

## Patentability of Plants: Technical and Legal Aspects

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According to Article 27.3(b) of the TRIPS Agreement, Members may exclude 'plants' from patentability, but they shall provide for the protection of 'plant varieties' either by patent or by an effective *sui generis* system or by any combination thereof. While this study focuses on the patentability of plants, alternative protection system (Breeder's right as a *sui generis* system) has not been ignored. There may be some overlap between these protection systems which need careful consideration. In view of the importance of the decision of countries to protect plant varieties, the study also gives an overview and assesses possibilities of the current patent laws and legal positions adopted by jurisprudence or doctrine particularly in the field of transgenic and hybrid plants.

**Keywords:** Plants, patent, breeder's right, plant variety, hybrid plants, transgenic plants

There has been a long practice of granting a patent protection for biotechnological inventions. In the United States and Europe, certain objections were raised against patentability of plants, resulting in particular, from the 'product of nature' doctrine<sup>1</sup> which considered the new plants as the fruits of nature's power.<sup>2</sup> In 1930, the United States took the initiative in patent protection for plants by introducing a bill in the Senate, proposing to discard doctrine of 'product of nature' and to make the legal condition of 'enablement'<sup>3</sup> more flexible. In this regard, American Plant Patent Act (PPA) of 1930 could be considered as the first legislation in which the field of patent applications has been developed for asexually propagated plants.<sup>4</sup> The other well-known system on this matter was in Germany<sup>5</sup>, where patents were granted for the plants on the basis of traditional patent rights in 1930.

Concerning the US position adopted on the matter, apart from PPA as a particular system of patent, in '*Hibberd*' decision<sup>6</sup> it was allowed that the plants can also constitute a patentable subject-matter under Article 35 USC 101 of Patent Act (PA) which relates to protection by US utility patent. Indeed, utility patents can consequently be granted in US for any new plant to whose creation man has contributed. Until 2002, 777 special plant patents and 222 utility patents in the field of plants were granted in US.<sup>7</sup>

In Europe also, certain efforts aimed at facilitating the patentability of plants by rejecting the doctrine of 'product of nature' were made. For example, in the judgement of French Court of First Instance (*GRASSE*) on 5 March 1963, it has been admitted that 'if the products of nature, mineral or vegetable, cannot be considered as an invention nor a discovery within the meaning of the 1st Article of the law of 5 July 1844, it is not the same for combination of first materials or utilization of certain natural phenomena for obtaining a new product. Because without human intervention, it would be inconceivable that such products can be realized by the forces of nature'.<sup>8</sup> Japan also followed US by encouraging patent protection for biotechnological inventions, particularly for plants. In fact, following deletion of exclusions related to patentability of plants in the Japanese patent examination guidelines, plants have become patentable in Japan since 1985.<sup>9</sup>

Generally, it is important to note that besides several granted patents in this field and recognized patentability of plant-related inventions, the patent rights application on this matter has not been always easy. In spite of general legal problems resulting from legislative adaptation of patent law to biotechnological inventions<sup>10</sup> including plants, more particularly other arguments based on the principal character of patent rights which excludes a priori the discoveries from patentable subject-matters, were raised against plant protection by patent rights. In

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other words, it is possible to reward inventor's creative and technical work by the patent, nevertheless, certain objections were raised on the fact that the patent does not make it possible for the breeders to obtain a monopoly on a variety which could be only discovered or exist without his intervention.<sup>11</sup>

These disadvantages led the breeders to present their arguments for elaborating a specific protection system which can be better adapted to their works.

The principles of an international protection were in particular drafted by the International Association of Plant Breeders for Protection of Plant Varieties (ASSINSEL).<sup>12</sup> Relevant negotiations succeeded when industrialized countries adopted 'International Convention for the Protection of New Varieties of Plants' in Paris in 1961, which resulted in the formation of International Union for the Protection of New Varieties of Plants (UPOV) in 1978.<sup>11</sup> This Convention did not oblige any country to modify its national legislations. Nonetheless, it has also been able to remove the obstacles to patentability of plants.

In order to specify and clarify main legal interaction between patent and plant variety rights which could particularly arise from the patent exclusion for plant varieties, this study is focused, in the first section, on the legal and technical evaluation of 'plant varieties' concept. The second section is dedicated to the patentability of plant products, in particular to the transgenic and hybrid plants. This section aims at evaluating possibility of obtaining patent protection for plants with regards to the relevant exclusion from patentability and positions adopted by the European and non-European jurisprudences and legislations. The last section considers relationship between patent and plant breeders' rights based on the international IPR agreements and the bilateral/regional treaties. This section also explores and analyses differences and overlaps between both the forms of protection from different perspectives particularly those relating to the patent exclusion for plant varieties.

