THE PATENTABILITY OF PLANT GENETIC INVENTIONS

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ABSTRACT
This paper, aiming to provide a global overview of issues specific to plant patentability, discusses also the general principles and specific exclusions to be taken into account, but without going into the details of patent rights granted and their scope. It aims to explain the distinctions and exclusions made for the purpose of patentability of plants in the patent offices of developed countries: plants vs. plant varieties (Europe), plants as higher life forms vs. their building blocks, i.e. gene sequences and cells (Canada); and finally micro-organisms v. plants (everywhere). It therefore focuses mainly on patent issues specific to plants, and for the most part does not address patent requirements and concerns that apply in the same way to all biotechnology inventions. It does not, for instance, go into the specific details of the patenting of gene sequences, but is limited to clarifying the distinction between plants and their gene sequences for patentability purposes. Finally, it addresses the role of the ordre public and morality exception in patent law concerning plant patents, as this has been addressed within European jurisprudence.

KEY WORDS

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Introduction

Patents on living organisms, including plants, have a long tradition of hotly contested debate. Whereas it was said for many years that living organisms were mere discoveries, this theory could, in the event of modern biotechnology, no longer be upheld. The ability to ‘reproduce’ nature by technical means, to isolate biological material invisible to the naked eye from its environment, to ‘decode’ the genetic structure of living organisms, and to alter, to recombine, these genes has changed the idea that products of nature were in any case ‘discoveries’ into the concept that technical ‘inventions’ applied to living organisms are possible.

In many (industrialized) countries today, the question is no longer whether or not plants, plant cells and plant gene sequences are patentable, but to what extent this is so. Therefore we aim in this paper to give an overview of law and jurisprudence specifically, and also of doctrine, on how plant genetic inventions will be patentable in the most important (industrialized) patent systems. Here, we will focus mainly on plant-specific issues, and leave aside for the most part issues regarding, for instance, gene sequences or micro-organisms in general.

Focusing primarily on Europe, the United States and Canada, this paper has been structured to discuss in Chapter I the general principles relating to plant patentability, and in Chapter II the specific distinctions and exclusions that are made. Finally, in Chapter III, there is an examination of the way in which environmental concerns and ethical objections have been dealt with in patent jurisprudence.
1 General Principles

The legal foundation of the patentability of plants *in general* is built upon the same basic principles as those that prevail for other inventions, namely that *any* type of invention in *any* kind of technology is largely considered as patentable subject-matter¹. Also, it has been agreed that there should be no discrimination in patent law between different areas of technology². For instance, in the Paris Convention, we read: *industrial property shall be understood in its broadest sense, comprising both manufactured and natural products.*³ Nevertheless, the question remains as to whether plants may be considered to be ‘inventions’. However, as *everything under the sun that is made by men*⁴ may be patentable, plants can hardly be excluded.

Most major international treaties on intellectual property address the issue of plant patentability in *specific* provisions.

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¹ Cf., for instance, Article 27 § 1 TRIPs Agreement (“patents shall be available for any inventions, whether products or processes, in all fields of technology”); Article 1 § 3 Paris Convention (industrial property shall be understood in its broadest sense, comprising both manufactured and natural products); Article 52 § 1 European Patent Convention (“European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.”); Article 14 of Decision 486 of the Andean Community on the Common Intellectual Property Regime (“The Member Countries shall grant patents for inventions, whether goods or processes, in all areas of technology, that are new, involve an inventive step, and are industrially applicable.”); Article 1709 § 1 of NAFTA (“each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “non-obvious” and “useful”, respectively.”); Article 6 of the Eurasian Patent Convention (“The Eurasian Office shall grant a Eurasian patent for any invention that is new, involves an inventive step and is industrially applicable.”) and Article 2 § 1 of the Agreement on the Creation of the African Intellectual Property Organization (“An invention that is new, involves an inventive step and is industrially applicable may be the subject of an invention patent”).

² Article 27 § 1 TRIP’s Agreement.


Under the **TRIPs Agreement**\(^5\), there is no general exclusion of inventions in the sphere of animate nature. On the contrary, we read in Article 27 that [WTO] members *may* exclude from patent protection *plants*\(^6\) other than *micro-organisms* as well as *essentially biological processes* for the production of plants (again, other than microbiological ones). Furthermore, the TRIPs Agreement neither excludes nor obliges the grant of patents for *plant varieties*, but requires nevertheless plant varieties to be protected either by patent protection or protection by a *sui generis* system\(^7\). The TRIPs Agreement thus only requires that micro-organisms, non-biological and microbiological processes be patentable.

In **Europe**, there is no general exclusion of inventions in the sphere of animate nature, either\(^8\). Here, on the regional level, the European Patent Convention\(^9\) does not address *plants* generally in its main articles, as does the TRIPs agreement, but nevertheless excludes *plant varieties* and *essentially biological processes* for the production of plants (except for *microbiological processes* and the products thereof) from patentability\(^10\). *Plant varieties*, thus excluded from patent protection, will however be protected under the


\(^7\) Article 27 § 3 (b) TRIPs Agreement. The openness of this provision has led to a quite disharmonized patentability of plants throughout WTO members. The *sui generis* possibility refers not only to the UPOV system. Indeed, it has been argued here that developing countries could use this opportunity to create a plant intellectual property system tailored to their needs (eg food security, biodiversity, farmer’s rights, resources control ...) See: CULLET, Ph., *Intellectual Property Rights and Food Security in the South*, 7 The Journal of World Intellectual Property 3 (2004).


\(^10\) Article 53 (b) EPC. See identically: Article 4 § 1 (a) & (b) Directive 98/44/EC.
European Union Plant Variety Regulation¹¹, which is based upon the UPOV system¹² and creates, as opposed to the European patent regime, a community-wide plant variety right. Finally, as to micro-organisms, the EPC explicitly requires that, in contrast to the TRIPs agreement, it is the *products* of microbiological processes that may be patentable, instead of using explicitly the term ‘micro-organisms’.

Since the amendment of the European Patent Convention for adaptation to the 1998’ European Union ‘Biotechnology’ Directive 98/44¹³, Rules 23b to 23e to the EPC¹⁴ have specified the same basic concepts of plant patentability as those that prevail for the European Union under the cited Directive 98/44/EC. Consequently, for the European Union as well as for the European Patent Office, *biological material*¹⁵ shall be patentable to the extent that it has been isolated from its natural environment or produced by means of a technical process, regardless of whether the same material has previously occurred

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¹⁴ The argument rose in the EPO 2005 Monsanto case that these rules and in particular Rule 23 (c) (b) to the EPC (stating that plants are patentable as long as the technical feasibility is not confined to a particular plant variety), are of that importance that its implementation into the European patent system should have been done in the European Patent Convention itself and not in its implementing regulations. The Technical Board however, referred to elder jurisprudence and judged that the decision of how to regulate is entirely a matter for the legislator as long as the Board does not see a conflict between a Rule and an Article (Technical Board of Appeal of the European Patent Office, *Herbicide Resistant Plants/MONSANTO*, 6 April 2005, T 179/01, § 9.), See further cases on the applicability of the Rules 23 (b) to 23 (e) : Opposition Division, *Oncomouse/HARVAR*D, Official Journal of the European Patent Office 475 (2003) and Technical Board of Appeal, *Transgenic Animals/HARVAR*D, T 315/03, Official Journal of the European Patent Office 246 (2005). On the specific applicability of Rule 23 e to the EPC: Technical Board of Appeal of the European Patent Office, *Relaxin/HOWARD FLOREY INSTITUTE*, 23 October 2002, T 272/95.

¹⁵ Whereby ‘biological material’ means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. (Rule 23 (b) (c) to the EPC and Article 2 (a) Directive 98/44/EC).
in nature\textsuperscript{16}. Hereby, plants have explicitly been found patentable provided that the technical feasibility of the invention is not confined to a particular plant variety\textsuperscript{17}.

In the NAFTA zone, we find a provision similar to TRIPs Article 27, stating that a NAFTA member state\textsuperscript{18} may exclude from patentability plants (other than micro-organisms) and essentially biological processes for the production of plants (other than non-biological and microbiological processes for such production). Nevertheless, NAFTA parties are obliged to provide plant variety protection by either patents, or ‘an effective scheme of sui generis protection’, or both\textsuperscript{19}. Hence it is clear that the NAFTA agreement, as much as the TRIPs agreement, does not attempt to harmonize the question of plant patentability. Consequently, we find among its member states differing, if not directly opposed, approaches.

In the United States, a distinction has not been made between plants and plant varieties, as in Europe, but instead between sexually and asexually reproduced plants\textsuperscript{20}. Whereas asexually reproduced plant varieties became patentable under the 1930 Plant Patent Act\textsuperscript{21}, sexually reproduced\textsuperscript{22}, or tuber propagated\textsuperscript{23} ones (other than fungi or bacteria) were protected by the 1970 Plant Variety Protection Act\textsuperscript{24}. Later on, as a result of the impact of Chakrabarty\textsuperscript{25}, it was decided in the Ex Parte Hibberd decision,\textsuperscript{26} and confirmed by the Supreme Court in its Pioneer Hi-Bred decision\textsuperscript{27}, that plants (e.g. plants per se, seeds and

\textsuperscript{16} Rule 23 (c) (a) to the EPC and Article 3 § 2 Directive 98/44/EC.
\textsuperscript{17} Rule 23 (c) (b) to the EPC and Article 4 § 2 Directive 98/44/EC.
\textsuperscript{18} The United States, Canada and Mexico.
\textsuperscript{19} Part Six, Chapter 17: Intellectual Property, Article 1709 § 3 of the North American Free Trade Agreement, 17 December 1992, 32 International Legal Material 296 and 32 International Legal Material 605.
\textsuperscript{20} See point 2.3 of this paper for a definition and further comments.
\textsuperscript{22} Whereby this includes: “...any production of a variety by seed, but does not include the production of a variety by tuber propagation.” (7 USC 2401 (6)).
\textsuperscript{23} Whereby this term means: „propagated by a tuber or a part of a tuber. “ (7 USC 2041 (7)).
\textsuperscript{26} United States Board of Patent Appeals, Ex Parte Hibberd, (1985) 227 USPQ 443.
\textsuperscript{27} United States Supreme Court, J.E.M. Agricultural Supply v. Pioneer Hi-Bred International, 10 December 2001, 534 US 124, 60 USPQ2d 1865.
plant parts\textsuperscript{29}) are also patentable under the General Utility Patent Act\textsuperscript{29}. However, plants in their natural form\textsuperscript{30} will not be patentable as they remain a mere discovery\textsuperscript{31}. Finally, in the United States, micro-organisms are patentable\textsuperscript{32} as well non-naturally occurring essentially biological processes for the production of plants\textsuperscript{33}.

In Canada, the situation, on first impression, is different from that in the US. Following the Harvard College case, there has been a general exclusion for patentability of higher life forms (multi-cellular differentiated organisms)\textsuperscript{34}. However, even though in the Harvard College case plant varieties were explicitly characterized as ‘a subset of higher life forms’\textsuperscript{35}, in the later Monsanto case, genes and cells contained in a glyphosate-
resistant plant were not considered to fall under the exclusion of ‘higher life forms’, but simply to be a gene and cell contained within a higher life form\textsuperscript{36}, and patent protection was not claimed for the latter.\textsuperscript{37} It has consequently been said that in Canada, higher life forms are not patentable \textit{per se}, but that its building blocks are\textsuperscript{38}. That, even though plants may not be patented in Canada, the patent holder of a plant cell or of a modified gene has the right to decide what they may do with the plant in question\textsuperscript{39} and that consequently, the case law in \textit{Monsanto} indirectly and in practical terms extends patent protection to the entire plant\textsuperscript{40}. The real difference in the Canadian approach thus probably lies only within the terms of the enforcement of the patent. A claim on organisms is easier to enforce: you are not required to prove that your gene sequence is actually used. Furthermore, it is arguable that discrimination takes place here, as plant varieties incorporating an engineered gene enjoy \textit{de facto} patent protection, whereas plant varieties made by traditional methods of plant selection will be protected only under PVR\textsuperscript{41}. Therefore, with regard to non-human higher life forms (i.e. animals and

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Supreme Court does not make much sense (Cf. J. DE BEER, \textit{Reconciling Property Rights in Plants}, 8 The Journal of World Intellectual Property 10 (January 2005)).

