from settled, these criticisms do expose some apparently unanticipated consequences of attempting to adapt a regime that was primarily designed to accommodate stable, homozygous organisms to organisms, such as sexually-reproduced plants, where no such uniformity can be expected. According to WIPO, the types of materials that are capable of being deposited were deliberately left open.<sup>223</sup> Whether or not this is an anachronism,<sup>224</sup> the use of the deposit system to supplement the description of heterozygous organisms raises questions to which the *Treaty* was apparently not designed to respond, and may not be capable of doing so.

### 4.3 The Relationship between Deposit and Description

Notwithstanding these concerns, it is widely accepted that the deposit requirement is supplementary to the written description requirement, and does not dispense with the need to fully describe the claimed plant. Thus, IP Australia states that ‘in addition to making a deposit of the inventive material under the Budapest Treaty, the applicant is required to provide as much descriptive information about the characteristics of the material as is possible at the time of making the application.’<sup>225</sup>

The Australian Patent Office has provided detailed guidance on the nature and extent of information that must be disclosed. In particular, the Australia Patent Office takes the view that in order to satisfy the sufficiency requirement contained in s. 40(2)(a) of the *Patents Act 1990*, the applicant must include in the specification a description of the full morphological, biochemical and taxonomic characteristics of the organism known to the applicant. For claims to plant varieties, a full description must be given of exactly how the claimed plant is prepared. This may include a description of the parental lines,<sup>226</sup> and how they were crossed in order to arrive at the claimed plant variety. In addition, parents of the variety must be easily available to the public in Australia (for example, commercially available or in an accessible depository) or be fully described themselves.<sup>227</sup>

Further, where the application contains claims to a complete plant, the entire organism must be described fully, with particular emphasis on the characteristics, or combination of characteristics, that are significantly different from known and related plants.<sup>228</sup> The specification must also provide a detailed taxonomic description of the plant. Characteristics to be included in the description, as appropriate, may include:

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criteria for examining the reproducibility of a technical teaching are the same in cases where the disclosure of a prior art document has to be judged’: at p. 424.

<sup>222</sup> T1026/02 [2004] EPOR 421, at p. 426.

<sup>223</sup> World Intellectual Property Organisation, *supra* n. 198.

<sup>224</sup> Certainly, this view was not shared, at least initially, by the German Federal Supreme Court, which, according to Bent et. al., ‘steadfastly refused to recognize a biological deposit as sufficient enabling “description” to support claims to living-matter inventions *per se*’: Bent, S., *supra* n. 117, at pp. 223-4.

<sup>225</sup> IP Australia, *supra* n. 101.

<sup>226</sup> For hybrid seeds, the parent must be fully described an available to the public. The different crosses conducted must be disclosed.

<sup>227</sup> IP Australia, *supra* n. 196.

<sup>228</sup> *Ibid*.

1. leaf characteristics (e.g. shape and length);
2. flower characteristics (e.g. colour, size, number of petals, presence or absence of sepals, pollen morphology, carpel and stamen number etc.);
3. stem characteristics (e.g. branching habits);
4. root characteristics;
5. fruit characteristics;
6. herbicide or pest resistance (if any); and,
7. scientific testing characteristics (e.g. isozyme analysis, DNA profiling, etc.), if available.<sup>229</sup>

Photographs must also be included in the description of the claimed plant.<sup>230</sup>

Perhaps the most important requirement for claims to a plant variety, the specification must, in addition to the broad description of the plant, include in the specification details of all steps required to reproduce the plant variety.

#### 4.4 Conclusion

Despite the perceived difficulties associated with complying with the written description and enablement requirements, they have seldom arisen as an issue in cases involving patented plant varieties or associated plant genetic materials.<sup>231</sup> As such, little is known about the way in which it might be applied to plants. What is clear is that the invention of the system for deposit of biological materials is widely regarded as having jettisoned what was regarded by industry for the better part of the past century as an insurmountable obstacle to the patenting of plants. This attitude marks a radical departure from that expressed in previous eras: whereas previously it was presumed that the written description and enablement requirements represented an intractable obstacle to the patenting of plants, today it is presumed that these requirements can readily be satisfied by making a deposit of plant seed with a recognised depository. It remains to be seen whether this *volte-face* will be vindicated. As noted above, the deposit system is no panacea for the problems associated with complying with the enablement requirement, particularly in regard to sexually-reproduced plants. It appears more likely, as Janis and Kesan alluded to almost a decade ago, that the enablement requirement (along with non-obviousness) is likely to remain the focus of the courts 'as the law of utility patents for plants continues to develop.'<sup>232</sup>

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<sup>229</sup>Ibid.

<sup>230</sup> Ibid. Prior to the commencement of the *Patents Act 1990*, Australian Patent Office practice required a supply of 40 colour photographs, an anatomical description and a description of how the claimed plant is distinct from other closely related varieties: Ayers, K., Castle, S., and Ross, M., *Background Paper on Australian Patents for Plants*, Woden: Australian Patent Office, 1989, at p. 19.

<sup>231</sup> The written description issue has arisen in the context of human genetic materials, particularly in the United States, where the question of whether a separate written description requirement exists apart from the enablement requirement has aroused considerable controversy. See *Regents of the University of California v Eli Lilly* 199 F. 3d 1559 (1997); *Enzo Biochem Inc v Gen-Probe Inc* 285 F. 3d 1013 (2002). In short, these decisions held that claims directed to materials of biological origin that describe the materials merely by reference to their function do not satisfy the written description requirement. Instead, the applicant or patentee must show that they are in 'possession' of the invention, e.g. by describing the structure, or partial structure, of the materials claimed, or by making a deposit of such materials. It would appear that this issue is now finally settled, and that there is indeed a separate written description requirement: see *Ariad Pharmaceuticals Inc v Eli Lilly & Co*, 598 F. 3d 1336 (2010).

<sup>232</sup> Janis, M. D., and Kesan, J. P., *supra* n. 103, at pp. 1161-1162.

# 5 Consequences of a Shift towards the Use of Patents to Protect Plant Innovations

## 5.1 Introduction

In this section we consider some of the likely implications of a shift towards the use of patents to protect plant innovations. In particular, we examine the major differences between patents and plant breeder's rights which are said to make patents more appealing to those who invest in plant innovation, namely:

- the absence of a research exemption in patent law;
- the absence of a farm-saved seed exception in patent law; and
- the scope of patent rights.

Before we consider these issues it is important to stress that, while these are important differences, they should not be overemphasised. This is because owners of plant breeder's rights frequently negate the effect of these exceptions under plant breeder's rights legislation through the use of what has been dubbed 'private legislation'; that is, the use of restrictive terms in licence agreements that regulate the use which farmers and researchers can make of protected propagating material which they have purchased. Whilst the absence of these exceptions in patent law arguably gives the patentee greater certainty in these areas, the ability of PBR owners to contract out of these defences essentially achieves the same result.

In practice, a shift towards the use of patents to protect plant innovation is likely to have the greatest impact upon research and breeding practices, particularly the use of biotechnological techniques and materials utilised in the transformation of plants. To some extent, these impacts are already being felt. What further impact they can be expected to have will depend in large part upon the nature and scope of any future research exemption introduced into Australian patent law. Before the recent Federal election, the Howard government announced its intention to amend the *Patents Act 1990* to incorporate a research exemption into Australian patent law. However, the nature and scope of the exemption was not made clear at that time. It is also unclear whether the Rudd Government supports the proposal. We consider some of the possible forms the exemption might take below.

## 5.2 Can Patented Materials or Processes be used for Research Purposes?

One of the reasons for the increasing interest in the use of patents to protect plant and animal innovation is the absence of a broad-ranging research or breeder's exemption in patent law.<sup>233</sup> In contrast to the position under UPOV, a cornerstone of which is a broad experimental use or 'breeder's exception', *any* use of a patented invention without the prior authorisation of the patentee will constitute *prima facie* infringement of the patent. The patent laws of most jurisdictions contain a limited defence which exempts acts done for *bona fide* experimental purposes from infringement. However, the nature and scope of permitted experimental use

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<sup>233</sup> The American Seed Trade Association has stated that 'open access to germplasm allowed under UPOV for breeding immediately upon commercialization has the effect of diminishing the developer's opportunity to earn a competitive return on research investments': American Seed Trade Association, *Position Statement on Intellectual Property Rights for the Seed Industry*, 15 July 2004 (<http://www.amseed.com/newsDetail.asp?id=97>).



differs from one jurisdiction to another. In general terms, two distinct approaches to the treatment of experimental use can be discerned among the major patent systems.

### **5.2.1 The Research Exemption in the United States**

At one end of the spectrum, represented by the United States, the experimental use defence is regarded as ‘truly narrow’ and has no application where the use has ‘the slightest commercial implication’ or where the act is done ‘in furtherance of the alleged infringer’s legitimate business interests’.<sup>234</sup> On this view of the experimental use defence, only acts performed ‘for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry’ are exempt from infringement.<sup>235</sup> Significantly, the United States Court of Appeals for the Federal Circuit held in *Madey v Duke University* that the activities of universities are inherently commercial and, as such, use of patented inventions by academic scientists and researchers in the United States will generally not be exempt from infringement under United States patent law.<sup>236</sup> Contrary to popular belief, academic researchers are not therefore exempt from patent infringement. Insofar as academic researchers have to date avoided liability for patent infringement, this is largely due to the fact that patentees have refrained from suing academic researchers for pragmatic or commercial reasons (for instance, seeking to enforce a patent once the research is commercialised), rather than any *per se* exemption of these activities from infringement.

### **5.2.2 The Research Exemption in Europe**

At the other end of the spectrum lies the approach of a number of European countries to the scope of the experimental use defence. The *European Patent Convention* stipulates only the grounds upon which a European patent may be granted, leaving individual members to determine what constitutes infringement of a European patent. Although it has not entered into force, the experimental use provisions contained in the patent laws of the majority of members of the *European Patent Convention* are modelled on Article 27(b) of the *Agreement Relating to Community Patents* (otherwise known as the *Community Patent Convention* or *CPC*) which states that ‘the rights conferred by a Community patent shall not extend to acts done for experimental purposes relating to the subject-matter of the invention’.<sup>237</sup>

To date, there have been few decisions in which the scope of this exception has been considered. However, the scope of the experimental use exception under German law (which contains in Section 11(2) identical wording to that used in the *CPC*) was considered by the German Federal Supreme Court in two cases – *Klinische Versuche (Clinical Trials) I*<sup>238</sup> and *Klinische Versuche (Clinical Trials) II*<sup>239</sup> – which the Australian Law Reform Commission described as the ‘high-water’ mark of the experimental use defence. Both cases concerned the use of patented pharmaceutical compounds in clinical trials: the first, for the purpose of identifying new therapeutic indications for the protein interferon-gamma, which is used to treat rheumatoid arthritis; the second, for the purpose of determining the most effective dosage form for the protein erythropoietin, which promotes the production of red blood cells and is used in the treatment of anaemia. In both

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<sup>234</sup> *Madey v Duke University* 307 F. 3d 1351 (2002), at p. 1362.

<sup>235</sup> *Ibid.*; *Roche Products Inc v Bolar Pharmaceutical Co Inc* 733 F. 2d 858 (1984), at pp. 862, 863. See *contra* Newman J’s dissent in *Integra Lifesciences Ltd v Merck KGaA* 331 F. 3d 860 (2003).

<sup>236</sup> The Court stated that although ‘major universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever ... these projects unmistakably further the institution’s legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.’

<sup>237</sup> Article 27(a) also exempts from infringement ‘acts done privately and for non-commercial purposes’.

<sup>238</sup> [1997] RPC 623.

<sup>239</sup> [1998] RPC 423.

cases the German Federal Supreme Court found that the respective uses fell within the scope of the experimental use exception.

In *Clinical Trials I*, the Court held that it would be inconsistent with the objectives of the patent system to exclude experimental acts which serve research and further technical development. The Court rejected the patentee's argument that allowing the defendant to use the patented compound in clinical trials would diminish the economic value of the patent. On the contrary, the Court took the view that the defendant's use of the compound in clinical trials in fact enhanced the value of the patent because the defendant would be unable to exploit the discovery of any new use of the compound without the permission of the patentee. More controversial was the Court's decision in *Clinical Trials II*, in which the Court held that the use of erythropoietin in clinical trials for the purpose of obtaining regulatory approval to market a particular dosage form of the drug was also exempt from infringement. The fact that the experimental use was carried out for a commercial purpose was irrelevant to the application of the exception.<sup>240</sup>

### **5.2.3 The Research Exemption in Australia**

Although the experimental use exemption remains uncertain in Australia, the exemption (to the extent that one exists) is thought to lie somewhere in between these two extremes. As with the United States, there is no statutory research exemption in the *Patents Act 1990*. Unlike the United States, however, there has been no Australian decision in which the existence or scope of an experimental use exception under Australian patent law has been considered. Despite the scarcity of case law, a number of arguments have been made in favour of the existence of a research exemption in Australian patent law.