### **Plant Variety: A Concept Based on the Taxonomic and Biological Characteristics**

Although the concept of 'plant variety' can be a priori important in the plant breeder's rights as a principal subject-matter of protection, evaluation of this concept is essential in the same way in the patent rights as a subject-matter excluded from protection, in particular under some national patent laws. Certainly,

in cases in which 'plant variety' is not the subject of an exclusion within the patentable subject-matters, evaluation of this concept would be also important, in particular for any possible interaction which could occur in this field between patent rights and plant breeder's rights. The reflexion already done by jurisprudence and doctrines on the possibility of 'double protection' of plants by the above-mentioned rights, can affirm this fact.<sup>13</sup>

The concept of 'plant variety' was not defined in UPOV, 1961. In its Article 2(2), various types of varieties were only enumerated by various modes of reproduction and multiplication existing in the plant field.<sup>14</sup> The UPOV, 1991 presented a definition of 'plant variety' which is more adapted to the scientific progress and techniques carried out in this field. Article 1(vi) of the UPOV, 1991 states that 'variety' means 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 regards to its suitability for being propagated unchanged'.

The distinctive character of plant variety could be related to physiological/morphological character or any other exterior general factor.<sup>15</sup> The legal definition of plant variety which was presented in UPOV, 1991, also affirms that a variety must be defined by characteristics which denote its difference with other varieties and its stability during reproduction process. A plant which does not satisfy these criteria is not regarded as a variety in terms of the UPOV. As per Article 1(v) of the UPOV, 1991, required biological characteristic to define 'plant variety' also depends on its genetic characteristics which resulted from a certain genotype.<sup>16</sup> Moreover, it is important to note that legal conditions of plant breeding rights which depend on the biological characteristics of plants such as 'stability' and 'uniformity', could also take part in the definition of plant variety. For example, according to 'stability', the plant variety could embrace all plants having the same genetic stable characteristics, including all successive generations.<sup>16</sup>

Regarding essential required characteristics for definition of 'plant variety', different jurisprudences

have been based, either alternatively or cumulatively, on the two general considerations resulting from them. The position adopted by the decision T 49/83<sup>17</sup> of EPO being based on the stable characters of the plant varieties which are not modified during their reproductions or successive multiplications (biological considerations) or that adopted by the decision G1/98<sup>18</sup> of EPO being based on the claim wherein specific plant varieties are not individually claimed (taxonomic considerations), would be the typical examples in this field.

In US, definition of 'plant variety' within Plant Variety Protection Act (PVPA), 1970 is in fact purely biological. It specifies identity of genetic characteristics of the plant varieties and, moreover, takes into account variations which are necessarily present when two parents produce a plant combining a part of the genetic information of each one. Since it was affirmed by American jurisprudence, 'variety' covered by the Plant Patent Act (PPA), 1935 consists of a given plant and its 'clones'.<sup>4</sup> In Europe, the European Patent Convention (EPC) does not give a definition for plant variety. However, jurisprudence is well directed towards delimitation of this concept.

The 'plant variety' was initially defined by the Board of Appeal of the EPO in the decision T 49/83<sup>18</sup> as multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after each propagation or every propagation cycle. Article 2(3) of European Directive 98/44 makes a reference to the concept of plant variety defined in Article 5 of EC regulation of 27 July 1994<sup>19</sup> which is based on the same definition presented by UPOV. The presented definitions of plant variety in Article 2 of Law of Patent, Layout Designs of Integrated Circuits, Plant Varieties and Industrial Designs, 2004, in Saudi Arabia, Article 2 of Law of Plant Breeding, 2000 in Jordan and Article 1 of Law of Plant Breeding, 2000 in Oman also conform to UPOV Convention, 1991.

### Patentability of Plant Products

Patentability of various plant products is not without difficulties. Their evaluation carried out by the EPO jurisprudence, caused, in certain cases, debates particularly on the patentability of transgenic plants. In other words, opinion already given on the possibility of transgenic plants protection by plant breeding rights because they meet the characteristics related to plant varieties concept<sup>20</sup>, was not completely admitted by doctrines.<sup>21</sup>

Before examination of the adopted positions in this matter by jurisprudence, it seems also important to specify that the European Directive 98/44 examines patentability of plants in its Article 4(2) laying out that a patent cannot be granted for a plant variety but can be granted for an invention if the technical feasibility of the invention is not confined to a particular plant variety. This distinction is well clarified in preamble of the Directive (considering n° twenty-nine to thirty-two)<sup>22</sup>, from which it arises preliminary that the plant varieties relate to the plant breeding rights but protection of plant breeding applies only to varieties which are characterized by their whole genome.<sup>23</sup>

Therefore, as the destination of protection systems of plant varieties is not principally the protection of plant generic inventions which exceed generally the varieties' cadre, patentability of various plant products, either of the whole plant or of the parts of plants, has already been subject to tight legal and technical evaluation which is based on plant variety concept to distinguish the cases which can be integrated in varieties' cadre from those which are held apart from this cadre.