\textsuperscript{36} Supreme Court of Canada, \textit{Monsanto Canada v. Schmeiser}, 21 May 2004, 1 Supreme Court Reports (Canada) 92 (2004). Again 5 to 4 majority. However, in their dissenting opinion, four judges held this distinction without meaning. Indeed, it is argued in doctrine that as ‘possession’ of a plant containing a patented gene constitutes a ‘use’ thereof and thus infringement of the patent, the reasoning of Canadian Supreme Court does not make much sense (Cf. J. DE BEER, \textit{Reconciling Property Rights in Plants}, 8 The Journal of World Intellectual Property 10 (January 2005). See also the previous decisions by the lower Courts in ‘Monsanto’: Federal Court Trial Division, Monsanto Canada Inc. v. Schmeiser, 2001, 202 F.T.R. 78, 12 C.P.R. (4\textsuperscript{th}) 204 and Federal Court of Appeal, Schmeiser v. Monsanto Canada Inc., 2003, 2 F.C. 165, 218 D.L.R. (4\textsuperscript{th}) 31.

\textsuperscript{37} G. LAW and J. MARLES, \textit{Monsanto v. Schmeiser}. \textit{Patent Protection for Genetically Modified Genes and Cells in Canada}, 13 Health Law Review 44 (2005), p. 46: “Many perceive the majority decision in Monsanto to be inconsistent with the Supreme Court of Canada’s holding in Harvard Mouse. However, the majority in Monsanto argue that their decision is, in fact, consistent with Harvard Mouse, noting that the gene and cell claims in Monsanto’s glyphosate-resistant plant patent are analogous to the plasmid and somatic cell culture claims which had been allowed by the Commissioner of Patents in Harvard’s patent for a genetically modified “oncomouse”. It was only the claim for the “oncomouse” itself, as a higher life form, which was denied, and Monsanto did not claim modified plants in its patent. Notably, both the majority and minority in Monsanto agree that the claims in Monsanto’s patent are valid.”


plants) it has been argued by the Canadian Biotechnology Advisory Commission (CBAC)\(^42\) that those should be made explicitly patentable, even though within limits such as the inclusion of the recognition of the farmer’s privilege\(^43\).

In summary, plants as such are excluded from Canadian patentability\(^44\), but microorganisms are not\(^45\), nor are plant gene sequences. Finally, essentially biological processes for the production of plants will not be patentable in Canada\(^46\).

### 2 Distinctions made for Plant Patentability

Having read the general principles that apply, we can see that plant-related inventions are divided into several groups. The patentability of plant-related inventions will therefore often depend on definitions made and interpretations given to the concepts of plant variety, micro-organisms and essentially biological processes. The borderlines between these scientific definitions usually originating from varying jurisprudence within different jurisdictions trigger distortion of the regulations between the different national or regional patent systems. In the next chapter we aim to define the narrow line between patentability and non-patentability of plants throughout the principal patent regimes in the world, focusing especially on that found within the European Patent Office.

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\(^{44}\) The same is true for Thailand (WTO Council for Trade-Related Aspects of Intellectual Property Rights, *Review of the Provisions of Article 27.3 (b)*, 18 February 2003, IP/C/W/273/Rev.1., p. 8.)


2.1 Essentially Versus Non-Essentially Biological Processes

2.1.1 Introduction

We have seen that under the TRIPs Agreement47 as well as under NAFTA48, essentially biological processes for the production of plants (other than microbially processes) may be excluded from patentability. A contrario, member states to these treaties may not exclude non-biological processes from patentability. Moreover, microbiological processes, being the exception to the exception, must also be patentable.

In Europe49,50, Canada, Korea, Thailand and South Africa51 essentially biological processes for the production of plants have indeed been excluded from patentability. However, in Australia, Japan, New Zealand and Romania these processes will be patentable52. Finally, in the United States, ‘naturally occurring’ essentially biological processes will not be patentable53.

For biotechnology, this distinction sits on the fence between the ‘traditional’ and ‘modern’ biotechnology54: whereas mating and cross-breeding or selective breeding will be essentially biological and thus not patentable in most legal systems55, genetic

47 Article 27 § 3 (b) TRIPs Agreement.
48 Article 1709 § 3 (c) of the North American Free Trade Agreement (NAFTA).
49 Including Bulgaria, Switzerland, Hungary, Iceland and Norway.
50 Article 53 (b) EPC and Article 4 § 1 (b) Directive 98/44/EC.
53 For this would fail to meet the patent requirements out of Section 101-103 of the US Patent Act. This comprises naturally occurring steps for the sexual or asexual reproduction of a plant (WTO Council for Trade-Related Aspects of Intellectual Property Rights, Review of the Provisions of Article 27.3 (b), 18 February 2003, IP/C/W/273/Rev.1., p. 26).
54 Cf Article 3 (i) of the Cartagena Protocol on Biosafety to the Convention on Biodiversity, 5 June 1992, 39 International Legal Material 1027 (2000), which reads: “Modern biotechnology means the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection”. However, note the much broader definition of ‘biotechnological inventions’ that is used in Rule 23 (b) § 2 to the EPC: “Biotechnological inventions are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.”
engineering will be viewed as a technical process\textsuperscript{56} and will may consequently result in eligibility for patent protection.

Generally, the exclusion applies only to processes and not to ‘the products thereof’ as is the case for micro-biological processes. Thus, neither product claims, nor so called ‘product by process claims’ will be affected by the non-patentability of biological processes\textsuperscript{57}. Furthermore, as the exclusion applies to the ‘production’ of plants, most processes that result in the death or the destruction of plants will be patentable\textsuperscript{58}.

\subsection*{2.1.2 Rationale}

Behind this exclusion lurks the long-established idea that the patent system is meant to cover technical processes\textsuperscript{59} and that essentially biological processes are actually discoveries: acts of nature\textsuperscript{60}. Moreover, as they occur naturally, these types of processes lack the ability to reproduce and cannot therefore be easily defined in terms of a patent description. Consequently, an essentially biological process, as opposed to modern biotechnology, is not considered to be a technical solution for a technical problem by a technical means.


\textsuperscript{58} See in the United Kingdom: NRDC’s \textit{Application}, 1961, RPC 134 and Swift’s \textit{Application}, 1962, RPC 37.

\textsuperscript{59} See for instance: S. BOSTIJN, \textit{Patenting DNA sequences (polymerolides) and Scope of Protection in the European Union: an Evaluation}, Background Study for The European Commission, Office for Official Publications of the European Communities, 2004, p. 12: “The EPO has traditionally held that an invention must be technical in order to be called a patentable invention, irrespective of whether the patentability requirements are being fulfilled.”

\textsuperscript{60} For instance, Hungary has excluded essentially biological processes from patentability under Article 1 of the Hungarian Patent Law as it considers it to be the same category as ‘discoveries’. (Cf. WTO Council for Trade-Related Aspects of Intellectual Property Rights, \textit{Review of the Provisions of Article 27.3 (b)}, 18 February 2003, IP/C/W/273/Rev.1., p. 25.).
2.1.3 Definition and Interpretation in the European Patent Office

2.1.3.1 Essentially biological = based upon the essence of invention and the totality of human intervention

In 1988, the Technical Board of Appeal of the European Patent Office, ruling in the Lubrizol case, argued that in defining ‘essentially biological’ one had to take into account the essence of the invention and the totality of the human intervention. The Technical Board said that, like all exceptions to a ‘general rule of this kind’, the exclusion of essentially biological processes had to be construed narrowly. Here, the necessity of human interference alone was not considered a sufficient criterion; instead, the essence of the invention took on a prominent role. Whether or not the totality and the sequence or the arrangement of the process steps occurred in nature was found to be of paramount importance:

The human interference must contribute something beyond a trivial level and it is not a matter simply of whether such an intervention is of a quantitative or qualitative nature. In the present case, which presents a multistep process, each single step as such may be characterized as biological in a scientific sense but, as the Board stated, the facts clearly indicate that the claimed process for the preparation of hybrid plants represent an essential modification of known biological and classical breeders processes, and the efficiency and high yield associated with the product give evidence of technological character.

Seven years later, the Lubrizol principles were confirmed, and they were further refined in the 1995 Plant Genetic Systems case. Here, the Technical Board seemingly adopted an intermediate approach between what was decided in Lubrizol and what was to be legally protected.

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64 Among the arguments raised by the appellants, it was argued that the fact alone that a living organism was used in the process did not render that process essentially biological. Further the appellants claimed that one had not only to take into account the biological or non-biological characteristics of the individual process steps, but that one also had to consider the characteristics of the end result, and that the only way of protecting this technology was to grant a patent whereby the risk of leaving the invention unexploited would be contrary to the public interest.
enacted in Directive 98/44/EC, three years later. Indeed, the Board specified that a process involving at least one essential technical step which could not be carried out without human intervention and which had decisive impact on the final result would be patentable\textsuperscript{66}. However, one can wonder here how one can define a non-essential biological process as ‘a process containing at least one essential technical step’ without going in circles. It was said, correctly, that a process claim was patentable because even though only the first steps in the production of the plant were to be considered ‘non-biological’ (e.g. recombinant DNA) these nevertheless had a decisive impact on the final result, notwithstanding the subsequent ‘biological’ steps of regenerating\textsuperscript{67} and replicating the plants and seeds. Without this first step (which could not occur without human intervention) the plants or seeds in question would not have had the desired distinctive character, which was actually triggered by the heterologous DNA integrated in their genome\textsuperscript{68}.

2.1.3.2 Essentially biological = if at least one step is biological

In 1997, the Technical Board of Appeal judging in Novartis, considered three approaches to interpreting the exclusion. Besides the above-mentioned Lubrizol/Plant Genetic Systems-criteria, and the criterion that would later on be approved in Directive 98/44/EC, a third approach, contrary to the actual situation, was considered that would involve the concept that if at least one step in a process were biological, the process would become essentially biological\textsuperscript{69}. By analogy to case law on Article 52 (4) EPC, only processes containing exclusively non-biological steps would then be patentable. However, neither here, nor in the subsequent 1998 Enlarged Board of Appeal decision on Novartis, was a final decision reached.


\textsuperscript{67} And even this regeneration step was not said entirely biological, but rather ‘agro technical’.


2.1.3.3 Essentially Biological = if at least one step is not biological

Since the 1998 Biotechnology Directive 98/44/EC and the subsequent adaptation of the EPC, the concept of an “essentially biological process” has been defined in European law as meaning a process which entirely consists of natural phenomena such as crossing or selection. Hence a process consisting entirely of natural phenomena will not be patentable today, unlike a process identifying at least one non-biological step, which will be patentable. Similarly, in the WTO review on the implementation of Article 27 TRIPs, the concept was defined as a process limited to those acts that are necessary for sexual or asexual reproduction of a plant. In other words, processes with no human intervention at all will be considered essentially biological and thus unpatentable. Nevertheless, the EPO still refers in some cases to the ‘essence’ of the processes. For instance, in Novartis III it was said that as the essence of the invention emphasized the fact that genetic engineering steps were performed, the process in question could not be considered essentially biological.

2.2 Plants versus Plant Varieties

2.2.1 Introduction

As mentioned above, the TRIPs Agreement says that WTO member states may exclude plants from patent protection, but requires that plant varieties be protected either by patent protection or by a sui generis system.

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70 A process for the production of plants will be essentially biological if: “it consists entirely of natural phenomena such as selective breeding” (Article 2 § 2 Directive 98/44/EC), or, more precise, “if it consists entirely of natural phenomena such as crossing or selection” (Rule 23 (b) (5) EPC).