Firstly, it is said that as the exclusive rights granted to a patentee are of a distinctly commercial character (as to which see section 13 and the definition of 'exploit' in Schedule 1), patented inventions may be used in a way that does not trespass upon the commercial interests of the patentee. The usual rejoinder to this argument is that a patent is, fundamentally, a negative right to exclude others from exploiting the patented invention, and, as such, any use of the invention infringes upon the commercial interests of the patentee in that it involves a lost opportunity to extract a license or royalty. Moreover, given the commercial nature of much of the research undertaken in universities today, it is becoming increasingly difficult to clearly distinguish commercial from non-commercial research.

Secondly, it is argued that persons other than the patentee ought to be permitted to make and use the invention in order to test the validity of the patent; for example, to ascertain whether it is useful or to ascertain whether the patentee has sufficiently described his or her invention. This, it is said, is implicit in the requirements relating to sufficiency of disclosure in section 40 of the *Patents Act 1990*. That section, among other things, requires the applicant for a patent to file a complete specification containing a full description of the invention, including the best mode known to the applicant of working the invention. This requirement would be idle and pointless,

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<sup>240</sup> The English Courts are yet to countenance this approach. In *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515, the English Court of Appeal accepted that an act directed towards a commercial end might legitimately fall within the scope of the exception if the act is done in order to discover something unknown, to test a hypothesis or to find out whether something which is known to work in specific conditions will work in different conditions, trials carried out in order to demonstrate to a third party (such as a regulatory body) that a product works or, in order to amass information to satisfy a third party, whether a customer or body, that the product works as its maker claims is not be regarded as acts done for 'experimental purposes'. The same result was reached by the New Zealand Court of Appeal in *Smith, Kline & French Laboratories Ltd v Attorney-General (NZ)* (1991) 22 IPR 143. Cornish, however, has argued that there is a strong likelihood that the *Clinical Trials* decisions will be followed elsewhere in the European Community: Cornish, W. R., 'Experimental Use of Patented Inventions in European Community States', (1998) 29 *International Review of Industrial Property and Copyright Law*, p. 735.

it is argued, if the public were prevented from using that information for any purpose during the term of the patent.<sup>241</sup> Moreover, it would be contrary to the public interest to require a person to obtain a licence from the patentee in order to test the validity of a patent. Whilst this argument has some merit, it leaves unanswered the question of whether the information contained in a specification can be used only for the purpose of testing the validity of the patent, or whether this information can also be used for other purposes, such as experimental use.

Besides arguments based upon implications drawn from the wording of the Act, an experimental use exception is also said to exist at common law. This argument finds support in the judgment of Sir George Jessel MR in *Frearson v Loe*,<sup>242</sup> where the Master of the Rolls said at pp. 66-7:

... no doubt if a man makes things merely by way of *bona fide* experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with a view to improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither using nor vending of the invention for profit, the mere making for the purpose of experiment, and not for a fraudulent purpose, ought not to be considered within the meaning of the prohibition, and if it were, not the subject for an injunction.

These comments support the idea that a common law experimental use defence exists, which is of substantially greater scope than the two ‘implied defences’ based upon the wording of the Act. However, whilst *Frearson v Loe* has been applied by both the Court of Appeal in New Zealand and the United Kingdom Court of Appeal, it has not been the subject of judicial consideration in Australia. Consequently, doubts have been raised about whether the decision represents the law in Australia. The fact that the case was decided late in the nineteenth century, a period far removed from the realities of the present day R & D environment, has added to this uncertainty.

In view of the uncertainty which exists with respect to the existence and scope of any experimental use exception under Australian patent law, the Australian Law Reform Commission recommended in 2002, as part of its enquiry into gene patenting and human health, that the *Patents Act 1990* be amended to include an express experimental use exception to patent infringement.<sup>243</sup> The ALRC suggested that the exemption should apply to acts done to study or experiment on the subject matter of a patented invention – for example, to investigate its properties or improve upon it. At a minimum, experimentation that seeks further knowledge about the patented invention and its uses should be exempt from liability for infringement. The ALRC also considered that the existence of a commercial purpose should be irrelevant to the availability of the defence, provided that the dominant or sole purpose of the use of the patented subject matter is study or experimentation. In essence, the position favoured by the ALRC is that research *on* a patented invention with a view to discovering something new about the patented subject matter (for example, identifying an alternative use for a patented gene or protein) should be exempt from infringement, whilst research *with* a patented invention (for example, the use of PCR, RNAi or *Agrobacterium*-mediated transformation) would be regarded as infringement. As such, the exception would not apply to the use of many of the patented research tools that have

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<sup>241</sup> This argument found favour with Newman, J. of the United States Court of Appeals for the Federal Circuit in *Integra Lifesciences Ltd v Merck KGaA* 331 F. 3d. 860 (2003). However, Newman, J. was dissenting judge in that case. Aldous, J. was more circumspect, however, in *Smith Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] 1 FSR 513.

<sup>242</sup> (1878) 9 Ch D 48.

<sup>243</sup> Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No. 99, Sydney: Australian Law Reform Commission, 2004, Chapter 13.

given rise to concerns about the potential for ‘anti-commons’ effects in biotechnology.<sup>244</sup> Moreover, the scope of the defence remains uncertain, particularly in relation to plant breeding. It is unlikely, for instance, that the exception would exempt the use of a patented plant variety to produce a new variety, since this would involve research *with* the patented variety rather than research *on* the patented variety. Despite this, the approach advocated by the ALRC is much closer to the position which obtains in Europe than to the much more restrictive approach adopted by the courts in the United States.

Prior to the release of the ALRC’s final report, the Parliamentary Secretary to the Minister for Industry, Tourism and Resources requested the Advisory Council on Intellectual Property to examine whether Australian businesses and researchers would benefit from the introduction of an experimental use provision into Australian patent law. In its final report, released in November 2005, ACIP also recommended that the *Patents Act 1990* be amended to include a definite experimental use defence, although its proposal differs from the one proposed by the ALRC in a number of material aspects. Whilst ACIP agreed that the existence of a commercial purpose should not adversely affect the ability of a party to invoke a defence of experimental use, it thought that the boundary between experimental use *on*, and experimental use *with*, a patented invention was insufficiently clear to be of assistance in defining the scope of the defence. Instead, ACIP recommended that the following exception be introduced into the Act:

The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of the patent.

Acts done for experimental purposes relating to the subject matter of the invention include:

- Determining how an invention works;
- Determining the scope of the invention;
- Determining the validity of the claims;
- Seeking an improvement to the invention.<sup>245</sup>

However, ACIP emphasised that these acts should not necessarily be regarded as permitted acts as they are still subject to the overarching test of whether they would unreasonably conflict with the normal exploitation of the patent.

It is questionable whether the test proposed by ACIP provides greater clarity regarding the scope of an experimental use defence than the proposal put forward by the ALRC. In particular, considerable confusion exists in relation to what constitutes ‘normal’ exploitation of a patent, and what type of conduct is likely to ‘unreasonably conflict’ with that exploitation. Moreover, the scope of the defence appears narrower than the ALRC recommendation. The first three acts

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<sup>244</sup> The ‘anti-commons’ effect arises when ownership of a patented technology is fragmented between a number of different owners with the consequence that the transaction costs of licensing the technology from the various different owners becomes a disincentive to its use. The development of beta-carotene rice is an oft-cited example of the potential for hold-ups in plant agricultural biotechnology. See Pray, C. E., & Naseem, A., ‘Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies’, (2005) 8 (2&3) *AgBioForum*, pp. 108-117.

<sup>245</sup> The defence proposed by ACIP is an odd amalgam of the wording of the experimental use defence in Article 27(b) of the *CPC* and Article 30 of the *TRIPs Agreement* (which is in turn derived from the three-step test applied to the permissibility of exceptions to infringement of copyright under the *Berne Convention for the Protection of Literary and Artistic Works*). Article 30 of the *TRIPs Agreement* allows Members to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. The three-step test from Article 9(2) of the *Berne Convention* establishes the criteria against which exceptions to the right to reproduce copyright material are to be assessed. The steps are (1) that reproductions may be permitted in special cases, but (2) are not to conflict with normal exploitation of the work, and (3) must not unreasonably prejudice the legitimate interests of the copyright owner.

referred to as ‘acts done for experimental purposes relating to the subject matter of the invention’ (determining how an invention works, determining the scope of the invention, and determining the validity of the claims) simply reflect the ‘implied defences’ referred to above – namely, that some degree of experimental use is permitted implied by the *Patents Act 1990* by virtue of the timing of the written description requirement. This supports a narrow view of the scope of the experimental use defence. The ACIP proposal also fails to provide any guidance as to the types of activities that are likely to qualify as improvements to the invention.

Despite these shortcomings, on 6 August 2007, the (then) Parliamentary Secretary to the Minister for Industry, Tourism and Resources, Bob Baldwin, announced the Government’s intention to amend the *Patents Act 1990* (Cth) to introduce for the first time in Australian patent law an express experimental use exception to patent infringement. In its response to ACIP’s report,<sup>246</sup> the Federal Government expressed ‘in principle’ support for the provision proposed by ACIP, although the exact form of any future experimental use exception remains unknown. Adding to the uncertainty, the Federal Government has stated that the Explanatory Memorandum accompanying any future Bill to introduce an experimental use defence will ‘clarify that acts done for experimental purposes relating to the subject matter of the invention may also include “seeking new uses for, or determining new properties of, the invention”’. This move is obviously intended to give effect to the recommendation of the ALRC and, in so doing, will not only increase the scope of the proposed defence, but also bring the Australian law closer to the position which obtains in Europe. However, the chosen means of implementing the ALRC’s recommendation (in an Explanatory Memorandum rather than the Bill itself) will do little to reduce uncertainty regarding the scope of any future defence. For example, will the use of a patented invention for the purpose of seeking new uses for, or determining new properties of, the invention also be subject to the qualification that such use must not unreasonably conflict with the normal exploitation of the patent, as is the case in relation to the other acts referred to in the draft provision? The fate of the proposal under the Rudd Government is also unclear.

Until such time as a clearly-defined and robust experimental use exception is introduced into Australian patent law, interest in the use of patents to protect plant innovations is likely to continue given the opportunity for increased revenue appropriation in the absence of an experimental use defence. Further, the disparity between the scope of the proposed exception and the scope of the breeder’s exemption under plant breeder’s rights legislation has the potential to compromise the latter, given the availability of dual protection under Australian law. Suppose, for instance, a variety of cotton has been genetically transformed for resistance to a certain disease, and the resulting variety is protected by both PBR and patent (for the gene conferring disease resistance). Under current interpretations of the scope of gene patents, any use of the protected variety by third parties in breeding programs, which may be undertaken without licence of the PBR owner under the *Plant Breeder’s Rights Act*, will infringe the patent over the gene. This is because the scope of patent claims to a gene extends to all materials in which the gene is incorporated and (in Europe, at any rate) performs its function. The existence of the patent for the gene therefore effectively negates the operation of the breeder’s exception under the *Plant Breeder’s Rights Act*.

For this reason, a number of attempts have been made (where the possibility of dual protection exists) to introduce into patent law a breeder’s exemption of equal or comparable breadth to that enjoyed by plant breeders under plant breeder’s rights legislation. Indeed, support for this proposition has come from unlikely sources. Among them, the International Seed Federation stated in its 2003 position paper on intellectual property that:

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<sup>246</sup> The Government’s response is available from: <http://www.ipaustralia.gov.au/pdfs/news/20070708.pdf>.

... further clarification is needed as regards the use of transgenic varieties containing patented elements and protected by Breeder's Right for further breeding. ISF is strongly attached to the breeder's exception provided for in the UPOV Convention and is concerned that the extension of the protection of a gene sequence to the relevant plant variety itself could extinguish this exception. Therefore ISF considers that a commercially available variety protected only by Breeder's Rights and containing patented elements should remain freely available for further breeding. If a new plant variety, not an essentially derived variety resulting from that further breeding, is outside the scope of the patent's claims, it may be freely exploitable by its developer. On the contrary, if the new developed variety is an e.d.v. or if it is inside the scope of the patent's claims, consent from the owner of the initial variety or of the patent must be obtained.<sup>247</sup>

To date, only France and Germany have introduced into their patent laws a breeder's exemption of comparable scope to that provided under UPOV. In both countries, patent protection on a biological product 'does not extend to acts done for the purpose of creating, or discovering and developing other plant varieties'.<sup>248</sup> Few other countries have indicated any interest in following in France and Germany's footsteps, and it has been suggested that the defence is inconsistent with the TRIPs Agreement.