### Transgenic Plants

The transgenic plant is a plant in which genome is modified by introduction of a gene which can be isolated from another plant, a bacterium, or any other organism. This gene can code a new protein, for example, a toxic compound for devastating insects and a substance which blocks multiplication of a virus.<sup>24</sup> Thus, if transgenic plants constitute, by definition, one or more plant varieties and if, for this reason, they are excluded from patentable subject-matter. In spite of legislative affirmation of transgenic plants, patentability by European Community, resulting in particular, from Article 4(2) of the European Directive 98/44, should specify that the preamble of this Directive (n° 32) also considers a limitation in this field by indicating that 'if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability'.

Therefore, in European Commission Report of 7 October 2002,<sup>25</sup> plant groupings of a higher taxonomic level than the variety, defined by a single gene and not by the whole genome, may be protected by patent if the relevant invention incorporates only one gene and concerns a grouping wider than a single plant variety. A genetic modification of a specific

plant variety is not patentable but a modification of wider scope, concerning, for example, a species, may be protected by a patent. Thus, to admit patentability of a genetically modified plant, it seems to be sufficient if the genetic manipulation is applicable to several plant varieties and not to a particular plant variety. However, this requires to be more examined by jurisprudences.

#### *The European Position, adopted by EPO*

The patentability of transgenic plants has been already examined, in many cases, by the EPO.

#### *Plant Genetic Systems Decision*

One of the most important decisions adopted by the Board of Appeal of the EPO in 21 February 1995 is the decision of *Plant Genetic System/Greenpeace*.<sup>22</sup> In this decision, the Board of Appeal pronounced, in particular, on the patentability of a claim relating generally to a plant 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 recognized by the polymerases of the mentioned cells.

Based on the reasons stated below, the Board considered that Article 53(b) of EPC excludes from patentability any product invention which encompasses a plant variety. It is argued that the transformed plants in the working examples are 'plant varieties' because they comply with the definition of this concept being distinguishable, uniform and stable in their relevant characteristics. Moreover, according to the Board, while the claim defines distinctive feature common in all plants covered by this claim, working examples show that the practical forms of invention's realization according to the claim lead to obtaining 'genetically transformed plant varieties'. Consequently, the subject-matter of the claim encompasses genetically transformed plant varieties showing the mentioned single distinctive feature, even though this claim is not drafted in terms of variety description. Indeed, the Board based on a large interpretation of the exception to patentability under Article 53(b) EPC, considered that a claim relating to plants might be rejected if it covers plant varieties in some of its particular forms of realization.

This decision has been criticized. Contrary to the evaluation carried out by the Board on the transgenic plants, some doctrines have been developed in this

matter estimating that a stable character is not adequate to create a 'plant variety', but it is also necessary that all character are stable.<sup>26</sup> The large interpretation of the exclusion, presented by the Board, which extends to the claims encompassing plant varieties, was also opposed by certain authors being based on the practice already followed in this field, in particular in the Harvard/Onco-Mouse decision.<sup>27</sup> In this decision, although the relevant claim lead to the creation of animal races (as excluded from patentability under Article 53 EPC), it seems that a restrictive interpretation of the exception was admitted by the Board of Appeal declaring that the claim of the mammals or rodents refers in fact to the higher taxonomic products than the race.<sup>11</sup>

However, the Enlarged Board of Appeal (EBA) decision of the EPO in its decision G 3/95 of 27 November 1995<sup>28</sup> having rejected the relation between the mentioned decisions, did not completely pronounce in this subject and therefore the question required to be examined in more details in the following decisions.

#### *Novartis Decision*

The patent application filed by the Novartis company entitled 'Anti-pathogenically effective compositions comprising lytic peptides and hydrolytic enzymes' was refused by the Examining Division based on a parallel comparison with EPO decision T 356/93. The relevant claims concerned to a transgenic plant and the seed thereof comprising recombinant DNA sequences, also to its preparing methods.