75 Article 27 § 3 (b) TRIPs Agreement.
In countries which have a tradition of protecting plant varieties by PVR/UPOV systems, whatever falls within the scope of PVR protection will mostly be excluded from patentability. Therefore, precise definition of the term ‘plant variety’ will be of importance in order to delimitate between the two. In Europe\textsuperscript{76} for example, as plant varieties are protected under Community Plant Variety Protection\textsuperscript{77}, inventions related to plants in general are not excluded from patentability \textit{provided that} the technical feasibility of the invention is not confined to a particular plant variety\textsuperscript{78}.

However, in countries which do not grant patents for plant-related inventions at all, but do confer PVR protection, the definition of plant varieties will obviously not serve to delimitate between patent and PVR protection, but instead to clarify what will be protectable under PVR and what will not. For example, the \textit{Andean Community} excludes plants from patentability\textsuperscript{79}, but protects plant varieties under Decision 345 on Common Provisions on the Protection of the Rights of Breeders of New Plant Varieties\textsuperscript{80}.

Finally, in certain countries, the two systems coexist. In \textit{Australia}, for instance, neither plants nor plant varieties are excluded from a ‘standard’ patent\textsuperscript{81}. Moreover, plant

\textsuperscript{76} Where Directive 98/44/EC is said to promote explicitly the fruitful coexistence of the patent- and plant variety system (R. MOUFANG, \textit{The Interface Between Patents and Plant Variety Rights in Europe}, WIPO-UPOV Symposium on Intellectual Property Rights in Plant Biotechnology, Geneva, October 9, 2003, WIPO-UPOV/SYM/03/6, p. 3).


\textsuperscript{78} See: Article 53 (b) EPC and the identical Article 4 § 1 (a) & (b) Directive 98/44/EC; Rule 23 (c) (b) to the EPC as well as Article 4 § 2 Directive 98/44/EC.

\textsuperscript{79} Article 20 (c) of Decision 486 of the Andean Community on Common Intellectual Property Regime, available at: \url{http://www.comunidadandina.org/ingles/treaties/dec/D486e.htm}.

\textsuperscript{80} Decision 345 of the Andean Community on Common Provisions on the Protection of the Rights of Breeders of New Plant Varieties, available at: \url{http://www.comunidadandina.org/INGLES/treaties/dec/d345e.htm}.

\textsuperscript{81} Even though it does exclude “plants and the biological processes for the generation of plants” from ‘innovation patent’ (Part III, Division I, Section 18 (3) of the Australian Patent Act, Act 83 of 1990, as amended, available), Innovation patents are designed to protect inventions that are not sufficiently inventive to meet the inventive threshold required for standard patents. They are an inexpensive and simple to obtain, but it can’t be enforced until after examination has been carried out and the patent is certified (see: \url{http://www.ipaustralia.gov.au/patents/what_innovation.shtml}). In Australia, it is consequently possible to obtain a patent for a patent claim that is not limited to a specific plant or animal variety, a patent claim that is expressly limited to a plant or animal variety and for a patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene. (See: WTO Council for Trade-Related Aspects of Intellectual Property Rights, \textit{Review of the Provisions of Article} 27.3 (b), 18 February 2003, IP/C/W/273/Rev.1, p. 5.)
varieties will also be protected under the 1994 Plant Breeder’s Rights Act. On this matter, Australia has expressed to the WTO that the grant of a right under one system does not in itself affect any entitlement under the other system, provided all condition for eligibility are met.

In this chapter we will mainly investigate how the concept of plant varieties is applied within the judicial system in which this distinction carries the greatest importance: that of the European Patent Office.

2.2.2 Rationale

The main rationale of this distinction is the avoidance of overlaps between patents and the sui generis systems of plant variety protection.

Historically, patent protection was considered inappropriate for the protection of new plants, and hence systems of plant variety protection were created.

The old UPOV Convention of 1961 banned such dual protection, but allowed countries to progressively implement the UPOV provisions. In consequence hereof, several


\[86\] Article 2 § 1 of the International Convention for the Protection of New Varieties of Plants, 1 December 1961, 815 United Nations Treaty Series 89, available at: http://www.upov.int/en/publications/conventions/index.html (Hereafter UPOV 1961): “Each member State of the Union may recognise the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. Nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species.”
countries excluded patent protection only for (some of) the plants figuring on the annexed list of varieties to the UPOV convention. Consequently, patents were granted in Europe at that time for plant varieties not featuring on the UPOV list or not featuring on the member states’ own ‘progressive’ list. It has been argued therefore that the rationale was not the exclusion of plant varieties per se, but only of those falling under plant variety protection. Hence in Europe, even though the 1991 Act of the UPOV Convention no longer prohibits dual protection, whatever is not protected under plant variety protection is to be protected under the patent system.

This rationale is, however, not unchallenged. It should be recalled here that plants being at a higher taxonomy rank than plant varieties, the distinction seems quite artificial. Logically, plants being higher up the taxonomy ladder, all plant varieties will automatically contain the fundamental genetic structure, the DNA, of the ‘plant’. Therefore claims related to plants in general can hardly avoid being also directed to varieties of plant. In other words, as patented subject-matter that contains genetic information extends in Europe to all material into which it is inserted and performs its function, one cannot exclude – in fact, on the contrary, one can hardly avoid – the concept that such material would be a plant variety.

87 Article 4 of UPOV 1961.
89 Recital 31 of the EU Directive 98/44: “Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants”. See also: Enlarged Board of Appeal of the European Patent Office, Transgenic Plant/NOVARTIS II, 20 December 1999, G1/98, Official Journal of the European Patent Office (2000) pp. 132–133.
90 Article 9 Directive 98/44/EC: “The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product in incorporated and in which the genetic information is contained and performs its function.”
2.2.3 Definition of ‘Plant Variety’

Here, the legal definitions are to be sought within PVR laws, and not in patent laws. As the UPOV system is quite widely established throughout the international community, the definition of ‘plant variety’ is effectively harmonised throughout the world.

Under UPOV, a plant variety shall be:

*a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder’s right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged.*

Consequently, in the United States and in Europe, the definition is identical, whereas the Andean Community seems to work to a different definition.

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*In Article 2 § 3 of the Directive 98/44/EC, for instance, the term of ‘plant variety’ is defined by reference to the definition in the European Union Regulation on Plant Variety Protection: “The concept of ‘plant variety’ is defined by Article 5 of Regulation (EC) No 2100/94.” See also Recitals 30, 31 and 32 of Directive 98/44/EC.

*Cf. Recital 30 of Directive 98/44/EC: “the concept “plant variety” is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties”.

*On December 15, 2005, the UPOV Convention was adopted by 60 countries and regional entities, among which the European Communities, the United States, Canada, Australia, China, Switzerland, Argentina, Brazil and the Russian Federation. See: http://www.upov.int/en/about/members/.


*Quite similar definition rules in the United States, where: “the term variety means a plant grouping within a single botanical taxon of the lowest known rank, that, without regard to whether the conditions for plant variety protection are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged” (7 USC 2401 (9)).

*Article 5 European Union’ Council Regulation 2100/94, 27 July 1994, on Community Plant Variety Protection, Official Journal L 227, 01/09/1994, pp. 1–30 (hereafter Regulation 2100/94/EC) and the identical Rule 23 (b) (4) EPC:

: “Object of Community plant variety rights
1. Varieties of all botanical genera and species, including, inter alia, hybrids between genera or species, may form the object of Community plant variety rights.
2. For the purpose of this Regulation, ‘variety’ shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:
The European Patent Office has ruled on many occasions on the issue of a correct legal definition of ‘plant varieties’, and referred on each of these to the UPOV definition. Roughly summarized, the EPO understands the term ‘plant variety’ to mean a plant grouping within a single botanical taxon of the lowest known rank. While reading EPO case law, one however sees that the UPOV definition of plant variety is apparently often mixed up with the UPOV criteria for plant varieties to be eligible for UPOV protection. For instance it was said that plant varieties are defined as those characterized by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics\textsuperscript{99} or, as a multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle\textsuperscript{100}. We believe however, as was ruled in Plant Genetic Systems: the UPOV definition of plant varieties should be employed irrespective of whether it would be eligible for protection under the UPOV Convention\textsuperscript{99}.

\textsuperscript{99} For the Andean Community, a plant variety will be a: “set of cultivated botanical individuals that are distinguished by specific morphological, physiological, cytological and chemical characteristics and can be perpetuated by reproduction, multiplication or propagation.” (Article 3 of Decision 345 of the Andean Community on Common Provisions on the Protection of the Rights of Breeders of New Plant Varieties, available at: http://www.comunidadandina.org/INGLES/treaties/dec/d345e.htm).


However, a plant defined by single recombinant DNA sequences is not such an individual plant grouping, but an abstract and open definition embracing an indefinite number of individual entities, as the taxonomic category within the plant kingdom to which plants belong is not specified\textsuperscript{102}.

2.2.4 Practical Application

2.2.4.1 Introduction

Having noted the general principle in law (that the technical feasibility of the invention as it stands in a patent claim may not be confined to a particular plant variety) and having absorbed the legal definition of the term ‘plant variety’, we will now aim to investigate where a borderline may be specified when a patent claim is or is not confined to a particular plant variety?

Basically, when a patent is granted, it is said to be valid for everything falling within the claim\textsuperscript{103}. In certain specific biotechnological patent applications (for instance nucleotide (DNA) sequences) the claims are said to be ‘representative’ ones. This means that, because describing every particular manifestation of the invention, and every product or process covered by the patent, would make the patent application at stake unworkable, the patentee may claim a broad range of products on the basis of a limited number of (representative) examples\textsuperscript{104}. Now, what happens if the claim indirectly covers a plant variety, or if it potentially encompasses a plant variety? Can the exclusion be circumvented merely by addressing more than a single variety in the claim? And what if


\textsuperscript{103} See Article 69 § 1 EPC: “The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.” See also Article 84 EPC: “The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.”.

a plant is not characterised by its whole genome, but merely by a particular gene? What if the patent claim covers an embodiment that does not fulfil the requirements for patentability (in casu a plant variety)? Will gene sequences and plant cells (microorganisms) of plants be patentable, in the knowledge that the plant varieties containing these sequences will fall within the scope of protection of the patent?

2.2.4.2 The Concept of Plant Varieties

2.2.4.2.1 General Principles

2.2.4.2.1.1 Unpatentable = Plants in genetically fixed form of a plant variety (determined peculiarities of their phenotype)

Back in 1983, the Technical Board of Appeal judged in the Ciba Geigy case that the wording of Article 53 (b) of the European Patent Convention precludes the equation of the plants and plant varieties\(^\text{105}\) and that Article 53 (b) EPC prohibits the patenting of plants (or their propagating material) only in the genetically fixed form of a plant variety. The criticism that in the drafting of the terms of the Convention the conception of plants generally was held by referring to plant varieties, and that the idea of ‘playing’ with the taxonomic range was only brought into the debate much later by clever patent lawyers, was hereby rejected. If the patent claim were to have been directed to plants distinguishable from other plants by stable features that were homogenous over the different generations, the patent would not have been granted. However, as the patent claim at stake was directed to any plant-propagating material treated with chemicals (an oxime derivate) to make it resistant to other chemicals, the Technical Board confirmed that the patent as the object of the treatment might also be propagating material which did not meet the essential criteria “for homogeneity of stability characteristic of a plant variety” (and thus was not restricted to plants that are characterised by the genetically determined peculiarities of their phenotype)\(^\text{106}\).