Finally, the effectiveness of any future research exemption will depend in large part upon the extent to which patentees are able to restrict its operation through the use of licensing conditions when patented plants or animals are placed on the market by a patentee, and the extent to which it is possible to enforce these conditions against downstream purchasers.<sup>249</sup> In obedience to freedom of contract, courts have generally left the parties to patent licences and assignments free to determine the scope and extent of obligations by mutual agreement between themselves. Thus, in *Incandescent Gas Light v Cantelo*, Wills, J. said:

The sale of a patented article carries with it the right to use it in any way that the purchaser chooses to use it, unless he knows of restrictions. Of course, if he knows of restrictions, and they are brought to his mind at the time of sale, he is bound by them. He is bound by them on this principle: the patentee has the sole right of using and selling the articles, and he may prevent anybody from dealing with them at all. Inasmuch as he has the right to prevent people from using them or dealing with them at all, he has the right to do the lesser thing, that is to say, to impose his own conditions. It does not matter how unreasonable or how absurd the conditions are. It does not matter what they are, if he says at the time when the purchaser proposes to buy or the person to take a licence: 'Mind, I only give you this licence on this condition,' and the purchaser is free to take it or leave it as he likes. If he takes it, he must be bound by the condition.<sup>250</sup>

However, the use of restrictive covenants in licensing agreements to negate policy-based exceptions to infringement of intellectual property rights (such as the farm-saved seed exception under the *Plant Breeder's Rights Act*) remains a controversial issue in intellectual property law. To date, no Australian court has considered the enforceability of these provisions. The general consensus, however, is that contractual provisions that override statutory protections from infringement of intellectual property rights are valid and enforceable. Courts in the United States

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<sup>247</sup> International Seed Federation, *ISF View on Intellectual Property*, 2003 ([http://www.worldseed.org/pdf/ISF\\_View\\_on\\_Intellectual\\_Property.pdf](http://www.worldseed.org/pdf/ISF_View_on_Intellectual_Property.pdf)). See also *Development of New Plant Varieties and Protection of Intellectual Property*, 1999 ([http://www.worldseed.org/Position\\_papers/IPprotectione.htm](http://www.worldseed.org/Position_papers/IPprotectione.htm)). The Plant Committee of the Intellectual Property Law Section of the American Bar Association has emphatically rejected this proposal. See <http://www.abanet.org/intelprop/summer2004/1002.pdf>.

<sup>248</sup> Ghijsen, H., *supra* n. 155, at p. 90.

<sup>249</sup> For example, Monsanto's North American 1998 'Technology Agreement' for Round-up Ready soybeans provides that purchasers must agree 'to not use this seed or provide it to anyone for crop breeding, research, generation of herbicide registration data or seed production.'

<sup>250</sup> (1895) 12 RPC 262.

have also inclined to this view. Nevertheless, on general principles, it is difficult to justify the use of such terms, and the issue warrants further consideration.<sup>251</sup>

### 5.3 Scope of Protection

Intellectual property rights are, like property rights generally, essentially negative rights. That is, intellectual property rights do not confer upon the grantee or owner of the right any positive entitlement to exploit the protected subject matter (i.e. make, use, sell etc. the protected subject matter).<sup>252</sup> Instead, the grant or subsistence of intellectual property rights merely confers upon the owner of the rights the power to prevent others from exploiting the protected subject matter without his/her authorisation. This feature of intellectual property is of particular significance for plant-related innovations because of the nature of the subject matter and, most notably, their ability for (self)-reproduction.

#### 5.3.1 Unconditional Sales of Patented Goods

On general principles, the sale of unpatented goods confers upon the purchaser all of the ordinary incidents of ownership, including the right to sell or dispose of the article.<sup>253</sup> However, patents represent, as Stephen J acknowledged in *Interstate Parcel Express Co Ltd v Time-Life International (Netherlands) B.V.*,<sup>254</sup> a ‘quite special case’. The special nature of patents arises by virtue of the scope and nature of the rights conferred by a patent. Unlike other intellectual property rights, a patent confers upon the patentee the exclusive right to ‘exploit’ the patented invention and to authorise another person to exploit the invention.<sup>255</sup> The scope of these rights varies according to whether the invention relates to a product or a process. Where the patented invention is a product, the patentee enjoys the exclusive right to make, hire, sell, or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things. On the other hand, where the patented invention is a process or method, the patentee enjoys the exclusive right to use the patented method or process only. In the case of a process the use of which results in a product, patentee’s rights extend to the products themselves.<sup>256</sup> However, it remains necessary for the patent owner to prove that any infringing products were made by the patented process.

As noted by Lord Bridge in *British Leyland Motor Corp Ltd v Armstrong Patents Co Ltd*, ‘[a] literal application of this language would lead to the absurdity that a person who acquired the patented goods would infringe the patent if he used or resold them’.<sup>257</sup> To avoid this conundrum, the courts have introduced a qualification of the principle that any use of, or dealing with, a patented invention placed on the market by the patentee gives rise to infringement of the patent. In the United States and Europe, this principle is known as the doctrine of ‘exhaustion’. The doctrine of exhaustion provides that once a patented invention is sold or placed on the market by the patentee, the patentee’s rights under the patent are ‘exhausted’ in relation to that product and the patentee is unable to exercise any of the rights under the patent against the purchaser. In effect, the doctrine of exhaustion treats patented products in the same way as unpatented products. A

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<sup>251</sup> The use of restrictive licensing terms to contract out of defences to copyright infringement is considered in the Copyright Law Review Committee’s report, *Copyright and Contract* (available from: <http://www.ag.gov.au/www/clrHome.nsf/AllDocs/RWP092E76FE8AF2501CCA256C44001FFC28?OpenDocument>).

<sup>252</sup> *Steers v Rogers* [1893] AC 232, at p. 235, per Herschell LC.

<sup>253</sup> Subject to any restrictions legitimately imposed by the vendor upon the purchaser’s full enjoyment of the property at the point of sale.

<sup>254</sup> *B.V.* (1977) 138 CLR 534.

<sup>255</sup> *Patents Act 1990*, s. 13. In comparison, copyright and trade marks essentially confer upon the owner a right of reproduction.

<sup>256</sup> *Patents Act 1990*, Sch. 1, definition of ‘exploit’.

<sup>257</sup> [1986] AC 577., at p. 623.

purchaser of patented goods accordingly enjoys all of the ordinary incidents of ownership in respect of the purchased article, including the right to use, modify, repair, dispose of, and resell it. However, the right to make the article according to the patented invention is not exhausted.<sup>258</sup>

The doctrine of exhaustion has not been accepted in Australia. Instead, the law implies from the sale of a patented article a fictional licence given by the patentee to the purchaser which authorises the purchaser to use the goods for their intended purpose and to sell or otherwise dispose of them.<sup>259</sup> This is known as the doctrine of 'implied licence'. The effect of the doctrine of implied licence is similar in effect to the doctrine of exhaustion insofar as the purchaser of the patented goods is free to deal with them as if they were not patented. As is the case with exhaustion, the implied licence given by the patentee to the purchaser of the patented article extends to subsequent purchasers deriving title to the patented article through the initial purchaser (for example, through sale or gift).<sup>260</sup> A further similarity between the doctrine of exhaustion and the doctrine of implied licence is that the scope of implied licence does not include the right to make the patented article anew.

### **5.3.2 Conditional Sales of Patented Goods**

An important limitation on both the doctrine of exhaustion and the doctrine of implied licence is the ability of the patentee to impose conditions upon the sale of the patented article. In much the same way as the vendor of goods is able to place restrictions on the use or enjoyment of goods offered by them for sale, a patentee is likewise free to impose limitations or conditions upon the exploitation of the patented article by the purchaser, such as prohibiting resale of the patented article or prohibiting the use of the patented article in breeding programs or for the purpose of research.<sup>261</sup> Generally speaking, these conditions are enforceable against the purchaser of a patented article provided that they are brought to the purchaser's attention at or before the time of sale. Consequently, a purchaser is not bound by any conditions purporting to restrict the use which can be made of a patented article purchased by him after the sale has been completed.<sup>262</sup> For this reason, conditions attaching to the sale of a patented article often appear on the article itself, as, for instance, is the case with seed-wrap or bag-tag licenses (although it may be questioned whether these terms are enforceable against the purchaser if they are not brought to his or her attention at the time of sale). Significantly (and somewhat controversially), courts in the United States have held that the doctrine of exhaustion is inapplicable where the sale or licence of a patented invention is subject to restrictive conditions.<sup>263</sup>

### **5.3.3 The Limits of Exhaustion/Implied Licence**

Another important limitation upon both the doctrine of exhaustion and the doctrine of implied licence that is particularly relevant to patented plants and animals is that neither doctrine permits the purchaser to make an article which embodies the patented invention. In other words, the doctrines of exhaustion and implied licence apply only to the articles actually sold. This has important ramifications for the operation of the doctrine of exhaustion and implied licence in relation to animate subject matter, such as plants and animals, which can be reproduced without direct human intervention. In particular, the patentee's rights in relation to subsequent generations of plants produced from patented seed that has been legitimately purchased by the purchaser are not exhausted, nor does the purchaser obtain any implied licence to use or deal

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<sup>258</sup> *Jazz Photo Corp v International Trade Commission* 264 F. 3d 1094 (2001).

<sup>259</sup> *Badische Anilin and Soda Fabrik v Isler* [1906] 1 Ch 605; *Interstate Parcel Express Co Pty Ltd v Time-Life International (Netherlands) B.V.* (1977) 138 CLR 534; *National Phonographic Co of Australia v Menck* [1911] AC 336.

<sup>260</sup> *Incandescent Gas Light Co v Cantelo* (1895) 12 RPC 262.

<sup>261</sup> However, this freedom is subject to competition laws.

<sup>262</sup> *Incandescent Gas Light Co v Cantelo* (1895) 12 RPC 262.

<sup>263</sup> *Mallinckrodt Inc v Medipart Inc* 976 F. 2d 700 (1992); *Monsanto Co v Scruggs* 249 F. 2d 746 (2001).



with second generation seed even in the absence of any restrictive term or condition in the licence limiting the purchaser's ability to save and use seed produced from seed legitimately purchased by them. Use of farm-saved seed without the authorisation of the patent holder therefore constitutes an infringement of the patent.

This point was made clear by the United States Court of Appeals for the Federal Circuit in *Monsanto Co v McFarling*,<sup>264</sup> a case involving a North American farmer (McFarling) who was found to have infringed Monsanto's patents for glyphosphate-resistant plant cells when he saved and replanted soybean seeds from a previous year's crop. McFarling argued that as he had initially purchased the soybean seeds used to produce the initial crop, Monsanto's rights in relation to the seeds saved from this initial crop had been exhausted. The US Court of Appeals for the Federal Circuit rejected this argument. The Court held that the first sale doctrine of exhaustion did not apply to the seeds saved by McFarling because not only did '[t]he original sale of seeds ... not confer a licence to construct new seeds', but also 'since the new seeds grown from the original batch had never been sold they entailed no principle of patent exhaustion'.<sup>265</sup> This reasoning was later upheld by the United States Court of Appeals for the Federal Circuit in *Monsanto Co v Scruggs*.<sup>266</sup> In addition, the Court of Appeals stated that '[w]ithout the actual sale of the second generation seed to Scruggs, there can be no patent exhaustion. The fact that a patented technology can replicate itself does not give the purchaser the right to use replicated copies of the technology. Applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder'.<sup>267</sup>

According to this reasoning, any use of second generation seed will amount to infringement of the patent irrespective of whether the initial sale of seed is subject to this prohibition or not, at least in respect of asexually produced plants and genetically-modified plants which contain a patented gene.<sup>268</sup> This leads to the potentially anomalous situation whereby any use of second generation seed, for example the sale of seed from wheat crops as grain, will amount to infringement of the patent even though the purpose of the initial sale or licence was the production of a commercial crop. In the *Monsanto* cases, this anomaly was avoided by the terms of the licence which permitted the use of the purchased seeds for the production of a single commercial crop. In Europe, this potential anomaly is avoided by the joint operation of Articles 8, 9 and 10 of the *European Biotechnology Directive*. Article 8(1) provides that the protection conferred by a patent on a biological material possessing specific characteristics shall extend to any biological material derived from the patented biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. Further, Article 9 provides that the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function. However, Article 10 provides that the protection conferred by Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market by the holder of the patent or with his consent, where the multiplication of propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication. Thus, a farmer does not infringe a patent simply by virtue of sowing a crop from patented seed or seed

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<sup>264</sup> 302 F. 2d 1291 (2002).

<sup>265</sup> 302 F. 3d 1291 (2002), at p. 1299.

<sup>266</sup> 459 F. 3d 1328 (2006).

<sup>267</sup> *Ibid.*, at p. 1336.

<sup>268</sup> For sexually produced plants, however, this will depend on the scope of the claims, in particular whether they may validly extend to progeny of patented varieties since these will rarely breed true-to-type.

containing a patented gene and producing further seed or propagating material containing a patented gene.

### ***5.3.4 The Scope of Claims to DNA under the European Biotechnology Directive***

The nature and scope of the extension of the protection afforded by Articles 8 and 9 was recently considered by the European Court of Justice, as well as by courts in Denmark, The Netherlands, Spain and the United Kingdom. In March, a Dutch court referred to the ECJ a number of questions relating to the interpretation of Articles 8 and 9, as well as questions regarding the relationship between the Directive and the pre-existing patent law of each member state. The litigation which gave rise to the referral concerns the shipment of soya meal containing traces of a DNA sequence from Argentina, where the DNA sequence is not patented, to the EU, where it is. Monsanto sued various European importers for patent infringement, alleging that the importation of the soya meal infringed claims to DNA sequences which, when transferred to, and expressed in, plants, confer resistance to glyphosate herbicides, and to methods of producing such plants.