The Appellant lodged an appeal against the decision of the Examining Division and submitted a statement of grounds of appeal. In particular, the Appellant argued that decision T 356/93 had inappropriately interpreted Article 53(b) EPC and should not be followed.<sup>29</sup> The raised questions which refer principally to interpretation of the exclusion under Article 53(b) EPC considering in particular the claims type and the technical character of transgenic plants, allowed EBA to adopt its position on the interpretation of Article 53(b) EPC. In this field, impact of the legislative evolutions in European Community on the adopted decision of EBA of 20 December 1999, should not be ignored either.

The adoption of European Directive 98/44 on the legal protection of biotechnological inventions of 13 October 1998 and EPC regulations modification of 16 June 1999 by adding a new chapter entitled

'biotechnological inventions', were indeed new evolutions carried out in this field.

The new Rule 23(c) of the aforesaid Regulation stipulates that 'biotechnological inventions shall be patentable if they concern (...) plants (...) if the technical feasibility of the invention is not confined to a particular plant (...) variety'. This provision conforms indeed to Article 4(2) of the European Directive 98/44 which goes clearly against the decision T 356/93.

The EBA adopted its decision on 20 December 1999 concerning the interpretation of Article 53(b) EPC. It indicated that the exception to patentability in Article 53(b) EPC, the first half-sentence, applies to plant varieties irrespective of the way in which they were produced. Therefore, in response to the asked question, EBA specified that plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.<sup>20</sup> However, EBA presented a detailed interpretation of Article 53(b) EPC to grant protection by patent to a claim on transgenic plants which can cover plant varieties. In this subject, it estimated that the claimed invention is generic and applicable to plants 'which may or may not be varieties' and not to a variety or varieties claimed *per se*.

In other words, 'a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it may embrace plant varieties'<sup>30</sup>. Regarding evaluation of transgenic plants based on the concept of 'plant variety', EBA being based on the definition presented in this field by UPOV, 1991 which characterize a plant variety either by its genotype or by a genotype combination, noticed that the claimed transgenic plants in the application are defined by certain characteristics allowing the plants to inhibit growth of plant pathogeneses, not by their entire constitution, thus this is not a plant variety and the relevant claim is allowable under Article 53 (b) EPC.

#### *Positions Adopted by non-European Countries*

In US, the transgenic plants could also be the subject of a patent. In the case law of '*Hibberd*'<sup>6</sup>, the applicant sought a utility patent for GM maize which contains increased level of free tryptophan, an amino acid. The patent examiner argued that since the Congress enacted two 'plant-specific statutes, i.e., PPA and PVPA, to provide specific intellectual property protection for plant breeders, the intent of Congress was to exclude plants from utility patent

protection. However, the Board of Appeals found there was no express congressional intent indicating that PPA and PVPA should pre-empt utility patent protection for plants. The Board of Appeals determined that the Congress enacted 'plant-specific acts' out of concern that plants would not qualify for patent protection and not because the Congress thought plants were inherently unpatentable. Thus, the Board of Appeals concluded that genetically engineered plants, seeds and plant tissue are patentable.

In October 1992, the American biotechnological company, Agracetus, was granted US Pat No 5,159,135, covering all genetically engineered cotton plants, regardless of their production process. The applied transgenic technique in this case was based, in fact, on a gene transmission which makes antibiotic resistant cotton cells.<sup>31</sup> It is the first time that a patent application was filed for all varieties of the same species, which could also conform to the European position adopted in particular by the Directive 98/44 in favour of patentability of the plant groupings from a higher taxonomic level than the plant varieties. Similarly, in March 1994, the American company was granted a European Pat No 301,749 B1 on all transgenic soy beans. It seems that the cotton and soy bean patents have broad coverage, meaning that the most comprehensive claims cover all cotton and soy bean seeds and plants which contain a recombinant gene construct, i.e. are genetically engineered.<sup>32</sup>

Japan allows also patentability of transgenic plants. Although there is not any explicit provision in this matter in the patent law of 1959, Japanese patent examination guidelines tackle clearly the question of transgenic plants by imposing necessary conditions for granting patents. The required characterization for transgenic plants, as well in the 'claims' as in the 'description', which could be based in particular on determination of their distinctive gene, indicates possibility of GM plants patentability in terms of Japanese patent examination guidelines.<sup>33</sup>

Concerning patentability of transgenic plants in the Middle East, it should be mentioned that patent laws of the Arab countries do not contain any provisions in this field. Among the countries having special systems of protection for plant varieties, the Iranian Act of Plant Variety Registration, Control and Certification of Seeds and Seedling, 2003 (in force), contains a provision which could give an idea to

analyse current situation about patentability of transgenic plants in Iran. Article 3(A) of this Act lays out that ‘the new cultivars should have distinct genetic characteristics and features as compared to previously registered and identified cultivars. The transgenic varieties shall be subject to the provisions of this Clause’.