Later, in the 1988 Lubrizol case, the Technical Board confirmed the principles established in Ciba Geigy, by stating that homogeneity and stability were characteristics prerequisite for a plant variety.¹⁰⁷

2.2.4.2.1.2 Unpatentable = Patent claims embracing or encompassing plant varieties

In the EPO Technical Board of Appeal 1995 Plant Genetic Systems decision, it was held that all claims embracing plant varieties should be unlawful.²⁰⁸

Consequently, a claim directed to plants possessing heterologous DNA stably integrated in their genome (to make them resistant to a type of herbicide) was declared unpatentable, even though it was not drafted in terms of a variety description (as no reference to a single botanical taxon on the lowest rank was made, and non-variety-specific enzymatic activity was actually in question).¹⁰⁹ The Technical Board justified its decision by virtue of the fact that the claimed subject-matter encompassed plant varieties, because, as opposed to what had been claimed in Ciba Geigy and Lubrizol, it related to modified plants that remain stable in their characteristics. Moreover, the Board said that as all working examples were plant varieties (for instance, tobacco plants), the practical forms of realization of the claim, even though drafted in general terms, were plant varieties.¹¹¹ Even though the Technical Board referred to the Ciba Geigy criteria, it broadened the scope of unpatentable inventions by utilising the word ‘encompassing’. Similarly, even though plant cells in general were not considered to be plants or plant


¹⁰⁹ The complete wording of the claim was: “Plant, non biologically transformed, which possesses, stably integrated in the genome of its cells, a foreign DNA nucleotide sequence encoding a protein having a non-variety-specific enzymatic activity capable of neutralizing or inactivating a glutamine synthetase inhibitor under the control of a promoter recognised by the polymerases of said cells.” (Technical Board of Appeal of the European Patent Office, Plant cells/PLANT GENETIC SYSTEMS, 21 February 1995, T 356/93, Official Journal of the European Patent Office (1995) 545, § 1).

varieties, a claim directed to plant cells (normally patentable as micro-organisms) contained in plant, was refused, because cells contained in a plant are actually differentiated cells that are morphologically and functionally organized to constitute a plant, and the claim did not, consequently, exclude plant varieties from its scope.

After the Plant Genetic Systems decision, it has been argued that as plant varieties are frequently used as starting point for the production of genetically engineered plants, such plants would no longer be patentable in most cases. Nevertheless, the ruling by the Enlarged Board of Appeal after the decision by the Technical Board of Appeal on Plant Genetic Systems did not see a conflict between the present case on the one hand and Oncomouse and Ciba Geigy on the other.

2.2.4.2.1.3 Unpatentable = Individually claimed plant varieties

Only a few years later, in the 1999 Novartis case, the Technical Board of Appeal was not followed by the Enlarged Board of Appeal in applying the principles of Plant Genetic Systems. After the Technical Board had argued that if a potential embodiment of a claim was a variety, and thus if an invention can embrace plant varieties, that invention should not be patentable, the Enlarged Board of Appeal refuted the decision and decided that plants can be patented as long as plant varieties are not individually claimed, even in cases where the invention might embrace plant varieties. As the delimitation between plants...
and plant varieties is to be fixed, in the sense that what does not fall within the subject-matter of PVR falls under the subject-matter of patents, claims that cover but do not identify a plant variety (not protectable under PVR, as they are not defined by their whole genome) will be patentable. Consequently, the Enlarged Board ruled that if an invention can be carried out by modifying plants that may or may not be varieties, it will be patentable, as it is not restricted to individual varieties.

The Enlarged Board of Appeal wanted explicitly to avoid claims for genes contained in plant varieties being excluded from patentability, and was afraid that the Technical Board’s view would exclude from patentability any genetic material for introduction into a plant. The Enlarged Board said that the rule that an invention would not be patentable when it covers an embodiment which itself does not fulfil the requirements for patentability is not without exception. Moreover, plant varieties were not excluded for being ineligible for patent protection per se, but to avoid dual protection with PVR.

In doctrine, it has been said after the Novartis case and the coming into force of Article 4 § 2 Directive 98/44/EC, that a plant variety or a group of plants that could be defined as a variety is not patentable unless they are considered to be embodiments of inventions that independently qualify for patent protection. Furthermore, one author apparently argues that the Enlarged Board of Appeal’s decision triggered an intentional

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121 Thereby referring to the unpublished decision T 361/87 of 15 June 1988 (were a claim directed to the use of the whole class of micro-organisms could be granted, although specific strains comprised in this class were not available to the public) and to Technical Board of Appeal of the European Patent Office, *Polypeptide expression/GENENTECH I*, 27 January 1988, T 293/85, Official Journal of the European Patent Office 1988.

122 Article 4 § 2 Directive 98/44/EC reads: “Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.”

element: whether or not the developing of a specific variety was necessarily the objective of the inventors. Also, the concern has been expressed that the distinction as made in Novartis was in the end somewhat artificial, as claims directed to plants characterized by the insertion of a specific nucleotide sequence do not fall under the definition of plant variety in the sense of the decision, and will thus be patentable, but will nevertheless extend in their scope to the plant varieties that will contain the specific nucleotide sequence. Finally, an analogy was made to problems that arose in patenting computer programs, namely that claims will be dressed up to appear as though they do not fall within a given exception. Jurisprudence in this area was consequently advised to provide guidance, under the reserve of the different rationales in both fields.

2.2.4.2.1.4 Unpatentable = Individually claimed plant varieties and inventions which technical feasibility is confined to a particular plant variety?

After Novartis, Directive 98/44/EC and the Rules to the EPC incorporating the principles of the said Directive into the EPC had come into force and ruled that plants are patentable as long as the technical feasibility of the invention is not confined to a particular variety. Consequently, the question rises as to whether this could be interpreted differently from the Novartis principle: as long as plant varieties are not individually claimed.

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125 See: Recital 31 of the Directive 98/44/EC: “Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants”


128 Article 4 § 2 Directive 98744/EC and Rule 23 (b) (c) to the EPC.
Today, even though the Novartis principles still stand and were confirmed in many subsequent cases, some EPO jurisprudence and authors apply both criteria simultaneously. Indeed, in the 2004 Phosphinothricin-Resistenzgen/BAYER case the Technical Board judged that the patent claims in question (directed to a certain nucleotide sequence, as well to the plant cells and the plants characterized by that gene) neither ‘individually claimed’ plant varieties, nor was their technical feasibility confined to a particular plant variety. However, even though both criteria were mentioned, they are apparently interpreted as having an identical meaning.

2.2.4.2.2 A Few Objections

In the cases discussed above, many arguments for and against patenting plants have been made. Among these, in Plant Genetic Systems, the argument arose that plant products from any generation after the first one would not constitute an invention.

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129 For instance in Technical Board of Appeal of the European Patent Office, Anti-Pathogenically Effective Compositions/NOVARTIS III, 6 December 2000, T 1054/96, § 1: “Claims 18 to 21 are directed to transgenic plant and embrace plant varieties. Yet, no plant variety defined by taxonomic name and further variety specific characteristics is individually claimed.”

130 T. HOWARD, The Legal Framework Surrounding Patents for Living Materials: a European/UK Focus, Paper presented at the Conference ‘Patenting Life’ in London, 1-2 December 2005, p. 7: a transgenic plant is 1) not expressed in plant variety terms and 2) that the invention is not confined to a particular plant variety will be patentable.

131 In the original German:

“1. Resistenzgen, codierend für das Protein der Aminosäuresequenz I (Anhang), indem [sic] als Startcodon ATG und als Stopcodon TGA verwendet werden und der GC-Anteil des Gens an den in Pflanzen angepaßt ist.”

“9. Pflanzen, deren Teile und Samen, gekennzeichnet durch ein Gen nach Anspruch 1, 2 oder 3.”


under Article 52 EPC. The Technical Board, however, refused the idea, stating that without the invention of the first generation the subsequent ones would simply not exist. Today, this matter has been settled by Article 8 § 2 of Directive 98/44/EC claiming that patent protection extends not only to the first generation of plants but also to the following generations, provided that they possess the same characteristics as do the first generation\textsuperscript{134}.

Furthermore, in \textit{Novartis}, the suggestion of a mere literal approach involving the concept that if several plants were claimed this would be adequate for the invention to be patentable\textsuperscript{135} was refuted by the Enlarged Board of Appeal. If a claim addressing several plant varieties would be patentable, but a claim addressing only one plant variety would not, this would, the Board said, be a notion quite alien to patent law in general\textsuperscript{136}. The substance, but not the wording, is decisive\textsuperscript{137}. It could, however, be argued here, taking the wording of Article 4 § 2 of the Directive 98/44/EC (that plants will be patentable as long the technical feasibility of the invention is not confined to a \textit{particular} plant variety), that when a claim is addressed to a \textit{particular} but to \textit{several} plant varieties, this claim would indeed be patentable\textsuperscript{138}. Later, in \textit{Novartis III}, it was however made clear again by

\textsuperscript{134} Article 8 § 2 Directive 98/44/EC: "The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics."

\textsuperscript{135} NB see: Protocol on the Interpretation of Article 69 of the Convention, adopted at the Munich Diplomatic Conference for the setting up of a European System for the Grant of Patents on 5 October 1973: "Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties." (The Protocol shall be an integral part of the Convention pursuant to Article 164, paragraph 1.).


the Technical Board that patent claims may be directed to seeds of transgenic plants as long as the seed of one or more plant varieties were not individually claimed.\textsuperscript{139}

In the same sense, the Enlarged Board of Appeal also rebutted the argument that distinction between plants and plant varieties becomes merely a matter of terminology, by arguing that a generic claim is not the consequence of the verbal skills of the attorney, but of whether or not the invention in question has general applicability. From this was raised the counterargument that this was the opposite approach to current jurisprudence concerning Article 52 § 4 ECP, ruling that if the claimed invention is not directed solely to a cosmetic effect, but is also necessarily defining a treatment of the human body by therapy as well, such a claim is excluded from patentability.\textsuperscript{140} However, analogies between Article 52 § 4 and 53 (b) EPC were generally refuted.\textsuperscript{141}

Remarkable in this context is also the 2003 Resistance Development/BAYER case. Here, a claim that was directed to ‘Brassica, tomato, tobacco, cotton or lettuce’ had been amended by the introduction of the word ‘cells’ after ‘Brassica, tomato, tobacco, cotton or lettuce’ and consequently was accepted as not claiming individual varieties.\textsuperscript{142} The Technical Board also seemed in this case to deviate from the Novartis principle in claiming that it is not the wording but the substance that is decisive, as it stated that the claims in question met the requirements of Article 53 (b) EPC, because they did not mention individual plant varieties.\textsuperscript{144} Moreover, the fact that claims directed to tomatoes generally would pose a patentability problem, as was the case in the above-mentioned judgement, is not generally accepted in doctrine, where it is usually said that a plant ‘variety’ is of a lower taxonomy than ‘tomato’, being the taxonomical ‘species’. A patent claim would in that view be non-patentable if it individually claimed a certain kind of


\textsuperscript{142} Technical Board of Appeal of the European Patent Office, Resistance Development/BAYER, 15 January 2003, T 149/98, Fact and Submissions I & II.


tomato. On the other hand, one can hardly imagine how an invention can affect ‘tomatoes’ as a ‘species’ without thereby creating new ‘varieties’ of tomatoes. However, what counts in European patent law is the individual claiming of a variety, point final.

2.2.4.2.3 A Few Examples

In the 1984 *Ciba Geigy*-case, propagating material of certain genera of plants (cultivated plants) treated with chemical agents (an oxime derivative), whether in the form of seeds or not, without specific varieties being claimed individually, was not considered to relate to an individual variety, but was instead found to relate to ‘any cultivated plants in the form of their chemically treated propagating material’.

After the Technical Board in *Plant Genetic Systems* had in 1995 refused claims directed to plants possessing a heterozygous DNA stably integrated in their genome (to make them resistant to a type of herbicide), the earlier approach was again adopted by the Enlarged Board of Appeal in the 1999 *Novartis* case, where claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which resulted in the production of antipathologically active substance, and the methods of preparing such plants, were held patentable. Recently, in 2005, the EPO Technical Board of Appeal granted a patent claim by *Monsanto* directed to a glyphosate-tolerant plant comprising a certain type of plant cell (claimed as well), in spite of the argument that herbicide-tolerant plants were of course meant to be grown in fields and that it was consequently a matter of general knowledge that it was only plant varieties that were of agricultural importance.