The patent includes claims to a DNA sequence encoding a Class II 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) enzyme, which, when transferred to and expressed in plants, confers resistance to glyphosate herbicides – in particular, Monsanto's 'Roundup Ready' herbicide. The patent also contains claims to methods of producing genetically-transformed plants that are tolerant toward glyphosate herbicide, and glyphosate-tolerant plant cells comprising the claimed DNA sequence. Certain of the claims to the DNA sequence also included the term 'isolated', a feature that was not without significance for the construction of the claims in the U.K. proceedings. The underlying purpose of the invention was to develop plants that would not be affected by Monsanto's glyphosate herbicide 'Roundup'. Monsanto has introduced this 'Roundup Ready' technology into a number of plant varieties, including soya, cotton, maize and canola (oilseed rape).

Monsanto alleged that the importers had, by importing the soya meal into the respective countries, infringed both the claims to the DNA sequence as such, as well as the claims to methods of producing genetically-modified glyphosate-tolerant plants. The company commenced proceedings against the European importers because they were unable to secure patent protection for the invention in Argentina. This followed attempts by Monsanto to broker an agreement with the Argentinean government whereby Argentinean exporters would be required to pay Monsanto US\$3 per tonne to export the soya meal and US\$15 per tonne upon importation into the EU.<sup>269</sup> Whilst Monsanto had succeeded in negotiating similar agreements with Brazil and Paraguay, it failed to convince the Argentinean government to adopt the proposed scheme. In an attempt to 'increase pressure on Argentinean growers',<sup>270</sup> and 'recoup payments it believed were due to it',<sup>271</sup> Monsanto decided to enforce its patents against various importers of the soybean meal into the United Kingdom, Spain, Denmark, and The Netherlands.<sup>272</sup>

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<sup>269</sup> Heath, C., 'The Scope of DNA Patents in the Light of the Recent Monsanto Decisions', (2009) *International Review of Intellectual Property and Competition Law*, 940 at p. 942.

<sup>270</sup> Kock, M. A., 'Purpose-Bound Protection for DNA Sequences: In Through the Back Door?', (2010) *5 Journal of Intellectual Property Law and Practice*, 495 at p. 496.

<sup>271</sup> Cohen, S., & Morgan, G., '*Monsanto Technology LLC v Cargill*: A Matter of Construction', (2008) *26 Nature Biotechnology*, 289 at p. 290.

<sup>272</sup> The Danish litigation still pending.

The primary question before each court was whether the ‘presence alone [of the claimed DNA sequence] is sufficient to constitute infringement of Monsanto’s European patent when the soya meal is imported into the European Community.’<sup>273</sup> Save for The Hague District Court, which stayed proceedings until the ECJ responded to the questions included in the referral, each court rejected this proposition. As a consequence, Monsanto was unable to establish infringement in any of the four countries in which proceedings were commenced, despite the fact that analyses of the composition of the meal undertaken by Monsanto revealed that traces of the claimed DNA sequence were present. It was also established that the plants from which the soya meal was derived had been planted in Argentina,<sup>274</sup> and that these plants contained the patented DNA sequence. As Pumfrey J noted in the U.K. litigation, the plants from which the meal was derived could very well be viewed as the ‘lineal descendants’ of the original transformed plant,<sup>275</sup> and this genealogy could be traced through to the fragments of DNA found in the imported meal. Monsanto were therefore able to establish that the patented DNA sequence was present in both the imported meal and the plants from which the meal was derived, and that the meal could legitimately be described as ‘the ultimate product of the original transformation of the parent plant.’<sup>276</sup> However, neither of these facts was sufficient to establish infringement in any of the national courts.

#### 5.3.4.1 *The Spanish Litigation*

In each of the national courts (save for the United Kingdom, which is discussed separately below), Monsanto argued that the importation of the soya meal constituted an infringement of the DNA sequence claim under both Article 9 and according to general principles of patent law. In relation to Article 9, Monsanto argued that this provision extends protection to products that incorporate the genetic material and in which the genetic material is able to fulfil a function. It is not necessary, in Monsanto’s view, to show that the genetic information is actively performing its function at the time of the infringement.<sup>277</sup> Instead, Monsanto argued that liability for infringement under Article 9 may be established by showing that the genetic information has performed its function in the past, or may perform its function in the future: it is enough that the function of the genetic information has been, or will be, effectuated.

Both the Commercial Court of Madrid and the Madrid Provincial Court of Appeal rejected this argument, with the latter describing it as ‘simplistic’.<sup>278</sup> According to both courts, Article 9 is to be interpreted in light of Recitals 23 and 24 of the Directive, which confirm that a mere DNA sequence without an indication of a function does not contain any technical information and is therefore not an invention, and that in order to comply with the industrial application criterion, it is necessary, in cases where a gene or a partial sequence of a gene is used to produce a protein, to specify which protein or part of a protein is produced, or what function it performs.<sup>279</sup>

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<sup>273</sup> *Case C-428/08 Monsanto Technology LLC v Cefetra BV*, para. 22.

<sup>274</sup> The production of Roundup Ready soybeans occupies half of the cultivated land in Argentina, and is its most important export product. Argentina exports more than half of its annual production to the E.U., with the residue going to China: Kock, M. A., *supra* n. 270; cf. Heath, C., *supra* n. 269, at p. 941-2.

<sup>275</sup> [2008] FSR 153, at p. 173. Likewise, the Commercial Court of Madrid found that the imported meal had been produced from soya beans containing the patented DNA sequence: *Roundup Ready Spain* (2009) 40 *International Review of Intellectual Property and Competition Law*, 233 at p. 236.

<sup>276</sup> *Ibid.*

<sup>277</sup> *Roundup Ready Spain* (2009) 40 *International Review of Intellectual Property and Competition Law*, 233 at p. 235.

<sup>278</sup> *Roundup Ready Spain II* (2009) 40 *International Review of Intellectual Property and Competition Law*, 971 at p. 975. Kock also points out that Monsanto’s argument is little more than a restatement of the requirement of industrial applicability, which renders the functional limitation in Article 9 ‘redundant and meaningless’: Kock, M. A., *supra* n. 270, at p. 498.

<sup>279</sup> It would appear that the reference to ‘function’ in Article 9 is synonymous with ‘industrial application’. Thus, the Madrid Provincial Court of Appeal rejected Monsanto’s argument that the function of the DNA sequence is to carry genetic information – instead, the sequence’s function is ‘for the coded enzyme to be able to generate antibodies

According to both courts, these Recitals limit the application of Article 9 to situations in which the genetic material continues to fulfil its function in the material into which it has been incorporated.<sup>280</sup> In other words, there is a direct relationship between patentability and the scope of protection.<sup>281</sup> The claims should therefore be construed ‘not only to include the mere sequence but also a given functionality that the invention must effectively exhibit, according to the actual claim interpreted with the description, with a given purpose.’<sup>282</sup> Therefore, it is ‘not enough to ascertain whether the genetic information under the patent is contained in the soya flour’: it must also be demonstrated that this product is actively and effectively performing ‘the specific biological function that supported the grant of the patent’,<sup>283</sup> since this is ‘the advantage which made it patentable.’<sup>284</sup>

In this regard, the Court considered that the function of the claimed DNA sequence is to confer glyphosate-herbicide-resistance upon plants into which the sequence is introduced, and that this function is only valuable during the vegetative phase of the plant when it can be treated with glyphosate-herbicides that kill all plants that do not contain the claimed sequence. Whilst both courts appeared to leave open the question of whether the defendants would have been liable for infringement if it were possible for the sequence to be isolated from the meal and re-utilised,<sup>285</sup> this outcome was foreclosed by virtue of the manner in which the soya meal was processed. After this process, the soya meal contained no functional genetic material: this had been ‘irreversibly inactivated.’<sup>286</sup> As the DNA sequence was not performing its function in the

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against a given enzyme so that the plant is resistant to glyphosate – and, ultimately, the actual transcription of the gene, synthesis of the protein, and multiplication in order to obtain transgenic plants that are resistant to that herbicide’: *Roundup Ready Spain II* (2009) 40 *International Review of Intellectual Property and Competition Law*, 971 at p. 978. See also Heath, C., *supra* n. 269, at p. 948: “Function”, it seems, refers rather to what the DNA sequence will actually do; in this case, having the property of “encoding a Class II EPSPS enzyme” the expression of which results in glyphosate tolerance in plants.’

<sup>280</sup> The function of the genetic material ‘obviously has to be fulfilled continuously in the new material in which it is incorporated’: *Roundup Ready Spain* (2009) 40 *International Review of Intellectual Property and Competition Law*, 233 at p. 237. It is also worthwhile to note that in the Court’s opinion the granting of patent rights constitutes ‘an exception to the principle of free trade’ enshrined in Art. 38 of the Spanish Constitution, and therefore ‘the patent law of Spain has to be interpreted restrictively’: at pp. 235-6.

<sup>281</sup> This argument was made by the defendants to the Dutch proceedings: *Monsanto Technology LLC v Cefetra BV* (2009) 40 *International Review of Intellectual Property and Competition Law*, 233 at para. 4.16.1.

<sup>282</sup> *Roundup Ready Spain II* (2009) 40 *International Review of Intellectual Property and Competition Law*, 971 at p. 975. Likewise, the Commercial Court held that the Recitals lead ‘us to the interpretation that the invention does not consist of the DNA sequence as such, but rather of the function it fulfils’: *Roundup Ready Spain* (2009) 40 *International Review of Intellectual Property and Competition Law*, 233 at p. 236. According to the Court of Appeal, ‘the importance of the product’s performing the said biological function is not a requirement that should be underestimated or diluted by interpretation’: at p. 976.

<sup>283</sup> *Roundup Ready Spain II* (2009) 40 *International Review of Intellectual Property and Competition Law*, 971 at pp. 975, 976, 977.

<sup>284</sup> *Roundup Ready Spain II* (2009) 40 *International Review of Intellectual Property and Competition Law*, 971 at p. 978. This reasoning appears to go further than the position advocated by the defendants, who, according to Kock, conceded that active performance of the function (i.e. active expression) at the time of the alleged infringement was too strict a requirement. Instead, the defendants emphasised that ‘the decisive question is merely as to whether the possibility exists for the genetic information ... to perform its function in the incorporating product’: Kock, M. A., *supra* n. 270, at p. 498.

<sup>285</sup> According to the Court of Appeal, ‘in order to ascertain a potential act of infringement that even indirectly relates to the act of importing soya flour, we must determine that the act of the defendant, where technically possible and meaningful to do so, consisted of the possible extraction of DNA from the said flour which could then be reintroduced into a plant cell capable of multiplying and becoming genetically active in order to obtain glyphosate-tolerant plants. However, this is not what we are dealing with in this case ...’: *Roundup Ready Spain II* (2009) 40 *International Review of Intellectual Property and Competition Law*, 971 at p. 978. Kock has argued that disablement of the DNA was ‘crucial’ to the courts’ conclusions regarding the application of Article 9: Kock, M. A., *supra* n. 270, at p. 497.

<sup>286</sup> *Roundup Ready Spain* (2009) 40 *International Review of Intellectual Property and Competition Law*, 233 at pp. 236-7.

imported meal, and was not capable of performing this function in the future, there was no infringement under Article 9. Thus, in contrast to the situation which arose in the proceedings commenced against the Canadian farmer Percy Schmeiser in Canada, it was not the case here that the alleged infringer was able to take advantage of the so-called ‘stand-by utility’ of the genetic information.<sup>287</sup>

#### 5.3.4.2 *The Dutch Litigation and the Referral to the European Court of Justice*

In the Dutch litigation, The Hague District Court concurred in principle with the reasoning employed by the Spanish courts in rejecting Monsanto’s argument that it is sufficient in order to invoke the extended scope of protection provided by Article 9, to show that the genetic information (the DNA sequence) *has* performed its function at a given time, or *could* again perform such function after being isolated from the product (the soya flour) and transferred to living material.<sup>288</sup> However, the court also observed that genes do not continuously perform their functions, even as part of an organism. For example, there are genes which are only activated in specific stress situations such as heat, drought or stress.<sup>289</sup> In light of this uncertainty, the court sought assistance from the European Court of Justice on this matter.