Thus, the question is to know if explicit reference to ‘transgenic varieties’ in this Act could exclude the ‘transgenic plants’ from the patentable subject-matter in Iran or not. Considering the fact that the former Iranian patent law had not stipulated any explicit exclusion of patentability for plants, patentability of transgenic plants seems to be permitted by this law. However, according to the new Iranian law on patents (adopted by the Parliament on 25 January 2008); the ‘genetic resources’ which could also include all types of plants, were explicitly excluded from patent application field. Nevertheless, reference of ‘transgenic varieties’ in the Iranian Act for plant breeding, which is based principally on the defined characteristics of plant variety in particular by UPOV, 1991, would lead us a priori to the conclusion that the ‘transgenic varieties’ indicated and protected by this Act could encompass ‘transgenic plants’ which would conform to the required characteristics and would be arranged as the lowest known rank in the taxonomic rank of ‘plant variety’ as a botanical taxon.

Apart from these explanations, obscurity remains about legal protection of another plant’s subject-matters such as the realized inventions on the plant’s genes (which confer, for example, resistance to a specific strain or to the whole strains of a particular pathogen) because, on the one hand, potentially the plant’s genes are the subject of an exclusion as ‘genetic components of genetic resources’ under the new Iranian patent law, and, on the other hand, there is a different technical and legal qualification regarding the concept of ‘plant variety’ under the Act of plant variety registration, control and certification of seeds and seedling.

In India, concerning patentability of transgenic plants, some amendments have been also made in the Patent Acts, 1970. But these amendments seem to be more in favour of patenting of the process for producing transgenic plants than patenting of transgenic plant itself. According to Section 3(i) of the Patents Act, the following is not an invention:

‘any process for the medical, surgical, creative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.’

In 2<sup>nd</sup> amendment, mention of ‘plants’ has been omitted from this Section. However, since Section 3(i) addresses principally ‘the process’ of human/animal treatments, the said amendment can be a priori interpreted as a possibility to grant patents for genetic modification process of plants. The second amendment has also added a new Section 3(j). This Section is based on Article 27.3(b) of TRIPS, and excludes as inventions ‘plants and animals including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals’.<sup>34</sup> According to this Section, what can be patented as an invention is production process of transgenic plants as not being essentially biological process, but patentability of derived products from such processes (transgenic plants) has not been explicitly specified by this Section. Therefore, transgenic plants may be interpreted as part of the provided general exclusion for ‘plants’ in this Section.

#### Hybrid Plants

The technique of ‘hybridization’ makes it possible to obtain new varieties or species presenting the desirable parental characteristics by choosing proper species or varieties and crossing them ‘scientifically’. Today, genetic engineering has become a complementary and an advanced technique for plant selection to obtain new plant varieties. Contrary to the transgenic technique which makes it possible to introduce a limited number of genes without upsetting other characteristics of the variety, hybridization between two plants makes it possible to mix about 50,000 genes in an order which is relatively unforeseeable. Therefore, patentability of hybrid plants implies a distinct evaluation and qualification with regard to the concept of plant variety.

In decision T 320/87 of EPO, known as *Lubrizol*,<sup>35</sup> the Board of Appeal admitted patentability of the claims relating to hybrid plants and seeds. In this subject, the Board concluded that hybrid seed and plants produced by such a seed, lacking stability in some trait of the whole generation population, cannot be classified as plant varieties within the meaning of Article 53(b) EPC. Indeed, the Board being based on

the recognized characteristics of plant variety considered that the claimed plant did not satisfy legal condition of 'stability'.

According to the Board, 'the invention relies on going back repeatedly to the parent plants for further propagation by cloning because hybrids resulting from crossing of the parent plants, one of which is heterozygous, do not provide plants which, when further sexually propagated, remain stable with respect to certain desired features. Even if the totality of the hybrid generation resulting from the crosses of the cloned selected parent plants were to comprise single individual plant which would be stable for a certain trait when further crossed and propagated, this fact does not in itself contradict the stated non-stability of the population taken as a whole.<sup>39</sup> In this regard, it is, however, advisable to notice that UPOV Convention, 1991 extends its protection to hybrid varieties whose production requires repeated use of the protected variety (Article 14.5).