145 Cf. G. VAN OVERWALLE, *The Current IPR Framework for Transgenic Crops and its Implications for Developing Countries*, in Seminar Sustainable Agriculture in the Third World: Defining a Role for transgenic Crops and Research, held in Brussels 26-27 March 2001, p. 92: “In terms of the current line of cases from the EPO, no patent protection is possible for the Charlotte variety of potatoes, but is possible to patent (the transgenic) potato.”


2.2.4.2.4 Hybrid Plants

The question can arise whether hybrid plants\textsuperscript{149}, whose characteristics are generally unstable over the generations, can nevertheless be regarded as plant varieties within the meaning of the EPC.

In the EPO 1988 Lubrizol case, hybrid seeds, and plants from such seeds, were considered not classifiable as a plant variety within the meaning of Article 53(b) EPC, as they lacked stability in some trait of the whole generation population (even though the totality of the hybrid generation claimed in a patent might comprise single individual plants stable for a certain trait)\textsuperscript{150}.

Nevertheless we notice that, even though the text itself of the UPOV 1991 Convention remains silent on the matter, many national plant-variety protection systems do include hybrid plants within the definition of ‘plant variety’. Indeed, such inclusions are found, \textit{inter alia}, in Europe’s Community Plant Variety Protection Regulation\textsuperscript{151} and in Australia’s Plant Breeder’s Rights Act\textsuperscript{152}.

Furthermore, this seems again to be based on a true UPOV eligibility assessment and not merely on the UPOV definition.

Finally, it is clear that even though hybrid plants are the result of a biological process, they are nevertheless patentable, as the exclusion from patentability of essentially biological processes applies only to processes and not to the products thereof.

2.2.4.2.5 Essentially Derived Varieties

In several EPO cases it has been argued that even though the invention in question was not technically confined to a certain variety, it could nevertheless be considered to be

\textsuperscript{149} Cf. http://en.wikipedia.org/wiki/Hybrid#Hybrid_plants


directed to an ‘essentially derived’ variety, in the sense of Article 13 of Regulation 2100/94/EC\textsuperscript{153}. In Phosphinothricin-Resistenzgen/BAYER, for instance, this was presented as a secondary argument: besides being an invention that was directed to a plant variety, the invention was said also to have been directed to an essentially derived variety, as it was shown that the plants as claimed in the patent were derived from only \textit{one} plant variety which was altered by only \textit{one} characteristic (herbicide resistance). The Technical Board, however, refuted this argument as in their view the distinction made under UPOV plant variety protection systems between essentially derived and not essentially derived varieties was not relevant for patentability. The Novartis principles would hence apply without differentiation: as in the present case the claims did not individually claim a plant variety (neither was the technical feasibility of the invention confined to a particular plant variety) neither would the claims \textit{a fortiori} individually claim essentially derived plant varieties\textsuperscript{154}. Accordingly the Technical Board refused to address this question to the Enlarged Board of Appeal.

Later, in \textit{Herbicide Resistant Plants/MONSANTO}, the argument resurfaced that the introduction of a gene coding for herbicide tolerance in the genome of a plant in a way that brings a stable transmission of these characteristics to the next generations, making the claims \textit{in casu} directed to ‘essentially derived varieties’\textsuperscript{155}. The Technical Board of Appeal, however, referred to the \textit{Phosphinothricin-Resistenzgen/BAYER} case\textsuperscript{156} discussed above, and subsequently refused to refer the question to the Enlarged Board of Appeal\textsuperscript{157}.

\textsuperscript{153} Article 13 § 6 Regulation 2100/94/EC reads: “For the purposes of paragraph 5 (a), a variety shall be deemed to be essentially derived from another variety, referred to hereinafter as ‘the initial variety’ when:
(a) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety;
(b) it is distinct in accordance with the provisions of Article 7 from the initial variety; and
(c) except for the differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of the characteristics that results from the genotype or combination of genotypes of the initial variety.”


\textsuperscript{155} Technical Board of Appeal of the European Patent Office, Herbicide Resistant Plants/MONSANTO, 6 April 2005, T 179/01, Summary of Facts and Submissions X.

\textsuperscript{156} Technical Board of Appeal of the European Patent Office, Herbicide Resistant Plants/MONSANTO, 6 April 2005, T 179/01, § 9.

\textsuperscript{157} These questions read, in German: “Sind Pflanzen patentierbar, wenn die beanspruchte
2.2.4.2.6 Heterozygous versus Homozygous Plants

In defining whether or not a patent claim is directed to a plant variety, the distinction between heterozygous and homozygous plants can be of importance. Indeed, as only when homozygosity is provided, a certain generation as a crossing result can be reproduced repeatedly\textsuperscript{158}, when one of the parent plants used as a source for production process is heterozygous with respect to a certain trait and thus will never breed through, the plants or seeds derived therefrom will not be stable in their characteristics and thus will not fall under the definition of a plant variety\textsuperscript{159}.

This will be the case for hybrid plants and seeds which are not aimed to be stable. Even though the totality of the hybrid generation claimed in a patent may comprise single individual plants stable for a certain trait, this would not contradict with the non-stability of the population taken as a whole, the Technical Board said in \textit{Lubrizol}\textsuperscript{160}.

Again, this also brings us back to the question whether one should use the UPOV criteria of protection to define a plant variety, or stick to the UPOV definition.

2.2.5 The Role of the Production Process in Obtaining Patents on Plant Varieties

Whether or not a plant variety has been produced by a microbiological, biological or technical (genetic-) process might have an influence on the patentability of the variety as a product. Indeed, the question has arisen on many occasions as to whether or not a plant variety has been produced by genetic engineering is relevant to its patentability.


On the other side the patenting of the process itself might also have an influence on the patent protection of a plant variety. Indeed, the European Patent Convention rules in Article 64 § 2 that when a patent is granted for a process, the protection thereof will extend to the directly derived products of that process.\(^{161}\) Under Directive 98/44/EC, this principle has explicitly been recognised as being applicable to biological material.\(^{162}\)

Now, what if the outcome of such a process is to be a plant variety that is excluded as such under Article 52 (b) EPC?\(^{163}\) What if the product of a microbiological process, patentable under Article 52 (b) EPC, is a plant variety?

2.2.5.1 The Directly Derived Products of a Patentable Process

The relationship between Article 64 § 2 EPC and Article 52 (b) EPC was thoroughly discussed for the last time in the 1999 Novartis case. Here, the Enlarged Board of Appeal concluded that when a claim to a process for the production of a plant variety is examined, Article 64 § 2 EPC is not to be taken into consideration.\(^{164}\) In motivating this decision, the Enlarged Board of Appeal said that even if the directly derived products are not patentable \emph{per se}, the protection conferred by the process patent might still extend to it because, because a product claim may encompass plant varieties, there is only ‘little room’ left to exclude a process claim from doing so.\(^{165}\)

Even though the Novartis case overruled the principles on the patentability of plant varieties, as set out in Plant Genetic Systems, the outcome concerning directly derived products of a patentable process was similar. Indeed, the Technical Board of Appeal

\(^{161}\) Article 64 § 2 EPC.

\(^{162}\) Article 8 § 2 Directive 98/44/EC: „The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.”

\(^{163}\) Article 52 (b) EPC: “plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof”; Article 4 § 1 (a) Directive 98/44/EC: “Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.”


ruled in the Plant Genetic Systems case that: by virtue of Article 64 § 2 EPC, the protection conferred by a European Patent to a process extends also to the product (e.g. plants) directly obtained by such a process.\textsuperscript{566}

Plant varieties that are the result of a non-essentially biological process that is patentable, and each of the following generation of plants that possesses the same characteristics,\textsuperscript{567} will thus be patentable.\textsuperscript{568}

2.2.5.2 Products of a Microbiological Process

On the issue of plant varieties being the product of a microbiological process (patentable under Article 53 (b) of the EPC), there has been protracted discussion as to how this would relate to the exclusion of plant varieties from patentability. In Plant Genetic Systems, it was for instance suggested that if a plant variety could have been the outcome of a microbiological process, this would have been patentable, whereas a few years later the Board ruling in Novartis rejected this view.\textsuperscript{569} Today however, the European Patent Convention, as amended by Rule 23 (c) (c) to the EPC, explicitly...


\textsuperscript{567} See Article 8 § 2 Directive 98/44/EC.


\textsuperscript{569} In 1995 the Technical Board said in Plant Genetic Systems that technical processes for producing a plant including a microbiological step may not be equated with microbiological processes and that consequently the result of such a process cannot be defined as a product of a microbiological process within the meaning of Article 53(b) EPC. The fact that the legislator referred to ‘microbiological processes’ and not to ‘essentially microbiological processes’ is said having indicated historically that he did not intend to include such technical processes. As the claimed plant varieties were the result of such a process, they were not considered patentable “as a product of microbiological processes”, even though an initial microbiological process step was admitted having had a decisive impact on the final result. (Today this is no longer relevant, as Rule 23 (c) (c) to the EPC now explicitly declares microbiological or other technical processes or products obtained by means of such a process patentable. This was not the case at the time of Plant Genetic Systems). Subsequently, in the 1999 Novartis case, it was said by the Technical Board of Appeal that as the legislator, at the time the EPC was drafted, could not conceive that plant varieties could be obtained with the help of techniques including microbiological steps and therefore couldn’t have intended protected plant varieties as products of micro-biological processes, but that nevertheless, the purpose was mainly to avoid dual protection, no matter how the plant variety was produced. Consequently, genetically engineered varieties were said covered by the prohibition on granting patents for plant varieties under Article 53(b) EPC even if the variety should in some sense be considered the product of a microbiological process. This was confirmed by the Enlarged Board of Appeal, thereby answering negatively to the question whether genetically engineering a plant can be generally considered to be a microbiological process.
provides that microbiological or other technical processes or products obtained by means of such a process are patentable, other than a plant or animal variety\textsuperscript{170}.

2.2.5.3 Products of Genetic Engineering

In Europe, whether or not the plant variety was obtained by genetic engineering does not have a bearing on its patentability. Recital 32 of Directive 98/44/EC (saying that if an invention consists only of genetically modifying a particular plant variety, and if a new plant variety is bred it will still be excluded from patentability, even if the genetic modification is the result not of an essentially biological process but of a biotechnological process) has now been incorporated in the EPC by its Rule 23 (c) (c) which provides, as mentioned above, that microbiological or other technical processes or products obtained by means of such a process, other than a plant or animal variety are actually patentable.

Prior to this, the matter had been discussed in the Novartis case. Here, the teleological argument was made that the legislator of the EPC at the time of the enactment could not have had in mind genetically engineered plants, and that the exclusion would therefore apply only to plant varieties made by biological processes. The Technical Board, however, refuted this argument by saying that the main rationale for the exclusion was the avoidance of overlaps with the UPOV system and that this had not changed at the time of speaking. Furthermore, this line of thinking would create discrimination between plants made by traditional breeding methods and plants produced by genetic engineering; a distinction that is not made in PVR rights either. Consequently, the exception to patentability in Article 53 (b), first half sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduces into an ancestral plant by recombinant gene technology are excluded from patentability.\textsuperscript{171}

\textsuperscript{170} Rule 23 (c), (c) EPC.

In *Australia*, in this context, it was explicitly stated in Section 6 of the 1994 PVR Act that *an organism may be treated as constituting a plant grouping within a single botanical taxon (in other words as a plant variety)* despite the fact that the genome of the plants in that plant grouping has been altered by the introduction of genetic material that is not from plants\(^{172}\).

### 2.2.6 An Intrinsic Approach

As a reaction to this technical debate, it has been argued in literature that instead of investigating, and arguing about, the meaning and scope of the phrase ‘plant variety’, a more intrinsic approach might be preferable\(^ {173}\). For plant biotechnological inventions, it was argued that as there would be no justification for the ‘product of nature’ doctrine, no justification to argue the lack of industrial application, no justification for non-novelty, non-inventiveness or impossibility of description, there would then remain no valid objections on which to deny patent protection for plant-based genetic inventions\(^ {174}\).