The court also sought the ECJ’s assistance in relation to Monsanto’s second argument – namely, that notwithstanding Article 9, the importation of meal containing traces of the DNA sequence constitutes an infringement according to the principle of absolute protection. Whilst the Spanish courts did not go on to consider Monsanto’s second argument, this point was taken up by The Hague District Court.<sup>290</sup> Monsanto argued that the Articles 8 and 9 did not apply to the patent in suit,<sup>291</sup> or, in the alternative, that the principle of ‘absolute protection’ continues to exist alongside the specific protection provided by Article 9. That is, Article 9 sets only a minimum standard of protection. The court opined that ‘there seems to be reason to assume that the Directive does not alter the absolute protection afforded by Sec. 53a (3) Patent Act, and rather provides for a minimum protection.’<sup>292</sup> Support for this interpretation was to be found in the wording of Article 9, which uses the verb ‘extends to’ and not, for example, ‘is limited to’, and

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<sup>287</sup> In *Monsanto Canada Inc v Schmeiser* [2004] 1 SCR 902, a majority of the Supreme Court of Canada found Canadian canola farmer, Percy Schmeiser, liable for infringement of Monsanto patents relating to genetically-modified ‘Round Up Ready’ canola. This decision was buttressed on the fact that although there was no evidence that Schmeiser had ever used Round Up herbicide on any of his canola crop, he was able to do so in the future if he so chose. Schmeiser had benefitted from this ‘stand-by’ utility throughout the lives of the infringing plants, and a majority held that this was sufficient to give rise to liability for patent infringement.

<sup>288</sup> *Roundup Ready Spain* (2009) 40 *International Review of Intellectual Property and Competition Law*, 233 at para. 4.20.

<sup>289</sup> *Ibid.*

<sup>290</sup> *Roundup Ready Netherlands* (2009) 40 *International Review of Intellectual Property and Competition Law*, 228.

<sup>291</sup> This argument was based on the dubious reasoning that the imported soya meal is not (biological) material within the meaning of Articles 8 and 9, which, accordingly, are inapplicable: see para. 4.17.1. Not surprisingly, this argument was resoundingly rejected by the court, which emphasised that these provisions should be construed as relating to the biological material for which the patent was granted, not the allegedly infringing material: *Roundup Ready Netherlands* (2009) 40 *International Review of Intellectual Property and Competition Law*, 228 at para. 4.19.

<sup>292</sup> *Roundup Ready Netherlands* (2009) 40 *International Review of Intellectual Property and Competition Law*, 228 at para. 4.27. On the other hand, Christopher Heath, a member of the Boards of Appeal of the EPO, has argued that given that the Directive is a compromise between ‘widely different perceptions on how biotechnological inventions should be protected’, it should not be viewed as setting a minimum standard of protection. Thus, the point of reference for determining the scope of biotechnological patents is not the absolute product protection contained in national patent law, but Articles 8-11 of the Directive. This means that if a patent claims that is relied on in an infringement action falls within one of the categories of Articles 8 or 9, the scope of protection is exhaustively determined by those provisions: Heath, C., *supra* n. 269, at p. 945. This interpretation is supported by the ECJ, which noted that in the interest of avoiding barriers to trade within the internal market, the Community legislature ‘intended to effect a harmonisation which was limited in its substantive scope, but suitable for remedying the existing differences and preventing future differences between Member States in the field of protection of biotechnological inventions’: *Monsanto Technology LLC v Cefetra BV*, Case C-428/08, 6 July 2010, at para.’s 55-6.

Articles 3(2) and 5(2), which confirm the patentability of isolated DNA.<sup>293</sup> However, the court considered that this reasoning was not sufficiently clear and decided to refer the issue to the European Court of Justice for a determination.<sup>294</sup>

Finally, the District Court also rejected the argument that the importation of the meal infringed the method claims. The Court held that whilst it can readily be accepted that the soy plants and the soy beans were directly obtained by the patented method, the processing to which the beans were subjected was 'too drastic to still assume a direct relationship between the method and the soy meal.'<sup>295</sup> Instead, what emerged from this process was a product with a 'new identity'.

Given the uncertainty surrounding the interpretation of the Directive and its relationship with domestic law, The Hague District Court stayed the proceedings and referred the following questions to the European Court of Justice:

1. Can Article 9 be invoked in circumstances where a product (the DNA sequence) forms part of a material imported into the European Union and is not performing its function at the time of the alleged infringement, but did perform that function previously or could possibly again be able to perform that function after it has been isolated from that material and introduced to the cell of an organism?
2. Does Article 9 prevent domestic patent law from additionally conferring absolute protection on the product (the DNA sequence) as such, regardless of whether the DNA performs its function, or is the protection provided by Article 9 exhaustive in the situations where the product consists of, or contains, genetic information, and the product is incorporated in material which contains the genetic information?
3. Does the fact that a patent was granted prior to the adoption of the Directive, and that absolute protection was provided under domestic law, affect the answer to question 2?
4. Do Articles 27 and 30 of the TRIPs Agreement affect the interpretation given to Article 9?

#### 5.3.4.3 *The European Court of Justice*

##### **The First Question**

Save for question 2, the ECJ answered each of these questions in the negative. In respect of the first question posed by The Hague District Court, the ECJ observed that Article 9 had been drafted in the present tense. This, according to the Court, implies that the genetic information must be performing its function 'at the present time and in the actual material in which the DNA sequence containing the genetic information is found.'<sup>296</sup> It follows from this that the protection

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<sup>293</sup> *Roundup Ready Netherlands* (2009) 40 *International Review of Intellectual Property and Competition Law*, 228 at para. 4.27. Article 3(2) provides that biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature, whilst Article 5(2) provides that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

<sup>294</sup> The court was also concerned that if the Directive did not permit absolute protection this would lead to 'the inconsistent situation that even an isolated DNA, as long as it is not further processed, would not be included in the scope of protection', presumably on the basis that the DNA is not capable of performing its function whilst it is isolated. However, this fear is unfounded: if the alleged infringement concerns isolated DNA then Article 9 does not apply, since, by definition, it has not been incorporated into any other material.

<sup>295</sup> *Roundup Ready Netherlands* (2009) 40 *International Review of Intellectual Property and Competition Law*, 228 at para. 4.5.

<sup>296</sup> *Case C-428/08, Monsanto Technology LLC v Cefetra BV*, 6 July 2010, at para. 35.

provided for in Article 9 is not available where the genetic information has ceased to perform the function ‘it performed in the initial material from which the material in question is derived.’<sup>297</sup> The function of the genetic information in the present case ‘is performed when the genetic information protects the biological material in which it is incorporated against the effect, or the foreseeable possibility of the effect, of a product [i.e. a herbicide] which can cause that material to die.’<sup>298</sup> The Court found that the patented genetic information was no longer capable of performing this function. Even if it happened to be customary to spray soy meal with herbicide, still the genetic information would not be able to perform the function of ‘protect[ing] the life of the biological material containing it’ because the information had been rendered ‘dead material’ by processing.<sup>299</sup> Nor was it possible to circumvent this interpretation by proving that the genetic material may be capable of once again performing its function. To allow protection to be revived by showing that the genetic information could be extracted from the soy meal and transferred to another organism, in which it can once again perform its function, would diminish the effectiveness of Article 9 since ‘in principle’ this potentiality could ‘always be relied on.’<sup>300</sup>

The Court also rejected Monsanto’s attempt to escape the limitations of Article 9 by resorting to the doctrine of ‘absolute protection’. It is a generally accepted principle that the scope of protection afforded by a European patent is ‘absolute’. Thus, in *Mobil/Friction Reducing Additive*, the Enlarged Board of Appeal of the EPO stated that ‘it is a generally accepted principle underlying the EPC that a patent which claims a physical entity *per se*, confers absolute protection upon such physical entity; that is, wherever it exists and whatever its context (and therefore for all uses of such physical entity, whether known or unknown.’<sup>301</sup> Whilst the Court acknowledged that the protection of a DNA sequence ‘is indeed absolute under the applicable national law’, it held that this principle was irreconcilable with Article 9. If sustained, Monsanto’s argument would render Article 9 ineffective.<sup>302</sup> According to the Court, the ‘[p]rotection accorded formally to the DNA sequence as such would necessarily in fact extend to the material of which it formed a part, as long as that situation continued.’<sup>303</sup> Here too, the Court appears to buttress this interpretation on Recitals 23 and 24 and Article 5(3) of the Directive: ‘Since the Directive thus

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<sup>297</sup> Ibid., at para. 38.

<sup>298</sup> Ibid., at para. 36.

<sup>299</sup> Ibid., at para. 37.

<sup>300</sup> Ibid., at para. 40.

<sup>301</sup> [1990] EPOR 73, at p. 83.

<sup>302</sup> This interpretation is disputed by Michael Kock, the Head of Intellectual Property at Syngenta International. Kock’s argument is that Article 9 is intended to address the problem of exhaustion of patent rights after the sale of a product – in particular, it was designed to provide an ‘extension of protection *for progenies* where otherwise exhaustion may occur’: Kock, M. A., *supra* n. 270, at p. 507 (emphasis supplied). Given that the imported meal has no capacity for reproduction, Kock argues that Article 9 should not apply, and national patent law – i.e. absolute product protection – should prevail. Whilst this intention is manifest in Article 8, this rendering of Article 9 is questionable. The concern embodied in the First Proposal is not exhaustion, but ensuring that inventions – in particular, DNA sequences – ‘which do not permit their direct exploitation but which must become part of another entity in order to be used effectively’ are protected. In the Commission’s view, Article 9 was necessary ‘in light of the variety of views on this issue for which existing patent laws provide no solution’ and to confirm that patent protection for a ‘biological product’ is not lost ‘if such product becomes part of a more complex final product even though such biological product is of essential importance for commercialising the final product’: COM(88) 496 Final – SYN 159, at p. 52. Patent rights must accordingly be ‘legislatively prescribed for any *final product* whose utility, commercial value or industrial applicability depends on a patented invention’: *ibid.* Therefore, it is clear that the Article 9 is concerned not with exhaustion, but with ensuring that a ‘final product’, whose ‘utility, commercial value or industrial applicability depends on a patented invention’ that is incorporated in that product, falls within the scope of that patent. Merely providing protection for the genetic information, which ‘on its own has no commercial value’, would provide ‘insufficient incentive for ensuring that necessary research is undertaken’: COM(88) 496 Final – SYN 159, at p. 52. Moreover, it is difficult to reconcile this reading with the wording of Article 9, which, in contrast to Article 8, refers to a product containing or consisting of ‘genetic information’, rather than ‘biological material’.

<sup>303</sup> Ibid., at para. 47.

makes the patentability of a DNA sequence subject to indication of the function it performs, it must be regarded as not according any protection to a patented DNA sequence which is not able to perform the specific function for which it is patented.<sup>304</sup> However, it is by no means clear that this interpretation is correct. The relevant provisions require only that the applicant indicate or specify what the function of the patented DNA sequence is. There is nothing else in the Directive which might be taken to indicate that the relevant claims must be so limited. In its absence, to interpret the scope of a claim to a DNA sequence *per se* as limited to the function(s) specified in the body of the specification is to read into the claim a limitation which is not there. Notwithstanding these doubts, the conundrum caused by the incompatibility of Article 9 with the principle of absolute protection remains.

Accordingly, the answer to the first question is that:

Article 9 of the Directive must be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function *for which it was patented*, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.<sup>305</sup>

Thus, in answering the first question, the ECJ essentially formed a view that the *raison d'être* of patents relating to genetic information is the disclosure of the function of that information. Absent this disclosure, the genetic information is not patentable. It follows that it should not be protected when it is not capable of performing this function. At the same time, the ECJ left unanswered the question of whether claims to genetic information attract the principle of 'absolute protection' in situations where Article 9 is not implicated. Despite the Court's emphasis upon the disclosure of function as being the foundation upon which patent rights are available, this should not be taken to suggest that the principle of 'absolute protection' is generally inapplicable to genetic information. Much is likely to depend on the use to which the genetic information is being put by the defendant. Moreover, as indicated above, it is not yet settled whether the Directive supports the limiting of the scope of claims to genetic information to the function(s) disclosed in the specification.

### **The Second Question**

The ECJ held that the Directive, in particular Article 9, does not merely set a minimum level of patent protection for biotechnological inventions, but is exhaustive with respect to the matters that are addressed by the Directive. The Court predicated this interpretation upon what it perceived to be the intentions of the Community legislature when drafting the Directive. According to the Court, the Community legislature's intention was to 'effect a harmonisation which was limited in its substantive scope, but suitable for remedying the existing differences and preventing future differences between Member States in the field of protection of biotechnological inventions.'<sup>306</sup> This interpretation was supported by a number of Recitals, which emphasised that the Community legislature's overarching concern in introducing the Directive was to remove barriers to trade. Such barriers are created by differences in the law and practices of individual Member States, which can act as a disincentive to trade between Member States (to the detriment of the industrial development of biotechnological inventions) and compromise the proper functioning of the internal market. The Court held that the purpose of the Directive would be negated by a 'minimalist harmonisation approach' that would allow Member States to provide protection above and beyond that provided by the Directive. This would have the effect of entrenching or creating differences with respect to such matters between Member States,

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<sup>304</sup> Ibid., at para. 44.

<sup>305</sup> Ibid., at para. 50.

<sup>306</sup> Ibid., at para. 55.