In US, patent can be also granted for the hybrid plants. For example, *Hybrid maize plant & seed* on which US Pat No 601,81,09 was granted for the hybrid seed X1086D, the hybrid plant produced from the seed, and variants, mutants, and trivial modifications of hybrid X1086D.

#### **Relationship between Patent and Plant Breeders' Rights**

The relationship between patent and plant breeders' rights can be analysed from different perspectives arising from the international obligations under different IPR treaties and from the differences and overlap between both forms of protection.

#### **Alternatives Available to a State**

The degree of discretion of national governments to choose an intellectual property form for protection of plant varieties has been determined particularly by the international and European legislative framework including UPOV, TRIPS and EPC. In this context, UPOV Convention, 1961 laid out in Article 2(1) that 'each Member State of the Union may recognize 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'. Consequently, two distinct types of efforts were carried out by different countries; the first one was directed towards development of a special protection system for the

plants (*sui generis* systems)<sup>36</sup> and the other, aimed at integrating an explicit exclusion of plant varieties from patentability in their patent system.<sup>37</sup>

The prohibition of 'double protection' which had been provided in UPOV of 1961 was thereafter removed in its revision of 1991. According to UPOV of 1991, the Member States can grant a special title protection or a patent or both of them for plants breeding under the conditions stipulated in the Convention. In this regard, it is also important to mention that the European Community decided to maintain the prohibition of plant varieties patentability, although it has not been imposed by the UPOV since 1991.

In 1994, TRIPS Agreement in Article 27.3(b) invites Members to protect plant varieties with patents or with a combination of patents and a *sui generis* system. This Article also allows the governments, the option of including plant varieties within their existing patent statutes and/or of enacting a separate statute applicable exclusively to plants. A number of governments in the industrialized world, including US, Japan, Australia, New Zealand, Sweden and UK, have capitalized on this opportunity by permitting plant breeders to obtain patent protection in new varieties provided that the eligibility requirements for a patent have been met.<sup>38</sup>

In December 2001, the US Supreme Court confirmed also that breeders could apply for both forms of protection with respect to the same variety.<sup>39</sup> As mentioned before, although such a result is prohibited by the 1978 UPOV Act but permitted as well under the 1991 Act to which US is a party. On the other hand, considering that UPOV is generally recognized as fulfilling the criteria of an 'effective' *sui generis* plant variety protection regime, a number of states have decided to take plant breeders' rights as a basis for a plant variety protection regime. In this sense, several treaties require also member states to ratify the 1991 UPOV Act. For example, the 2004 US-Central America Free Trade Agreement (Article 15.1.5)<sup>40</sup>, the 2002 US-Chile Free Trade Agreement (Article 17.1.3)<sup>41</sup>, the 2000 US-Jordan Free Trade Agreement (Article 4.1)<sup>42</sup> and the 2000 EU-Mexico Free Trade Agreement (Article 36.1.2) as well as certain Euro-Mediterranean Association agreements<sup>43</sup> all mandate UPOV as the appropriate mechanism to protect plant breeders' rights.<sup>44</sup> Such obligations seems to limit the discretion of these countries (stipulated in TRIPS Agreement) to tailor their required national laws.

### *The Differences and Overlaps between Both Forms of Protection*

Although the plant breeders' rights seem to be better tailored than the patent to particular characterization of plants, the scope of patentable subject-matter can also cover plants. In other words, as plant-related innovations are not limited to 'specific plant varieties', the protection of breeder's right can be insufficient in this field. New techniques of plant improvement by the genetic engineering (which were not considered at the time of the development of breeder's right) can be a subject of patent protection properly. The EBA of EPO in *'Novartis'*<sup>32</sup> decision also confirmed that the plant breeding rights, indeed aims at protecting specific varieties and not generic plant innovations. The plant breeding rights can be also distinguished from patent rights relying on the fact that the first one does not relate to processes but to plant and its reproduction material. Moreover, as breeder's right permits protection of new created plant varieties in which relevant characteristics must remain unchanged after repeated propagation, biotechnological inventions which have not been realized to produce specific varieties, could be protected in the framework of patent rights.

Another difference between the plant breeders' rights and patent protection lies in the scope of protection granted. While plant breeders' rights is always limited to a specific plant variety and gives only a monopoly rights for its selling/marketing (not for germplasm in seed), the monopoly rights of patent can be granted not only for a specific DNA sequence but also for a whole set of plants.

The rights conferred to plant breeders also differ from patent rights insofar as they provide much more extensive exceptions to the rights conferred than patents. The rights of breeders do not extend to acts done privately and for non-commercial purposes, to acts done for experimental purposes, to the use of protected variety for the purpose of breeding other varieties (Article 15 UPOV, 1991) and the right to commercialize such other varieties as long as they are not essentially derived from the protected variety.