### 2.2.7 Conclusion

In conclusion, in Europe\(^ {175}\) today, the rule established in *Plant Genetic System* that patent claims may *not embrace* plant varieties no longer stands\(^ {176}\), as four years later in *Novartis* it was decided that plants can be patented as long as plant varieties are *not individually claimed*. Thus, a patent claim that is *not* limited to a specific plant variety, even though it

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\(^{175}\) Including Iceland and Switzerland, but without Norway (none of these countries is a member of the European Union, but Switzerland and Iceland are members of the European Patent Office). Moreover, according to a WTO 2003 review, Romania has exactly the opposite approach (WTO Council for Trade-Related Aspects of Intellectual Property Rights, Review of the Provisions of Article 27.3 (b), 18 February 2003, IP/C/W/273/Rev.1., p. 7).

may be limited to a *group* of plants where the group is defined through reference to a shared characteristic such as incorporation of a particular gene, will be eligible to be patented\textsuperscript{177}. In other words, broad-based patent claims are more likely than narrow ones to see themselves realised.

In Canada and Norway\textsuperscript{178}, however, patents on plants will be refused whether or not plant varieties are individually claimed\textsuperscript{179}. In the United States, Australia, Hungary\textsuperscript{180}, Japan, Korea, New Zealand and Zambia, the opposite will however be true\textsuperscript{181}.

### 2.3 Sexually versus Asexually Reproduced Plants

#### 2.3.1 Introduction

In the United States, as a result of not being regarded as amenable to written description\textsuperscript{182}, plants were not held to be patentable until the 1930s **Plant Patent Act**\textsuperscript{183}, whereby, however, only *asexually* reproduced plant *varieties* were held to be patentable\textsuperscript{184}. This Plant Patent Act utilises different criteria for patentability, weaker ones than those governing the general US utility patent. However, the scope of protection granted by plant patents is very similar to that of the classical patent. Indeed,


\textsuperscript{178} Norway neither a member of the European Union, nor of the European Patent Office and is consequently not bound by neither the Directive 98/44/EC, nor by Rules 23b to 23e to the EPC.


\textsuperscript{180} In the said WTO document (WTO Council for Trade-Related Aspects of Intellectual Property Rights, *Review of the Provisions of Article 27.3 (b)*, 18 February 2003, IP/C/W/273/Rev.1., p. 6.) Hungary is mentioned as belonging to the group of countries where patents are also granted for claims expressly limited to a plant variety. However, as Hungary is a member of the EPO, one wonders how this can be compliant with Rules 23b to 23e to the EPC and with the established EPO jurisprudence of, among others, the Novartis case.


\textsuperscript{184} NB: even though the word ‘variety’ has been used, it does not seem that the US legislator wanted to make a similar distinction as rules under the European Patent Convention. In 1930, there was no UPOV/PVR system in the United States. The term ‘variety’ was probably used as a synonimous for ‘plant’.
the Plant Patent Act merely requires that the applicant shall ‘invent’ or ‘discover’ (1) a new and distinct variety of asexually reproduced plants(185), which shall only be described “as complete as is reasonably possible(186)”. Once a patent is granted, the patent holder will be able to exclude others from asexually reproducing, from using, and from offering for sale or selling the plant so reproduced (or any parts thereof) in the United States(187 188).

On the other hand, sexually reproduced(189), or tuber propagated(190) plant varieties (other than fungi or bacteria), excluded from the Plant Patent Act were protected only in 1970 by the Plant Variety Protection Act(191). For the purpose of this act, the traditional UPOV criteria of novelty, stability, distinctiveness and uniformity apply as requirements(192).

As a result of the impact of Chakrabarty(193), protection for both asexually and sexually reproduced plant varieties became possible under the general Utility Patent Act(194). USPTO decided in Ex Parte Hibberd in 1985 that after Chakrabarty there was no reason to

185 “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, may obtain a patent therefore, subject to the conditions and requirements of this title.” (35 USC 161)
186 35 USC 162.
187 “In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced.” (35 USC 163)
188 See J.L. JETER, Agricultural Biotechnology: US Policy Regarding Patent Applications, 2 Oklahoma Journal of Law & Technology 20 (2004), footnote 7: “See 35 U.S.C. §§ 161-164 (2000); see also Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347, 1377 (5th Cir. 1976) (“novelty” refers to newness in its conception); Jacobson Bros., Inc. v. United States, 512 F.2d 1065, 1068 (1975) (“non-obviousness” is a prerequisite of any patent and simply requires that the creation or improvement not be obvious at the time the invention was made); Yoder, 537 F.2d at 1379 (“We think that the most promising approach toward the obviousness requirement for plant patents is reference to the underlying constitutional standard that it codifies namely, invention”); In re Greer, 484 F.2d 488, 490-91 (Cust. & Pat. App. 1973) (the U.S. Court of Customs and Patent Appeals has interpreted the description provision “as complete as is reasonably possible” to mean that there is no requirement for a “how-to-make” disclosure in a plant patent application); Ex parte Solomons, 201 U.S.P.Q. (BNA) 42 (1978) (the less strict description requirement is due to the impossibility of producing the patented plant from a description, because it must be asexually reproduced).”
189 Whereby this includes: “...any production of a variety by seed, but does not include the production of a variety by tuber propagation.” (7 USC 2401 (6)).
190 Whereby this term means: „propagated by a tuber or a part of a tuber.” (7 USC 2041 (7)).
192 7 USC 2402.
194 35 USC 101.
exclude this possibility, as neither the Plant Patent Act nor the Plant Variety Protection Act was narrowing the scope of what is otherwise patentable. In 2001, this was confirmed by the US Supreme Court in the *Pioneer Hi-Bred* case. Consequently, plants can today be protected in the United States under the Plant Patent Act, the Plant Variety Protection Act and the general Utility Patent Act.

The interrelation of these systems provides important empirical material about the utility and the practical application of dual protection between patents and PVRs. It has been said in this context that empirical material shows that that plant variety rights fall into disuse when patents are available. However, in *Pioneer Hi-Bred*, it was said that since 1985 over 5,000 PVP certificates had been issued, whereas only 1,800 Utility Patents for plants had been granted. Further, questions arise as to how the PVR exceptions of ‘breeder’s rights’ and ‘farmer’s privilege’ can be applied on UPOV-protected plants that will also be patented. Finally, the question remains as to how the Plant Patent Act and Utility Patent Act interrelate.

Finally, it must be said that the United States is not the only country making a distinction between sexually and asexually reproduced plants. South Korea, for instance, holds only asexually reproduced plants as patentable.

### 2.3.2 Rationale

The rationale of protecting only asexually reproduced plants in 1930 seems to have been generated by a combined set of issues relating to politics and amenability to

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disclosure\textsuperscript{200}. Furthermore, in 1930, the United States Congress was said to be of the idea that sexual reproduction did not permit the stable maintenance of desirable bred characteristics. Moreover, in the 1920s farmers received seeds from the US government’s Free Seed Program. Thus the need for protecting seeds was not acute, as there was hardly any market for it.

2.3.3 Definition

Traditionally, \textit{asexual} reproduction takes place through grafting, budding or similar. It produces offspring with a genetic combination that is identical to that of the single parent, so the offspring could be termed a clone\textsuperscript{201}.

On the other hand, \textit{sexual} reproduction is approximately defined as reproduction by seed.

2.4 Plants versus Micro-organisms

2.4.1 Introduction

The TRIPs Agreement allows WTO member states to exclude from patent protection plants \textit{other than micro-organisms} as well as essentially biological processes for the production of plants \textit{other than microbiological ones}\textsuperscript{202}. The same is true under the NAFTA agreement\textsuperscript{203}. In Europe, plant varieties and essentially biological processes for the production of plants will not be patentable, \textit{except for microbiological processes and the products thereof}\textsuperscript{204}. In all these systems micro-organisms must thus be patentable\textsuperscript{205}. Also, microbiological products conceived by traditional fermentation or biotransformation


\textsuperscript{202} Article 27 § 3 (b) TRIPs Agreement.

\textsuperscript{203} Article 1709 § 3 (c) of the North American Free Trade Agreement.

\textsuperscript{204} Article 53 (b) EPC. See identically: Article 4 § 1 (a) & (b) Directive 98/44/EC.

processes, as well as those manipulated by genetic engineering, will be patentable\textsuperscript{206}. Specifically, the disclosure requirement has been adapted to micro-organisms by internationally allowing the deposit as a sufficient disclosure for patent purposes in the Bupadest treaty\textsuperscript{207}.

Due to the similarity of these provisions, the degree of harmonisation of patentability of micro-organisms is very high. Indeed, micro-organisms will be patentable in the Andean Community\textsuperscript{208}, Europe\textsuperscript{209}, the United States, Canada, Australia, New Zealand, Japan, Korea, Hong Kong, Thailand, South Africa and Zambia\textsuperscript{210}.

2.4.2 Definition & Interpretation

Generally, micro-organisms (or ‘microscopic’ organisms) are described as being organisms invisible to the naked eye; subject to microbiology\textsuperscript{211}. Bacteria\textsuperscript{212}, viruses\textsuperscript{213}, cells\textsuperscript{214} and archaea\textsuperscript{215} are the most frequently cited examples of micro-organisms. In patent law, however, no definition of this term exists.

In European patent law\textsuperscript{216}, microbiological \textit{processes} shall mean any process involving, or performed upon, or resulting in, microbiological material\textsuperscript{217}. The products \textit{thereof} will be


\textsuperscript{208} Article 20 of the Andean Community’ Decision 486: “The following shall not be patentable……(c) Plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes” (emphasizes added).

\textsuperscript{209} Including Switzerland, Bulgaria, Iceland, Romania, Hungary and Norway.


\textsuperscript{211} See: http://en.wikipedia.org/wiki/Micro_organism.

\textsuperscript{212} See: http://en.wikipedia.org/wiki/Bacteria.


understood as encompassing products which are made or modified by microorganisms, as well as new micro-organisms as such. The term micro-organisms will include plasmids, viruses and all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Among others, cells derived from multicellular plants and their culture, human and animal cells, cell lines, fungi, algae, viruses, plasmids and protozoa will thus be patentable.

Indeed, plant cells do not fall under the definition of plants or plant varieties, but are instead considered to be microbiological products in the broad sense.

In Canada for instance, even though plants were explicitly characterized as a subset of higher life forms in Harvard College and thus held not patentable, in the later Monsanto case genes and cells contained in a glyphosate-resistant plant were not considered to fall under the exclusion of ‘higher life forms’, but were simply specified as “a gene and cell contained within a higher life form”, which itself was not claimed.

217 Rule 23 (b) (6) to the EPC.
220 For instance in Plant Genetic Systems, the following claim was declared patentable: “Plant cells, non biologically transformed, which possess a heterologous DNA stably integrated in their genome, said heterologous DNA containing a foreign nucleotide sequence encoding a protein having a non-variety specific enzymatic activity capable of neutralizing or inactivating a glutamine synthetase inhibitor under the control of a promoter recognized by the polymerases of said plant cells.” (Technical Board of Appeal of the European Patent Office, Plant cells/PLANT GENETIC SYSTEMS, 21 February 1995, T 356/93, Official Journal of the European Patent Office 1995, 545, § 1).
224 Supreme Court of Canada, Monsanto Canada v. Schmeiser, 21 May 2004, 1 Supreme Court Reports (Canada) 902 (2004). Again 5 to 4 majority.
225 G. LAW and J. MARLES, Monsanto v. Schmeiser. Patent Protection for Genetically Modified Genes and Cells in Canada, 13 Health Law Review 44 (2005), p. 46: “Many perceive the majority decision in Monsanto to be inconsistent with the Supreme Court of Canada’s holding in Harvard Mouse. However, the majority in Monsanto argue that their decision is, in fact, consistent with Harvard Mouse, noting that the gene and cell claims in
Nevertheless, in EPO’s *Plant Genetic Systems*, a claim directed to *plant cells* which are *contained in a plant*, was refused on the ground of non-patentability of plant varieties, because such cells are differentiated, and morphologically and functionally organized to constitute a plant, and consequently the scope did not exclude plant varieties. With the actual ‘Novartis’ principles, however, this consideration is no longer the accepted standard, as today claims directed to plants will be patentable as long as plant varieties are not individually claimed, even though they may encompass plant varieties.