‘thereby fostering barriers to trade.’<sup>307</sup> Accordingly, ‘in so far as the Directive does not accord protection to a patented DNA sequence which is not able to perform its function, the provision interpreted precludes the national legislature from granting absolute protection to a patented DNA sequence as such, regardless of whether it performs its function in the material containing it.’<sup>308</sup>

### The Third Question

The Court also held that the Directive applies to patents that were granted prior to the commencement of the Directive. The Court reaffirmed settled case law to the effect that newly introduced Community legislation applies immediately to ‘the future effects of a situation which arose under the old rule.’<sup>309</sup> Thus, where a patent has been granted by a Member State and, according to the national law of that Member State, the invention claimed in the patent enjoys absolute protection, the patentee is unable to rely upon national patent law in so far as that law is inconsistent with the Directive. Referring once more to the paramount purpose of the Directive, the Court stated that any other interpretation might result in the emergence of differences in the scope of protection as between Member States, and compromise the substantive harmonisation desired by the Community legislature.

### The Fourth Question

Finally, the Court held that although it is necessary to ‘supply an interpretation in keeping with the TRIPS Agreement’, it confirmed that ‘the provisions of the TRIPS Agreement are not such as to create rights upon which individuals may rely directly before the courts by virtue of European Union law.’<sup>310</sup> In any event, the Court opined that Articles 27 and 30 of TRIPs are concerned with patentability and exceptions to the rights conferred by a patent, respectively. Article 9, on the other hand, pertains to the scope of protection conferred by a patent on its holder. Further, the Court rejected the notion that even assuming that the reference in Article 30 of TRIPs to ‘exceptions to the rights conferred’ could be construed as encompassing not only exclusions to the rights of patentees but also limitations upon those rights, Article 9 could not be considered either ‘to conflict unreasonably with a normal exploitation of the patent’, nor ‘unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties’, within the meaning of Article 30 of the TRIPS

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<sup>307</sup> Ibid., at para. 59. Michael Kock provides an alternative account of the Directive’s negotiating history. Rather than removing barriers to trade, Kock emphasises that the Commission’s predominant concern was to create ‘greater opportunities ... for the patenting products consisting of or containing genetic information, such as a particular DNA segment’, and to ‘‘extend’’ the protection for DNA sequences beyond what a patent normally confers’: Kock, M. A., *supra* n. 270, at p. 505. It follows from this that ‘Articles 8 and 9 are an addition and not an alternative or limitation to the provisions of general patent law.’ However, this argument cannot be sustained. If the intent of Chapter 2 of the Directive, including Article 9, was to create ‘greater possibilities’ and ‘extend’ the protection for DNA sequences beyond what a patent normally confers, then one would naturally expect that Article 9 would provide *greater* protection than general patent law, i.e. absolute product protection. Yet, that is plainly not the case here. Moreover, in his summary of the Commission’s legislative intent, Kock omits to mention the none too insignificant qualification that in situations where the DNA has been incorporated into a more complex product, the scope of patent protection should only ‘extend to all products in which the particular genetic information which was essential for the invention *remains of essential importance for the products concerned*’: COM(88) 496 Final – SYN 159, at p. 51 (emphasis supplied).

<sup>308</sup> *Case C-428/08, Monsanto Technology LLC v Cefetra BV*, 6 July 2010, at para. 62. This interpretation was unaffected by Article 1(1), which provides that ‘Member States shall protect biotechnological inventions under national patent law’ and, ‘if necessary, adjust their national patent law to take account of the provisions of this Directive.’ According to the Court, Article 1(1) requires Member States, where necessary, to adjust their national patent law to take account of the provisions of the Directive, ‘that is, in particular, those effecting exhaustive harmonisation.’

<sup>309</sup> Ibid., at para. 66 (referring to *Case C-334/07 P, Commission v Freistaat Sachsen* [2008] ECR I-9465).

<sup>310</sup> Ibid., at para.’s 71-2.

Agreement.<sup>311</sup> The interpretation of Article 9 of the Directive is therefore unaffected by Articles 27 and 30 of the TRIPs Agreement.

#### 5.3.4.4 *The United Kingdom Patents Court*

The litigation in the U.K. is unique insofar as it involves the application of domestic patent law, rather than the provisions of the Directive, due to transitional provisions which limit the application of the Directive to patents filed on or after 28 July, 2000 (the patent was filed in 1991).<sup>312</sup> Notwithstanding this anomaly, in *Monsanto Technology LLC v Cargill International SA*,<sup>313</sup> Pumfrey J found the patent to be valid, but not infringed by the importation of the soy meal into the United Kingdom. Pumfrey J accepted that there was ‘no real doubt that the meal, or a very substantial part of it, is produced from Round Up Ready soybeans in Argentina.’ That being so, the questions raised by the proceedings were: whether importation of such meal is capable of infringing any of the method claims; and, if, as was alleged by Monsanto, the meal contains ‘at least genomic fragments of the whole of the Round Up Ready gene’, whether any of the claims relating to genomic material were infringed? Pumfrey J answered both of these questions in the negative.

#### *The Method Claims*

In the United Kingdom, the extent of protection for a patented process includes not only the process itself, but also products ‘directly obtained’ by the use of that process.<sup>314</sup> The issue for the court was whether the DNA sequence contained in the imported soy meal could be considered to be a product ‘obtained directly’ by the use of the claimed methods. Monsanto claimed that it should be so considered, based on the Court of Appeal’s judgment in *Pioneer Electronics Capital Inc v Warner Music Manufacturing Europe GmbH*.<sup>315</sup> There, the Court of Appeal stated that, ordinarily, the direct product of a process is the article that is produced at the end of the process. The article will continue to be so regarded despite further processing as long as it retains its identity or ‘essential characteristics’. According to Pumfrey J, the phrase ‘directly obtained by means of the process’ therefore means ‘the immediate product of the process’, or ‘where the patented process is an intermediate stage in the manufacture of some ultimate product, that product, but only if the product of the intermediate process still retains its identity.’<sup>316</sup>

Monsanto argued that the product had retained its essential characteristics, in particular the Round Up Ready gene sequence which was, according to Monsanto, what ‘made the invention patentable’. This was rejected by Pumfrey J for two reasons. First, the direct product of the claimed process was original transformed plant produced in accordance with that process. Pumfrey J observed that this process ‘is hardly an everyday operation’ (‘it appears to have been done once so far as this action is concerned’), and in this case, was carried out many generations ago. In the intervening period, ‘soybeans have been grown by seedsmen or retained by farmers

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<sup>311</sup> *Ibid.*, at para. 76.

<sup>312</sup> The U.K. is the only jurisdiction in which a transitional period applies. However, the validity of the transitional provisions must now be questioned in light of the ECJ’s response to the Third Question. The validity of these provisions in light of E.U. law was previously questioned: Kock, M. A., *supra* n. 270, at p. 509. The notion that the Directive shall not apply to patents granted prior to the date of its introduction was also criticised by the Advocate General in his opinion: ‘Directive 98/44 was drawn up with the principal objective of promoting the market and competition in EU territory. Given that context, to interpret that directive in such a way as to accommodate an interpretation of patents which varied according to the date of their award would cause problems ... legal certainty would be seriously undermined if the precise scope of a patent fell to be delimited by reference, not to the claims for which it was awarded, but to the date of the award’ (para. 67).

<sup>313</sup> [2008] FSR 153.

<sup>314</sup> In particular, the rights to use, import, and dispose of the product, or offer to do any of those things: *Patents Act 1977*, section 60(1)(c).

<sup>315</sup> [1997] RPC 759.

<sup>316</sup> [2008] FSR 153., at p. 173.

for planting; the plants have been grown and the new beans harvested; and after some generations the harvested beans have been processed into the [imported] meal ...<sup>317</sup> Whilst Pumfrey J conceded that, and that it was possible to regard the imported meal as both the ‘ultimate product of the original transformation of the parent plant’, his Honour was not convinced that the meal could ‘be properly described as the direct product of that transformation’, a title reserved for the original transformed plant.<sup>318</sup>

Secondly, Monsanto’s argument confused the ‘informational content of what passed between the generations (the Round Up Ready genomic sequence) with the product, which is just soybean meal with no special intrinsic characteristics from one of the generations of plants.’<sup>319</sup> Here, ‘product’ is defined in material terms: it must be possible to trace the starting materials used in the process into the product which emerges from the process. This product may be subject to further transformation, but it must retain its material identity. ‘It must be close to the truth’, said Pumfrey J, ‘that the generation of plants producing the beans from which the ... meal was manufactured *did not have an atom in common with the original transformed plant*’.<sup>320</sup> Pumfrey J also cautioned against talking of reproductive material ‘having in some way passed between the generations.’<sup>321</sup> Whilst reproductive material does pass between the first and second generations, ‘*the same material* does not pass further. Copies pass thereafter.’<sup>322</sup> Thus, there must be physical continuity between the starting materials acted upon by the claimed process, and the products which come into being at the end of this process; a genealogical connection will not suffice.

#### *The Product Claims*

The primary issue in relation to infringement of the product claims was the meaning that was to be attributed to ‘isolated’. The patent contains a number of claims to ‘isolated’ DNA sequences which encode a class of enzymes known as ‘Class II EPSPS enzymes’. Monsanto argued that the claims to ‘isolated’ DNA were infringed by importation of meal which was found to contain traces of the DNA sequence. Pumfrey J rejected this interpretation of the claims. Although commonplace in claims to genetic material, particularly in the United States, Pumfrey J noted that ‘isolated’ was a surprising word to use considering the argument maintained by Monsanto. Monsanto’s argument was also difficult to reconcile with structure of the specification itself. ‘What is striking about these claims’, said Pumfrey J, ‘is that down to claim 14 (the method of transforming the plant) they all essentially relate to the laboratory work.’<sup>323</sup> ‘It makes sense in this context’, Pumfrey J continued, ‘to have claims relating to each of the stages in transforming the plant, starting with the isolated sequence and proceeding through the sequence appropriately topped and tailed to transforming a plant using that molecule.’<sup>324</sup> Given this context, Pumfrey J concluded that ‘isolated’ means ‘separated from other molecular species in the form of a purified DNA fragment’ for the purpose of cloning and amplifying in a plasmid DNA.<sup>325</sup> In other words, the word ‘isolated’ implies that ‘the DNA is ready for use within a laboratory to carry out a recombinant DNA technique.’<sup>326</sup> Accordingly, the allegation of infringement of these claims

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<sup>317</sup> Ibid.

<sup>318</sup> Ibid.

<sup>319</sup> Ibid.

<sup>320</sup> Ibid. (emphasis supplied).

<sup>321</sup> Ibid.

<sup>322</sup> Ibid., at pp. 173-4 (emphasis supplied).

<sup>323</sup> Ibid., at p. 183.

<sup>324</sup> Ibid.

<sup>325</sup> Ibid.

<sup>326</sup> Cohen, S., & Morgan, G., *supra* n. 271, at p. 290. The same interpretation was arrived at by The Hague District Court, which held that the defendants ‘correctly take the view that these claims cannot have been infringed because the DNA is not present in isolation, but is contained in the soya flour. The court cannot agree with Monsanto in its argument that the DNA sequence was isolated from its natural environment – the bacterial chromosome – and inserted into the DNA of the soya plant and that the flour of the bean should, for that reason, be considered an

failed, notwithstanding the fact that the DNA sequence was found to be present in the allegedly infringing product.

Pumfrey J also made some observations on the potential scope of Monsanto's claims which it is worthwhile to set out in full:

The DNA present in the meal, such as it is, is entirely irrelevant to the meal as an animal feedstuff, is present in small, variable, quantities and may not be present at all if processing conditions are changed. It is not in any serious sense genetic material. It is just the remains of the material which was in the soybeans from which the material was extracted. This, it seems to me, is irrelevant.<sup>327</sup>

Presumably, it is irrelevant to the issue of infringement, for Pumfrey J then goes on to say that it may raise a question of damages – in particular, as to whether there was a causative relationship between the acts of infringement ('as opposed to acts which are not infringing by English law') and the loss suffered by Monsanto. However, Monsanto did not properly plead this point. Moreover, Pumfrey J noted that there is, generally, no authority in favour of trace quantities of infringing material being held not to infringe, and some authority against it. It would also appear that Pumfrey J did not regard the fact that the DNA found in the meal had lost its 'essential characteristic' as genetic material, and was not capable of performing its function at the time of the alleged infringement, as relevant to infringement of the product claims. Nor does the fact that the defendants performed acts of infringement in respect of only trace quantities of the claimed DNA sequence necessarily absolve them from liability. Finally, Pumfrey J confirmed that once a plant has been transformed in accordance with the claims, 'all its progeny for the future will infringe.'<sup>328</sup> That is, any plant containing the claimed DNA sequence will infringe these claims, provided, it seems, the infringing plant was initially transformed in the manner described in the patent. Whether claims to genetic material that has been incorporated into the genome of a plant by a non-technical procedure, such as genetic drift, will be regarded as infringed, as was the case in *Monsanto Canada Inc v Schmeiser Enterprises Ltd*,<sup>329</sup> remains unclear.