In this context, it is important to specify that according to Article 14.5 UPOV, 1991, scope of the breeder's rights is extended to varieties which are predominately derived from the initial variety and preserve essential characteristics as they result from the genotype or combination of genotypes of the initial variety. Thus, in order to protect a new variety

produced from another protected variety, it requires creating a variety which is not regarded as very near to the protected variety and is distinguished from this one by new genetic characteristics resulting from a more essential and more technical manipulation. Such human technical advanced intervention at molecular level could consequently make difficult to specify the line of demarcation between the patent right and plant breeder's right, particularly in terms of the notion of 'invention'.<sup>45</sup>

In terms of eligibility requirements of protection, there are also differences between patent and plant breeders' protection. For example, under UPOV, a variety is 'novel' if it has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety.<sup>46</sup> 'Novelty' is thus defined entirely by commercialization while under patent law it refers to the fact that the variety did not previously exist.

A critical discussion of the legal practice under EPC, including key cases *'Plant Genetic Systems'* and *'Novartis'*, also shows actual overlap of IP rights in plants. In these cases, the EPO confirmed that claims to patent protection which are broadly drawn to encompass 'plants' or an invention broader than a single variety may be patented, even though such claims may encompass multiple varieties. Based on EPO decisions, although a patent can only be granted for plants and not for a specific plant variety, breeding, trade and cultivation of plant varieties based on that patent, can in fact be controlled as if a patent had been granted for the varieties. If, at the same time, plant breeders' rights can also be granted, an overlap between these protection rights becomes obvious.<sup>47</sup>

Patent protection for plant varieties as a result of process claims and the 'variety constituents' principle could also cause problems at the interface between both systems of protection. Beside Article 53(b) EPC which excludes plant varieties from patentability, Article 64(2) EPC and Article 8(2) of European Directive 98/44/EC on the legal protection of biotechnological inventions extend protection of a patented process to directly obtained products of such processes.<sup>48</sup> In this context, some questions have been raised whether patent protection of a process can extend to a plant variety as a directly obtained product of this process or whether the variety can constitute, in such a case, an eligible subject-matter for patent protection. The EBA, in *Novartis II* decision, regarded Article 64(2) EPC, irrelevant in this context,

argued that Article 64(2) EPC would not rule questions of patentability but would rather concern its scope. The EBA ruled that ‘protection conferred by a process plant is extended to the products obtained directly by the process, even if the products are not patentable *per se*’.<sup>20</sup> This decision reveals again the problem of the *de facto* overlap of plant variety rights and patents, especially if plant variety rights are also granted for the same plant variety for which patent protection is sought as a result of a patented process.<sup>49</sup>

The principle of ‘variety constituents’ in the Community Plant Variety Rights (CPVR)<sup>50</sup> could cause conflicts between patent and plant variety protection as it defines a plant variety not only consisting of entire plants but also of parts of plants capable of producing entire plants (so called ‘variety constituents’).<sup>51</sup> If each single plant cell can be considered as a variety constituent, it could be qualified as a protectable plant variety. At the same time this plant cell may also be patentable which might affect interface between both systems of protection.<sup>50</sup>

### Conclusion

The reason for plant variety exclusion of protection by patent, particularly in Europe<sup>52</sup>, could be indeed based on the fact that those are already protected by a special title, i.e. the plant breeder’s right which appeared in UPOV Convention. In this context, it’s important to specify that UPOV, 1991 does not contain a clear preference for the form of the protection. The member states are absolutely free to choose the form of protection and even to provide cumulative rights. The prohibition of ‘double protection’ under UPOV, 1961 also cannot be considered as regulating the interface between both forms of protection or as an absolute prohibition on patents for plant varieties. The need to address plant breeders’ rights was in fact based on the deficiency of the patent system in protecting the results of traditional plant breeding effectively at that time which led consequently to the establishment of the UPOV system of plant variety protection.

The main conclusion that can be taken from this argument is that an effective protection of plant varieties can be a priori provided by considering the main logic of establishment of each protection system. This refers principally to a protection system for ‘plant breeding’ and a protection system for ‘inventions’ including plant-related inventions.