Furthermore, there has been much discussion in Europe as to precisely what will constitute a microbiological process and what will not. In 1995 the Technical Board said in *Plant Genetic Systems* that technical processes for producing a plant *including a microbiological step* may not be equated with microbiological processes, and that consequently the result of such a process cannot be defined as a product of a microbiological process within the meaning of Article 53(b) EPC. The fact that the legislator referred to ‘microbiological processes’ and not to ‘essentially microbiological processes’ is said having indicated historically that he did not intend to include such technical processes. As the claimed plants were the result of such a process, they were not considered patentable “as a product of microbiological processes”, even though it was admitted that an initial microbiological process step had had a decisive impact on the final result. However, here again, this reasoning would no longer have a legal effect today, as Rule 23 (c) (c) to the EPC now explicitly declares patentable

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* Monsanto’s glyphosate-resistant plant patent are analogous to the plasmid and somatic cell culture claims which had been allowed by the Commissioner of Patents in Harvard’s patent for a genetically modified “oncomouse”. It was only the claim for the “oncomouse” itself, as a higher life form, which was denied, and Monsanto did not claim modified plants in its patent. Notably, both the majority and minority in Monsanto agree that the claims in Monsanto’s patent are valid.”

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microbiological or other technical processes, or products obtained by means of such a process.

2.5 Naturally Occurring Substances versus Isolated Substances ‘As They Occur in Nature’

2.5.1 Introduction

One of the basic principles of patenting biotechnology in most patent systems is that biological material is not patentable as it occurs in nature\(^2\), but that it becomes patentable once it has been isolated from its natural environment, even though the substance had previously occurred in nature and even though it might remain identical to the one occurring in nature\(^2\).

2.5.2 Rationale

Many grounds have been brought forward to substructure this distinction. Most frequently cited rationale of excluding the patenting of materials ‘found in nature’ is that they would not constitute an ‘invention’ for the purpose of patent law, but only a mere, and unpatentable, discovery\(^2\). Furthermore, lack of novelty\(^2\) and lack of inventiveness\(^2\) have been raised here.

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\(^2\) In this sense USPTO held in its notice on animal patentability: “The Board’s decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 USC 101 or 102. An article or manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article” (United States Patent and Trademark Office, Notice: Animals-Patentability, 1077 Official Gazette of the United States Patent & Trademark Office 8, 21 April 1987.).

\(^2\) See Article 3 § 2 of Directive 98/44/EC. “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.” and the quite identical Rule 23 (c) (a) to the EPC: “Biotechnological inventions shall also be patentable if they concern: (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature”.

\(^2\) See for instance: United States Supreme Court, Funk Brothers Seed Co. versus Kalo inoculant Co, 333 US 127, 76 USPQ 280 (1948): “An unknown compound or composition of material merely discovered from nature in not patentable.” See also the statement of Hong Kong in: WTO Council for Trade-Related Aspects of Intellectual Property Rights, Review of the Provisions of Article 27.3 (b), 18 February 2003, IP/C/W/273/Rev.1., p. 28: “It is probably the case that the finding of a new substance or micro-organism occurring freely in nature is a discovery.”. Furthermore, the statement of Japan in that same document on p. 28: “An invention is required to be creation under the Japanese Patent Law. In this connection, mere discoveries, including materials existing in nature or natural phenomena, where no creation of technical ideas is
On the other side, the rationale of including ‘isolated’ biological materials in the patent system seems to be that by the very fact of the isolation the discovery turns into a potentially patentable invention. Indeed, it has been accepted quite widely throughout the patent offices that once a biological material has been isolated from its natural environment, the substance no longer can be considered as a discovery, but instead becomes an invention, as the material does not occur in nature ‘in that state’. The same is true for substances identical to the ones in nature but produced by means of a technical process.236

Generally, the idea constitutes a practical application of the general principle that a discovery would be mere knowledge about something existing in nature, whereas an invention implies the ability of a human being to apply this knowledge in a technical way: the “technical teaching” theory versus the “product of nature” doctrine, or the doctrine of “knowledge” versus “applied knowledge”. In Chakrabarty, earlier, it was said by the US Supreme Court that the relevant distinction was not between living and inanimate things, but between products of nature – whether living or not – and human-made inventions. Similarly, the German Federal Patent Court held, in the

made purposefully, do not fall under inventions. Therefore, it is impossible to obtain a patent which claims materials existing in nature or natural phenomena.”. Moreover, South Africa on page 29: “Although this aspect is not covered specifically, the Act states that anything which consists of a discovery shall not be an invention for the purposes of this Act.” Finally, the Statement of the Slovak Republic on page 29: “Because mere discoveries, including materials existing in nature, do not meet all mentioned criteria, they are not patentable.”.


236 Cf. Rule 23 (c) (a) to the EPC and Article 3 § 2 Directive 98/44/EC.


239 See on the doctrine of living organisms not being patentable because of their special nature: United States Board of Patent Appeals, In re Bergy, 563 F. 2d 1031, 195 USPQ 344.

Cyclisches Dekapeptid Antamanid case, that naturally occurring micro-organisms cannot be patent-protected unless the inventor demonstrates a reproducible method whereby naturally occurring micro-organisms may be reproduced by human means\textsuperscript{241}.

2.5.3 Interpretation

The borderline between biological material found in nature and the one identical to material in nature but isolated from its natural environment may sometimes be very narrow. In Australia, for instance, if there has been any technical intervention of man to change the form of the product from that in which it existed in nature, the product would be patentable, provided it meets the requirements of patentability\textsuperscript{242}.

The question arises here as to whether the isolated biological material still meets the requirement of inventiveness if the isolation has been executed by a known process. Countries such as Switzerland therefore require both the substance and the process for its isolation to be new\textsuperscript{243}. Thus, here, if a naturally occurring substance is isolated for the first time, and will thus be considered novel, it will not be patentable for being obvious if its isolation has taken place by a known process.

One example of a biological material that sits on the fence of this distinction is nucleotide sequences. Nucleotide (or DNA- or gene) sequences evidently occur in nature, in every living organism, but they are not ‘living’ organisms themselves, and they do not occur in isolation in nature. Consequently, they will be patentable, even without there being any DNA recombination, provided that one has attributed a function to the given sequence\textsuperscript{244}.

\textsuperscript{241} Bundespatentgericht, Cyclisches Dekapeptid Antamanid, 28 July 1977, GRUR 238 (1978).


\textsuperscript{244} This will be the case in most legal systems around the globe. Basically, gene sequences will be treated as chemical compounds in the European Patent Office. This brings along their patentability provided that one has isolated them for the first time together with the discovery of one of their functions. (Cf. so called ‘Stoffpatente’ and the German Federal Court ‘insulin’-case). Discussion however subsists as to the extent to which nucleic sequences might be patentable. In the United States for instance, a practical burden
There is in patent law no systematic equation between plant gene sequences on the one hand and plants or plant varieties as such on the other. For instance, whereas Canada excludes plants from patentability\(^{245}\), genes contained in a glyphosate-resistant plant have nevertheless been said to be patentable\(^{246}\). Similarly, even though in Europe ‘plant varieties’ are excluded from patentability, nucleotide sequences are currently patentable. In EPO’s 2005 *Monsanto* case for example, a claim to an isolated nucleotide sequence encoding a certain enzyme\(^{247}\) and one other to an isolated nucleotide sequence exists in the strongness of the inventiveness requirement. Indeed, it will not always be possible to demonstrate that a process of isolation of a gene sequence has not started with ‘reasonable expectation of success’ (See: S. MERRILL, R. LEVIN, and M. MYERS (Eds.), *A Patent System for the 21st Century*, Washington, National Academies Press, 2004, p. 6.). This is probably becoming a global problem as with the so called ‘automatisation’ of genetic decoding, inventiveness is no longer evident. Is a newly isolated genetic sequences patentable if isolated by a known or obvious process? Here, a basic question raises as to whether patents in biotechnology should be considered as mere investment measures without thus requiring a real invention or a real inventiveness. Furthermore, some patent systems have implemented (whereas others (eg Switzerland) are currently discussing) the limitation of the scope of protection of gene sequence patents to the industrial application as disclosed (See: S. BOSTIJN, *Patenting DNA sequences (polynucleotides) and Scope of Protection in the European Union: an Evaluation*, Background Study for The European Commission, Office for Official Publications of the European Communities, 2004, pp. 62–65). Finally, discussion persists whether or not the mere isolation of such a sequences is sufficient to alter the discovery into an invention and practical questions arise in the area of partial gene sequences (eg SNPs and ESTs) concerning their industrial application and overlapping (See: S. BOSTIJN, *Patenting DNA sequences (polynucleotides) and Scope of Protection in the European Union: an Evaluation*, Background Study for The European Commission, Office for Official Publications of the European Communities, 2004, pp. 40–43 (invention v. discovery) and pp. 51–53 (partial gene sequences). A different approach has been proposed here by Phillipe Jacobs and Geertrui van Overwalle consisting in no longer granting patents on the gene sequences themselves, but only for the medicinal products, new vaccines or other products that are developed on basis of DNA. This approach would end the discussion on whether gene sequences are (as they are today) to be considered as mere chemical compounds, or whether these are something more than chemical substances as they touch upon life and evolution. It would also imply de facto purpose bound protection (See: G. VAN OVERWALLE and P. JACOBS, *Opinion: Gene Patents A Different Approach*, European Intellectual Property Review (2001), 505–506).

\(^{245}\) Supreme Court of Canada, *Harvard College v. Canada (Commissioner of Patents)*, 5 December 2002, 4 Supreme Court Reports (Canada) 45 (2002), § B (4).

\(^{246}\) Supreme Court of Canada, *Monsanto Canada v. Schmeiser*, 21 May 2004, 1 Supreme Court Reports (Canada) 902 (2004). However, in their dissenting opinion, four judges held this distinction without meaning. Indeed, it is argued in doctrine that as ‘possession’ of a plant containing a patented gene constitutes a ‘use’ thereof and thus infringement of the patent, the reasoning of Canadian Supreme Court does not make much sense (Cf. J. DE BEER, *Reconciling Property Rights in Plants*, 8 The Journal of World Intellectual Property 10 (January 2005).

\(^{247}\) “An isolated DNA sequence encoding a Class II EPSPS enzyme, said enzyme being an EPSPS enzyme having a Km for phosphoenolpyruvate (PEP) between 1-150µM and a K(glyphosate)/Km(PEP) ratio between 3-500, which enzyme is capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID No:3 and SEQ ID No:5.” (Technical Board of Appeal of the European Patent Office, *Herbicide Resistant Plants/MONSANTO*, 6 April 2005, T 179/01, Submission and Facts § VII)
encoding a certain protein was accepted as readily as a recombinant DNA sequence comprising a heterologous promoter which functions in plant cells.

Not all countries have however agreed upon patenting biological material when isolated from its natural environment. Thailand for instance, does not accept patent claims on plants, nor on extracts of plants, and will consequently exclude modified as well as naturally existing plants from patent protection.

Finally, in the United States, whereas subject matter indistinguishable from the form in which it is found in nature is said to be not patentable, an isolated and/or purified composition containing naturally occurring subject matter that exhibits new or unexpected properties will nevertheless be patentable.