It is also worthwhile to note the similarities between the decision of the English Patents Court and the approach taken by a minority of the Supreme Court of Canada in *Monsanto Canada Inc v Schmeiser Enterprises Ltd*. The claims of the patent in that case were drafted in strikingly similar terms to those of the soybean patent, with the exception that the term 'isolated' was replaced with the term 'chimeric'. In particular, the patent included claims to a chimeric gene construct, in which the coding sequence encodes a EPSPS, expression vectors comprising the gene construct, glyphosate-resistant plant cells that have been transformed with the gene construct, and methods for producing glyphosate-resistant plants and plant cells. Applying a purposive construction of Monsanto's claims, the minority held that the scope of those claims extended to 'the genetically-modified chimeric genes and cells in the laboratory prior to regeneration – and the attendant process for making the genetically-modified plant.'<sup>330</sup> The minority held that this construction was necessary in order to avoid an interpretation which would extend the scope of the claims to the whole plant, as this result was proscribed by the Canadian Supreme Court's decision in

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isolated DNA sequence or should include the same. The average person skilled in the art will understand the concept of an isolated DNA in the sense it is ordinarily understood, i.e. a DNA that normally is released from the cell of an organism for further processing': *Roundup Ready Netherlands* (2009) 40 *International Review of Intellectual Property and Competition Law*, 228 at para. 4.4.

<sup>327</sup> [[2008] FSR 153., at p. 187.

<sup>328</sup> [2008] FSR 153., at p. 183.

<sup>329</sup> [2004] 1 SCR 902.

<sup>330</sup> *Ibid.*, at para. 139. '... the plant cell claim cannot extend past the point where the genetically modified cell begins to multiply and differentiate into plant cells, at which point the claim would be for every cell in the plant, i.e. for the plant itself.'

*Harvard College v Canada (Commissioner of Patents)*,<sup>331</sup> wherein the Supreme Court held that claims to higher organisms are invalid.<sup>332</sup> Consequently, the gene construct and transformed cell claims were not infringed by not the planting of seeds containing the gene construct and transformed cells.

However, in a departure from Pumfrey J's reasoning, the minority in *Schmeiser* held that the progeny of the original transformed plant was not covered by claims to the DNA sequence. According to the minority, the only use that would constitute infringement involves 'using the chimeric gene in its isolated form to create an expression or cloning vector or a transformation vector and using the transformation vector to create a transgenic plant cell. The use claimed for the plant cell extends to the isolated plant cell in a laboratory culture used to regenerate a "founder plant" but not to its offspring.'<sup>333</sup> However, this departure best viewed as a peculiarity of Canadian patent law: to extend protection to progeny of the original transformed plant would have transgressed the majority's proscription against the protection of higher life-forms in *Harvard College*.

#### 5.3.4.5 Response to the ECJ's Decision

*Monsanto v Cefetra* is the single most important decision on the patenting of biotechnological inventions to be delivered by a European court. Not surprisingly, the biotechnology industry has been critical of the ECJ's decision, for whom the decision symptomatic of a general antipathy towards biotechnology and genetically-modified organisms in European society. More specifically, the decision is seen as diminishing the scope of protection of biotechnological inventions. It is said that the decision erodes the 'generally accepted' principle of absolute protection – that is, that a claim to a product confers upon the patentee rights to exclude others from making and using the claimed invention, by any means and for any purpose. As noted above, prior to the ECJ's decision it had generally been assumed that genetic materials attracted the same degree of protection as any other sort of chemical compound – i.e. protection is 'absolute'. However, this argument overlooks the fact that whilst the patentability of isolated DNA, including fully-transcribed genes, was accepted by the Opposition Division of the EPO in *HOWARD FLOREY/Relaxin*,<sup>334</sup> the scope of such claims remains highly contentious, as evidenced by the amendments recently introduced by the French and German governments to their patent laws limiting the scope of protection for 'human' genes and DNA sequences to the function(s) 'concretely' disclosed in the patent specification.<sup>335</sup> Indeed, writing shortly before the ECJ handed down its decision, one of the most vocal critics of that decision lamented that 'today a political majority seems to favour purpose-bound protection'<sup>336</sup> – that is, the scope of claims to genes should be limited to the purpose of the invention as identified by the inventor in the patent specification.

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<sup>331</sup> [2002] 4 SCR 45.

<sup>332</sup> '... the plant cell claim cannot extend past the point where the genetically modified cell begins to multiply and differentiate into plant cells, at which point the claim would be for every cell in the plant, i.e. for the plant itself': [2004] 1 SCR 902, at para. 138.

<sup>333</sup> *Ibid.*, at para. 161.

<sup>334</sup> [1995] EPOR 541.

<sup>335</sup> Introduced in 2004, Article L613-2-1 of the French Intellectual Property Code states that 'the scope of a claim covering a gene sequence shall be limited to the part of that sequence directly related to the specific function that is concretely disclosed in the description; The rights created by the grant of a patent including a gene sequence shall not be invoked against a subsequent claim covering the same sequence if that claim itself satisfies the conditions of Article L611-18 [relating to non-patentable subject matter] and discloses another particular application of that sequence.' §1a, para.4 of the German patent law states: 'if the subject of the invention is a sequence or partial sequence, which is identical in structure with the sequence or partial sequence of a human gene, then the use – for which the industrial applicability has to be concretely described according to para. 3 – has to become part of the patent claim.'

<sup>336</sup> Kock, M. A., *supra* n. 269, at p. 503.

Kock objects that ‘this will was not clearly expressed when the Directive entered into force.’<sup>337</sup> That might well be so, however the Monsanto litigation reveals yet another dimension to the debate about the propriety of the doctrine of absolute protection. As the lawyers who represented Cargill in the English litigation have pointed out, ‘if infringement had been found in this case, it would have meant that any product containing an intact DNA molecule derived from any genetically modified organism would have been an infringement of any patent right directed at those gene sequences used to construct that genetically modified organism.’<sup>338</sup> Elaborating on the possible ramifications of this result, Christopher Heath, a member of the EPO’s Boards of Appeal, ‘[i]f Monsanto’s position were correct, similar cases could arise for the importation of cotton, the RR variety of which Monsanto has started selling in India without corresponding patent protection. Any trace of the protected DNA in, say, imported jeans or t-shirts would allow the patentee to raid the premises of any manufacturer or shop commercially manufacturing or selling these goods – an interesting, but somewhat worrying scenario.’<sup>339</sup> In contrast, rarely, if at all, do owners of chemical patents attempt to prosecute their product claims against the manufacturers of products in which the compound is incorporated. The doctrines of exhaustion and implied licence deny the validity of such claims (although the application of these doctrines to plants raises special problems), as does the physical transformation of the patented compound during the manufacturing process.<sup>340</sup> Thus, whilst Monsanto attempted to invoke the now familiar trope that the patenting of biotechnological inventions is merely a continuation of past practices, that claim failed precisely because it was a radical departure from that tradition. By the same measure, the ECJ’s decision should not be taken as a discriminatory gesture against biotechnology inventions, but an affirmation of affirmation of the previously accepted scope of claims to chemical compounds.

Moreover, the harm that is alleged to accrue from the decision has been exaggerated. Kock and others have expressed concern that the court’s decision undermines the value of product patents over isolated DNA sequences and research tools, such as expressed sequence tags (‘ESTs’). Kock argues that ‘[a]pplying the requirement of “performing its function” in Article 9 to DNA sequences in general – irrespective of whether isolated or integrated – as the Advocate General holds, would deny protection to a (sic) isolated DNA sequence as such (e.g. in a reaction tube), because it cannot perform its function.’ According to Kock, ‘[t]his would exempt any use of isolated DNA as a research or diagnostic tool from patent protection, which the Directive certainly did not intend.’<sup>341</sup> A number of objections to this argument are immediately apparent. First, as both the ECJ and the English Patents Court emphasise, the ‘function’ of a DNA sequence is the function designated by the applicant in the specification. Here, the function of the claimed DNA sequence is to confer glyphosate-herbicide-resistance upon plants into which the sequence is introduced. However, the ‘function’ of the DNA sequence need not necessarily be the biological function of the gene, as Kock seems to assume, but may also be some artificial or experimental function attributed to the DNA sequence by the applicant. Thus, if the applicant stipulates that the claimed DNA sequence is useful as a research tool, then provided this use is ‘specific, substantial and credible,’ the claimed DNA sequence will be perform its function whenever it is used for this purpose. Moreover, the objection is fatally flawed, for Article 9 is

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<sup>337</sup> Ibid.

<sup>338</sup> Cohen, S., & Morgan, G., *supra* n. 271, at p. 291.

<sup>339</sup> Heath, C., *supra* n. 269, at p. 956.

<sup>340</sup> A notable exception to this generalisation is the unsuccessful attempt by the patentee in *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76, to extend protection of a pro-drug to its active metabolite when made inside the human body. Claims to intermediary products are the only other exception.

<sup>341</sup> Kock, M. A., *supra* n. 269, at p. 507. See also p. 512: ‘A DNA sequence should be entitled to compound protection as such and not only under the circumstance where it performs its function. Otherwise an isolated DNA sequence would not enjoy protection, because it cannot perform a function in its isolated form.’

only enlivened in circumstances where the protected genetic information has been incorporated into another organism.

There are, however, good reasons to doubt Cohen and Morgan's suggestion that 'third-party importers of, and those companies using, such derivative products within the food industry can rest a little easier following the [English Patent Court's] judgment.'<sup>342</sup> It will be recalled that the Supreme Court of Canada found Percy Schmeiser liable for patent infringement because he was unable to rebut the presumption that he intended to use the invention (glyphosate-resistant canola), if he had not already done so. In particular, his possession of seed containing the patented DNA sequence gave rise to a presumption that he intended to utilise the 'stand-by utility' of the invention if and when he chose to do so. But, this presumption cannot be sustained where the 'invention' is 'dead matter' that is not capable of being utilised. It is perhaps for this reason that Monsanto strove to convince the courts that the DNA sequence was capable of being isolated from the meal and re-used to produce genetically-modified plants. Only then would it have been possible to impute a presumption that the meal importers intended to take advantage of the stand-by utility of the invention, although it is likely that the defendants would have readily been able to rebut this presumption. Moreover, it is much easier to conceive of the invention as a genetically-modified plant, the reproductive material of which Schmeiser was in possession of, rather than an isolated DNA sequence.

Ultimately, Monsanto's claim failed because it avariciously attempted to claim protection over products that are derived from *the invention*, rather than activities which make use of the invention. As Heath notes, 'the inventive merit of the DNA sequence does not lie in providing the sequence as such (otherwise it would not be patentable if no further function has been disclosed), but rather in the sequence encoding glyphosate-tolerant EPSPS.'<sup>343</sup> Further, to the extent that the Directive limits the scope of protection to those products that exhibit the specific characteristic of the invention, 'this is no more than to require a claim interpretation commensurate to the contribution the invention has made to the state of the art.'<sup>344</sup>

To be sure, Pumfrey J's observations will provide some solace to owners of patents for biotechnological inventions. In particular, Pumfrey J's suggestion that a person may be held to infringe product claims to DNA sequences even though the sequence was not performing its function at the time of the infringement represents a departure from the position under the Directive. So too, is the mode of analysis adopted by the English Patents Court and other national courts which were bound to apply the provisions of the Directive. In the former case, the court was predominantly concerned with issues of claim construction; in the latter case, the courts were preoccupied with statutory construction and the divination of legislative intent. While Pumfrey J's judgment provides pointers to the underlying position at common law, the decision turned primary on matters of claim construction. As such, the extent to which U.K. patent law differs from the position under the Directive remains unclear. Finally, Pumfrey J's questioning of the relevance of the quantity and nature of the DNA found in the allegedly infringing material to the issue of liability, leaves open the possibility that downstream users may yet be liable for certain dealings with materials containing a patented DNA sequence.

#### 5.4 Farm-saved Seed

It follows from what is said above regarding the effect of the doctrines of exhaustion and implied licence that the use of second generation seed for any purpose without the authorisation

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<sup>342</sup> Cohen, S., & Morgan, G., *supra* n. 271, at p. 291.

<sup>343</sup> Heath, C., *supra* n. 269, at p. 948.

<sup>344</sup> *Ibid.* Heath therefore concludes that 'a purpose-bound protection for gene sequences may be more in line with the fundamental principles of patent law than an absolute product protection might be': at p. 954.

of the patentee will generally constitute infringement of patents claiming plant genes, cells, seeds or varieties. Along with the absence of a robust breeder's exemption in the patent laws of most jurisdictions, this is cited as a major influence upon the increasing interest in the use of patents to protect plant innovation. In the United States, a number of attempts have been made to rely upon the farm-saved seed exception in the *Plant Variety Rights Act 1970* as defence to proceedings for patent infringement. Unsurprisingly, these attempts have met with little success. In Europe, a limited farm-saved seed exception is provided by Article 11(1) of the European *Biotechnology Directive*, which states that the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent (or with his consent) for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm. In effect, this exception is identical to that provided by section 17 of the *Plant Breeder's Rights Act*. However, the farmer's privilege under the *Biotechnology Directive* applies only to certain plant species and groups, including various types of fodder plants, cereals, potatoes, and oil and fibre plants. Moreover, a farmer who purports to rely on the defence must pay an equitable remuneration in respect of the propagating material to the patentee. The remuneration must be 'sensibly lower than the amount charged for the production of the protected material of the same variety on the same area with the holder's authority'. The requirement to pay equitable remuneration does not, however, arise if the farmer is a 'small farmer'.<sup>345</sup>

In addition, Article 11(2) provides farmers with a defence in relation to the breeding of animals. More specifically, Article 11(2) provides that the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of a patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity. The scope of this defence is potentially very broad. Whilst it is clear that the intent is to permit the use by farmers of the progeny of patented livestock, the scope of the defence is not defined in the Directive. Unlike the farm-saved seed defence, no provision is made for the payment of equitable remuneration to the patent holder for the privilege.