3 Patents on Plants and the ‘Ordre Public and Morality’

Under the TRIPS Agreement, WTO member states “may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

Very similar provisions are to be found in the NAFTA, in the European Patent Convention and in Directive 98/44/EC. One difference remains extant, however,

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248 “An isolated DNA sequence encoding a protein which exhibits EPSPS activity where said protein is capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5.” (Technical Board of Appeal of the European Patent Office, Herbicide Resistant Plants/MONSANTO, 6 April 2005, T 179/01, Submission and Facts § VII)

249 See Section 9 § 1 of the Thailand Patent Act.


251 Article 27 § 2 TRIPS Agreement.

252 Article 1709 § 2 of the North American Free Trade Agreement (NAFTA): “A Party may exclude from patentability inventions if preventing in its territory the commercial exploitation of the inventions is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent.”
where the European provisions do not specify: *including to protect human, animal or plant life or health or to avoid serious prejudice to the environment*, as does the TRIPs Agreement. Specifically for biotechnological inventions, Recital 39 of the said Directive emphasizes the particular importance of this principle *in view of the potential scope of inventions in this field and their inherent relationship to living matter, whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention*. In this context, it is important also to note Rule 23 (b) § 1 of the EPC, stating that Directive 98/44/EC shall be used as a supplementary means of interpretation for the purpose of the European Patent Convention.

### 3.1 Ordre Public and Morality of Patenting Plants under the European Patent Convention

As mentioned, under Article 53 (a) of the EPC, European patents will not be granted for “inventions the publication or exploitation of which would be contrary to *ordre* public or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States”. *A contrario*, neither will the approval of the exploitation by national laws or regulations make the invention *per se* conform to morality or the *ordre public*.255

Here, a distinction must be made between the two concepts. Whereas the notion of ‘*ordre public*’ comprises the protection of security and physical integrity of individuals in a society, the concept of *morality* affects, for the purposes of the EPC, the belief of right and wrong in the culture inherent within European society. Morality will thus, *inter alia*,

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253 Article 53 (a) EPC: “inventions the publication or exploitation of which would be contrary to “ordre public” or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States”.

254 Article 6 § 1 Directive 98/44/EC: “Inventions shall be considered unpatentable where their commercial exploitation would be contrary to orden public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.” See also Recital 36 (reiterating the TRIPs principle) and Recital 37 of the Directive (stressing the principle for the purpose of the Directive and using the term ‘must’ where TRIPs says ‘may’).

involve the question of whether or not public opinion is opposed to a certain invention, and the *ordre public* will, encompass, among other concerns, environmental ones.\(^{256}\)

In the 1995 EPO *Plant Genetic Systems* decision, the Opposition Division replied to the opponents’ argument that patenting plant life forms in general is contrary to the morality and/or the *ordre public*, and that the European Patent Office was not the proper forum for discussing the pros and cons of genetically engineering plants. However, this general statement did not prevent the Opposition Division from investigating the matter and concluding that the invention in question (herbicide-resistant plants) did not contravene Article 53 (a) EPC. As a result, the Opposition Division set exacting criteria for an invention to be contrary to Article 53 (a) EPC. The claimed invention was specifically said to be not contrary to the *ordre public* and morality, because the invention “did not belong to that *extreme* category of inventions which could be regarded as so *abhorrent* to the vast majority of the public, as to render the granting of a patent *inconceivable*.”

At the Technical Board of Appeal, the appellants submitted that plant genetic resources were to be considered the ‘heritage of mankind’, and that the patenting thereof would go against the ‘availability without restriction’ and the ‘intact preservation’ of these resources for further generations. However, a Swiss opinion poll and a Swedish survey were presented in order to demonstrate that public opinion was against genetically engineered plants. Furthermore, environmental concerns were raised, supported by studies warning that the treated plants would themselves become weeds and that herbicide resistance would spread to other plants, so that ecosystems would be damaged.

In this case, the Technical Board initially bore in mind that exceptions to patentability, particularly in relation to plants and animals, must be construed narrowly.\(^{257}\) Hence,

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seeds and plants would not constitute an exception *per se* to patentability merely because they represent ‘living matter’ or because they should remain as ‘common heritage of mankind’. The Technical Board said that the issue should instead be settled by examining each case individually and deciding whether or not a particular living organism is to be considered contrary to the *ordre public* or morality.\(^{258}\)

With regard to the *ordre public*, the Technical Board established the principle that claimed subject matter that is likely to seriously prejudice the environment can and should be excluded from patentability for being contrary to the *ordre public*. Issues of biosafety and biodiversity immediately come to mind.\(^{260}\)

In substructuring its decision that the invention in question was not considered likely to seriously prejudice the environment, the Technical Board made a noteworthy statement on its actual role in the regulatory framework of plant patentability: *The board agrees with the appellants' submission that patent offices are placed at the crossroads between science and public policy. However, at this crossroads patent offices are not alone, but find themselves side-by-side with an increasing number of other authorities and bodies, in particular regulatory authorities and bodies, whose function is inter alia to ensure that the exploitation of a given technology, regardless of whether it is protected by a patent or not, takes place within the regulatory framework provided by laws, international treaties, administrative provisions, etc.*\(^{261}\)

However, the Technical Board said that the Patent Office finds itself in an unsatisfactory position, as, pending the decision on the grant of a patent, the results of scientific tests will normally not be available and the EPO has no authority to carry out tasks which should properly be the duty of a special regulatory authority constituted to that effect.\(^{262}\)

Therefore, for the purpose of Article 53 (a) EPC, the threat to the environment must be


sufficiently substantiated\textsuperscript{263}. Consequently, in the present case the Technical Board noted that the appellant’s arguments were based on the possibility that undesirable, destructive events might occur, and consequently did not consider the claimed invention as contrary to the \textit{ordre public}\textsuperscript{264}.

With regard to \textit{morality}\textsuperscript{265}, the strict criterion employed by the Opposition Division for anti-morality was dropped, and it was replaced by a criterion stipulating that invention that is contrary to the \textit{conventionally accepted standards of conduct of the European culture}\textsuperscript{266} may not be granted a patent. In this case, the survey among Swedish farmers and the Swiss opinion poll were not accepted as being decisive elements in assessing patentability with regard to Article 53 (a) EPC, it being considered that the respondents did not reflect the moral norms deeply rooted within European society, but were instead liable to unpredictable and short-term fluctuation of opinion, easily influenced – and, in the case of the farmers in particular, tending to reflect their interests only so far as their specific sector was concerned. Moreover, the named enquiries did not concern the actual invention in question, and hence were of only minor relevance in the analysis of individual cases. Finally, analogically to the provision stating that an invention shall not be deemed contrary to morality because of being prohibited under a national law, a national survey or opinion poll could not be a sufficient criterion\textsuperscript{267}.


\textsuperscript{265} Public morality has been discussed for the first time in relation to plant patentability in the EPO ‘Lubrizol Transgene Expression’-case. Here, the Opposition Division only held inventions contrary to the ‘ordre public’ or morality in extreme cases which are universally regarded as abhorrent. See: G. VAN OVERWALLE, \textit{Biotecnology patents Europe: from law to ethics}, in \textit{Biotechnology}, in STERCKX, S. (Eds.), Patents and Morality, Ashgate Publishing, Aldershot-Burlington-Singapore-Sydney, Second Edition, 2000, p. 200: “...the actual patent related to an invention which might be used for creating new plants, the nutritive value of which exceeds that of conventionally obtained plant, and the consideration that the plants covered by that patent might give rise to a better management of food shortage in the world, the Opposition Division ruled that the exploitation of such an invention cannot consequently be considered immoral or against public order and decided that a violation of art 53 (a) was not evident.”


Generally, the Technical Board established that plant biotechnology, like any other tool, can be used for constructive or destructive uses, and that it would be against morality if a misuse or destructive use of these techniques were to be proposed. The decisive criterion would be whether or not the invention in question would be directed to such a use. In the case under discussion here, it was consequently decided that the claimed techniques for the production of herbicide-resistant plants and seeds could be considered to be a misuse or destructive use of plant biotechnology.

Later, in 2004, the Technical Board had the opportunity to express itself again in the Phosphinothricin-Resistenzgen/BAYER case on issues of morality and ordre public. Here, the appellant argued that in making a distinction between discoveries and inventions there is an ethical frontier, in the sense that life forms cannot be said to be human inventions, nor to be subject of a monopoly right. To this, the Technical Board replied that given the criteria as set out in Plant Genetic Systems, a breach neither of morality nor of ordre public was found here. The Board hereby argued that by the promulgation of these techniques this could not be said to be a breach of morality.

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268 Interestingly, the Technical Board assessed plant biotechnology quite positively: “In this respect, it has to be considered that plant biotechnology is a technology which aims at accomplishing practical improvements or advances in the area of plants by using modern scientific knowledge. The development of this technology inevitably allows a better understanding and control of the natural phenomena linked to plants. However, in the board’s view, this does not render activities in this technical field intrinsically wrong. Indeed, in the board’s judgment, plant biotechnology per se 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. However, compared with traditional breeding techniques, genetic engineering techniques applied to plants allow a more powerful and accurate control of genetic modifications. Plant biotechnology allows punctual gene modifications as well as the introduction into a given plant of genetic material from unrelated species of plants and from organisms other than plants. These techniques are an important tool to assist in plant breeding, which enables the performance of manipulations that would simply not be feasible by means of traditional breeding techniques.” (Technical Board of Appeal of the European Patent Office, Plant cells/PLANT GENETIC SYSTEMS, 21 February 1995, T 356/93, Official Journal of the European Patent Office (1995) 545, § 17.1)


271 Technical Board of Appeal of the European Union, Phosphinothricin-Resistenzgen/BAYER, 15 June 2004, T 475/01, Facts and Submissions X.

272 See in the original German: „Zwar ist der Kammer nicht nur aus der von dem Beschwerdeführer eingereichten Entgegennahme (D5) bekannt, daß eine Ausweitung des Patentrechts auf (höhere) Lebewesen und deren Gene von vielen Bürgerinnen und Bürgern abgelehnt wird, diese Ablehnung ist jedoch nicht mit einem Verstoß gegen die öffentliche Ordnung und die guten Sitten im Sinne des Artikels 53 a) EPU gleichzusetzen (siehe in T 356/93 insbesondere den Punkt 15 der Entscheidungsgründe).“ (Technical Board of Appeal of the European Union, Phosphinothricin-Resistenzgen/BAYER, 15 June 2004, T 475/01, § 9.)
of Article 4 § 1 & 2 of Directive 98/44/EC together with Article 53 (b) and Rule 23 (c) (b) to the EPC (allowing plant genetic inventions to be patented provided that their technical feasibility is not confined to a particular plant variety) a consensus was reached, and made legally enforceable, that such patents are against neither morality nor the ordre public.\footnote{Technical Board of Appeal of the European Union, \textit{Phosphinothricin-Resistenzgen/BAYER}, 15 June 2004, TF 475/01, § 10 & 11.}

**Conclusion**

In comparing the situation in Europe, the United States and Canada, we observe several different approaches to patentability. Whereas in Europe it is plant varieties that have been excluded from patent protection, Canada excludes plants themselves from patentability and the United States excludes neither of these.

However, in the end, the scope of protection granted for plant-related inventions will be reasonably similar in all these patent systems. Indeed, plant cells and plant genes are patentable in Canada, and inventions related to plants ‘in general’ will be patentable in Europe. Bearing in mind the principle that patent protection for biological material expands to every material in which it will be contained, plant varieties apparently fall within the scope of protection of European patents anyway, just as plants ‘as such’ will end up patent-protected in Canada as well.

Consequently, the relevance of these distinctions is debatable. What is the relevance of excluding plant varieties from European patent protection if a plant variety containing a patented gene ends up being protected in any case? Similarly, in Canada, what is the relevance of excluding ‘plants’ but patenting plant cells and gene sequences?

We have seen that ethics and environmental concerns have not yet been accepted by the European Patent Office as a basis on which to refuse the granting of a patent, even though these arguments deeply pervade European public opinion. In relation to these concepts, there is a need to be objective: are there links to sustainable development?
Human rights? Might they be considered as the thin end of the wedge for normative systems outside the law?

Finally, it should be noted that the patent office is only one small part of the legal framework surrounding genetic-engineering inventions, and that the patent office might not, therefore, be the correct authority to deal with these issues. We must recall here, too, that a patent may not be equated with permission to use or commercialize an invention, but that it constitutes merely a negative right, i.e. that of excluding others from doing so.
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