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<sup>345</sup> As defined by Article 14(3) of the *Council Regulation* (EC) No 2100/94 of 27 July 1994 on Community Plant Variety Rights.



## 6 Conclusion

Presently, the legal landscape for the protection of plant varieties is in a state of flux. Larger breeders, particularly agricultural biotechnology companies, are dissatisfied with the UPOV settlement. Over the past few decades, breeders have sought to reform the present plant breeders' rights system, arguing for greater international harmonisation of domestic plant breeders' rights legislation, as well as a general extension of protection to harvested materials and reform of the system of protection for essentially derived varieties to include specific agronomic traits introduced into a variety.<sup>346</sup> Breeders are also seeking to 'modernise' fundamental tenets of the plant breeders' rights regime, namely the breeders' exemption and the farm-saved seed provision, by introducing fetters upon the ability of growers and researchers to freely invoke these concessions to the variety owner's monopoly – in the former case, by either suspending the exemption for a period of time after the grant of the plant breeders' right, or by requiring the user to make 'appropriate remuneration' to the PBR owner during this period of time; and, in the latter case, by requiring the grower to remunerate the PBR owner for further propagative use of farm-saved seed, albeit at a rate substantially lower than the normal royalty fee.<sup>347</sup> Finally, breeders are also frustrated with the difficulty of enforcing plant breeders' rights. To this end, breeders have agitated for the introduction of a general right to information from growers regarding reproduction of protected varieties, and for the assessment of infringement to be supplemented with, or replaced by, molecular-biological analyses.<sup>348</sup>

In other words, in the interests of maintaining 'the incentive to develop new high-quality plant varieties with improved characteristics', breeders are seeking a more 'appropriate balance between the interests of plant breeders and the public'<sup>349</sup> by attempting to procure an expansion of the scope of the rights accorded by PBR, whilst at the same time attempting to diminish the scope of the rights accorded to the users of protected varieties.<sup>350</sup> The disaffection for the plant breeder's rights system has also found expression in the resurgence of interest over the past few decades in the use of the patent system to protect plant varieties. However, the recent Monsanto litigation confirms that the patent system is no panacea for these concerns either, at least in Europe. Indeed, the Monsanto litigation highlights a curious development in the protection of plant varieties: whilst the extension of the scope of plant variety protection to include both essentially derived and dependant varieties has brought the scope of plant variety protection closer to patents,<sup>351</sup> at the same time patentees are attempting to procure PBR-like protection for patented inventions. A number of commentators have suggested that at least some of the adverse consequences that may arise from the ECJ's decision may be 'compensated for by adapting protection strategies' – for example, by including direct claims to harvested goods and derived products, such as soy meal, or by obtaining plant variety protection in those countries which offer protection for imported harvested goods and direct products.<sup>352</sup> In other words, one of the effects of the decision could be that plant breeders will increasingly rely on dual protection

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<sup>346</sup> Kock, M., Porzig, S., & Willnegger, E., 'The Legal Protection of Plant Biotechnological Inventions and Plant Varieties in Light of the EC Biopatent Directive', (2006) *37 International Review of Intellectual Property and Competition Law*, 135 at p. 146.

<sup>347</sup> *Ibid.*, at pp. 145-6.

<sup>348</sup> *Ibid.*, at p. 146.

<sup>349</sup> *Ibid.*, at p. 145.

<sup>350</sup> This is, of course, a familiar trope that has been employed by owners of intellectual property throughout its history.

<sup>351</sup> Sherman, B., & Hubicki, S., 'The Killing Fields: Intellectual Property and Genetic Use Restriction Technologies', (2005) *28 University of New South Wales Law Journal* 3, 740.

<sup>352</sup> Kock, M. A., *supra* n. 270, at p. 513.

of new plant varieties, or shift attention back to the use of plant variety protection as the primary form of intellectual property protection for plants in Europe. Indeed, the decisions of the ECJ and the Dutch, Spanish and United Kingdom courts highlight a seldom acknowledged fact that, in some instances, the scope of protection granted to a variety that is protected by PBR may be greater than that enjoyed by a patentee of the same variety. In particular, whilst in certain circumstances the plant breeder's rights system extends protection to derivative (harvested) products and products derived from harvested materials,<sup>353</sup> the litigation involving Monsanto's Round Up Ready soybean patent suggests that the scope of patent protection does not extend this far – at least in Europe.<sup>354</sup>

At the same time the Monsanto litigation was unfolding in Europe, another case was being decided which has the potential to radically reconfigure the legal landscape relating to the patenting of DNA sequences in the United States. The District Court of New York recently held that certain patents owned by Myriad Genetics relating to diagnostic testing methods for identifying one's disposition to breast and ovarian cancers were invalid on the ground that the patents claim unpatentable subject matter.<sup>355</sup> Although the decision concerns a medical diagnostic test, it will, if upheld, have a profound impact on the patentability of genes and other naturally-occurring compounds in the United States. In *Association for Molecular Pathology v United States Patent and Trademark Office*,<sup>356</sup> Sweet DJ held that claims to isolated DNA sequences coding for BRCA1 and BRCA2 proteins were invalid in light of a 'clear line' of Supreme Court precedent which establishes that purification of a 'product of nature' cannot, without more, 'transform it into patentable subject matter' unless the purified product possesses 'markedly different characteristics' from the naturally-occurring substrate.<sup>357</sup> Sweet DJ was unconvinced by arguments put forward by Myriad as evidence of the purportedly 'markedly different characteristics' of the claimed DNA sequences relative to the native DNA sequence. In particular, Sweet DJ rejected Myriad's argument that the removal of non-coding, intronic sequences from the native DNA sequence conferred markedly different characteristics upon the claimed purified DNA – namely, the ability to utilise the purified DNA sequence in applications for which the native DNA is unsuitable.<sup>358</sup> The removal of non-coding introns did not render the purified DNA sequences markedly different from the native DNA sequence because these cDNAs are the result of the 'natural phenomena of RNA splicing' of pre-mRNA into mature mRNA.<sup>359</sup> Moreover, the purported utilities which were said to demonstrate the marked difference between the claimed DNA sequences and the cognate native sequences were found to be 'primarily a function of the nucleotide sequence identity between native and isolated BRCA1/2 DNA.'<sup>360</sup> Indeed, the 'entire premise' behind Myriad's genetic testing is that the 'claimed isolated DNA retains, in all relevant respects, the identical nucleotide sequence found in native DNA.'<sup>361</sup> So too, the use of isolated BRCA1/2 DNA in the production of BRCA1/2 proteins or in gene therapy also relies on the identity between the native DNA sequences and the

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<sup>353</sup> For example, see ss. 14 and 15 of the *Plant Breeder's Rights Act 1994* (Cth.).

<sup>354</sup> In light of the ECJ's decision, inventors shall also be forced to reconsider their approaches to the drafting of claims to DNA sequences and other naturally-occurring substances. As Cohen and Morgan observe, the term 'isolated' is one that has commonly been used in biotechnology patents, primarily in deference to the perceived mandate of certain U.S. authorities. However, they counsel that 'patentees should no longer consider that the inclusion of such a term within its patent's claims confers a *de facto* monopoly on any product containing this DNA sequence': Cohen, S., & Morgan, G., *supra* n. 271, at p. 290.

<sup>355</sup> 702 F. Supp. 2d 181 (2010).

<sup>356</sup> *Ibid.*

<sup>357</sup> *Ibid.*, p. 227.

<sup>358</sup> Such as molecular diagnostic tests, biotechnological processes (e.g. the production of pure BRCA1 and BRCA2 protein), and in medical treatments, such as gene therapy.

<sup>359</sup> 702 F. Supp. 2d 181 (2010), p. 230.

<sup>360</sup> *Ibid.*, p. 231.

<sup>361</sup> *Ibid.*

sequences contained in the isolated DNA molecule: '[w]ere the isolated BRCA1/2 sequences different in any significant way, the entire point of their use – the production of BRCA1/2 proteins – would be undermined.'<sup>362</sup>

Sweet DJ also rejected the argument that 'DNA is "no different" than other chemicals previously the subject of patents.'<sup>363</sup> According to Sweet DJ, DNA is *essentially* different to other chemical compounds. This difference partakes of the informational content of DNA: DNA, in particular the ordering of its nucleotides, 'serves as the physical embodiment of laws of nature – those that define the construction of the human body.'<sup>364</sup> Insofar as earlier authorities support the notion that purified chemical compounds are patentable subject matter (a proposition which Sweet DJ denied),<sup>365</sup> these authorities should not be taken to confer patentability on DNA sequences because they fail to take into account the unique informational quality of DNA.

In light of DNA's 'unique qualities as a physical embodiment of information', Sweet DJ held that none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA render the claimed DNA 'markedly different'. 'This conclusion', Sweet DJ opined, 'is driven by the overriding importance of DNA's nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form. The preservation of this defining characteristic of DNA in its native form mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature.'<sup>366</sup> Ultimately, the purification of the native DNA did not alter its 'essential characteristic – its nucleotide sequence – that is defined by nature and central to both its biological function within the cell and its utility as a research tool in the lab.'<sup>367</sup> The requirement that the DNA to be used first be isolated is a 'technological limitation to the use of DNA in this fashion', rather than a difference 'in kind'.<sup>368</sup>

In June 2010, Myriad lodged an appeal against Sweet DJ's decision, which shall be heard by the United States Federal Court of Appeals for the Federal Circuit. If the decision is upheld, it will have important ramifications for the patenting of genetically-modified plants. Although whole plants will continue to be patentable, genes that confer particular agronomic traits on plants when introduced into plant germplasm may no longer be patentable. Given that most infringement actions relating to genetically-modified plants have been based on infringement of claims to isolated DNA sequences and transformed plant cells, this will obviously limit the scope of patents for genetically-modified plants. It is widely expected that the Federal Court of Appeals will overturn at least some aspects of Sweet DJ's decision. Whatever decision is reached by the Federal Court of Appeals, it seems likely that its decision will be followed by an appeal to the U. S. Supreme Court. While few observers appear willing to predict the outcome of any appeal to the Supreme Court, it is certain that a final resolution of the proceedings, and the question of whether isolated gene sequences are patentable subject matter under United States law, will take years to determine.

In the same month, a cancer advocacy group, Cancer Voices, commenced proceedings in the Federal Court of Australia seeking revocation of Myriad's Australian BRCA1 and BRCA2

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<sup>362</sup> Ibid.

<sup>363</sup> Ibid., p. 228.

<sup>364</sup> Ibid.

<sup>365</sup> According to Sweet DJ, the cases that are usually invoked in support of the patentability of DNA and other naturally-occurring compounds are not concerned with the question of subject matter at all, but with novelty and/or obviousness.

<sup>366</sup> 702 F. Supp. 2d 181 (2010), p. 229.

<sup>367</sup> Ibid., p. 231.

<sup>368</sup> Ibid.

patents on the basis that the claims do not relate to any manner of manufacture, being directed to ‘discoveries’ rather than ‘inventions’. It remains to be seen what impact Sweet DJ’s decision will have on the outcome of the Federal Court litigation. Unlike the position in the U. S., where the Supreme Court and a number of lower courts have on several occasions considered the patentability of naturally-occurring compounds, there is scant Australian authority directed to this question. In contrast to claims made by some, Sweet DJ’s decision does not rest on any distinction between invention and discovery, but on the necessity of demonstrating ‘marked differences’ between the characteristics of the claimed subject matter and its cognate natural substrate. Such a distinction has no basis in Australian patent law. Indeed, somewhat remarkably, given that the first gene patents were issued over two decades ago, the case will be the first occasion on which the Federal Court will have the opportunity to rule on the validity of gene patents, presuming, of course, that the matter goes to trial.

This instability is by no means peculiar to genetically-modified plants. In Europe, the patentability of traditionally-bred varieties remains uncertain, but will soon be clarified when the Enlarged Board of Appeal of the EPC hands down its eagerly awaited decision in the joined proceedings in *Plant Bioscience/Broccoli*<sup>369</sup> and *State of Israel/Tomatoes*.<sup>370</sup> Together, these developments indicate that the contours of the intellectual property landscape relating to the protection of plant varieties, both genetically-modified and traditionally-bred, are still shifting and uncertain, a situation which is likely to continue for some time to come.

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<sup>369</sup> (2007) 12 *Official Journal of the European Patent Office* 644.

<sup>370</sup> (2008) 11 *Official Journal of the European Patent Office* 523.