In this sense, ‘plant variety’ as the statutory subject-matter of the *sui generis* system is typically like an ‘invention’ as the statutory subject-matter of the patent system and any inter-relationship between both legal systems can be a priori analysed in the light of the definition and delimitation of both statutory subject-matters. However, many efforts have been exclusively made to compare ‘plant variety’ with its ‘equivalent’ as a patent exclusion or a patent non-statutory subject matter. This kind of comparison does not seem to lead to adjust the exact boundary between patent and plant breeders’ rights and on the contrary, lead to legal problems and overlaps particularly arising out of different evaluations of ‘plant varieties’ in different situations. The definition of ‘invention’ as the statutory subject-matter of patent is broad enough to encompass ‘plant variety’. An ‘invention’ can cover ‘plant varieties’, but ‘plant varieties’ can not be considered as a patentable ‘invention’ if they do not comply with the patentability requirements.

Therefore, it seems that removing exclusion of plant varieties from patent laws can be considered as an appropriate solution for effectively protecting plant varieties which meet patentability requirements. As a reasonable solution for protecting plant varieties which do not meet patentability requirements, the plant variety rights can also keep the *status quo*. This argument fits better with the main logic of establishment of both forms of protection: protection of ‘plant breeders’ on the one hand, and a protection of ‘inventors’ on the other hand.

### References

- 1 According to this doctrine, the products which exist in nature, even those artificially multiplied, were not the result of a creative process and consequently, were not inventions as such.
- 2 Overwalle Geertrui, Patent protection for plants: A comparison of American and European approaches, *The Journal of Law & Technology*, 39 (1999) 149.
- 3 It’s a condition of American Patent Act (Section 112) upon which an invention must be reproducible by the person skilled in the art without his excessive efforts.
- 4 Roux-Vaillard Stanislas, *Les Jurisprudences Française Et Américaine Comparées En Matière De Condition De Brevetabilité* (Presses Universitaires de Strasbourg, Strasbourg), 2003 p. 261, 265.
- 5 Beier F K, Crespi R S and Straus J, *Biotechnology and Patent Protection* (OCDE, Paris), 1989, p. 67.
- 6 *Ex parte Hibberd*, *United States Patents Quarterly*, 1985 443.
- 7 Henson-Apollonio Victoria, *La Protection Par Brevet Du Matériel Végétal* in Colloque OMPI-UPOV sur la coexistence des brevets et du droit d’obtention dans la promotion des innovations biotechnologiques, (WIPO, Genève) 2002, WIPO-UPOV/SYM/02/4.

- 8 TGI GRASSE, JCP 1963. II: 13297.
- 9 Dutfield Graham, *Intellectual Property Rights and the Life Science Industries; A Twentieth Century History* (Ashgate, England), 2003, 161-162.
- 10 There are various circumstances in which the law might be criticised for failing to adapt to technological changes. Uncertainty in the applicability of law to new technologies or desire to shape the direction of technological development to meet social and economical goals are in general some reasons for adapting of exiting rules to technical changes or calling new rules. The influence of the technical developments in the field of biotechnology on patent law is also different depending on legal concepts/notions having been already established in the law. These concepts can be generally categorised as 'hard concepts' being objective and defined precisely, and as 'flexible concepts' being subjective and suitable for different evaluations. In other words, patent law embraces the biotechnological inventions using a priori its' traditional legal concepts. Any legislative adaptation of the legal concepts depends on the capacity of their own logic in the absorption of new knowledge resulting from such inventions.
- 11 Bouvet Thomas, *La Protection Juridique De L'innovation Végétale* (Université de Versailles-Saint-Quentin-en Yvelines, Versailles), Thèse de Doctorat, 2000, p. 85, 91, 513.
- 12 ASSINSEL, the International Association of Plant Breeders for the Protection of Plant Varieties, was founded in 1938. It is a non-profit organization of national associations and individual companies. It seeks to increase recognition of plant breeders' contribution to world agriculture and horticulture, and promotes protection of intellectual property rights. ASSINSEL is composed of 45 organizations involved in plant breeding in over 31 developed and developing countries, which, in turn, represent more than 1000 companies worldwide. It is active in the following countries: Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, Croatia, Czech Republic, Denmark, Finland, France, Germany, India, Ireland, Israel, Italy, Japan, Kenya, The Netherlands, New Zealand, Norway, Poland, Slovakia, South Africa, Spain, Sweden, Switzerland, UK, USA and Yugoslavia.
- 13 Buffet Delmas d'Autane Xavier and Doat Amandine, La protection des plantes: entre brevet et certificat d'obtention végétale, *Propriété Industrielle*, 5 (2004) 8-13.
- 14 Article 2(2) of UPOV, 1961 stipulates that the term 'variety' applies to 'any cultivar, clone, line, stock or hybrid which is capable of cultivation'.
- 15 Galloux J C, *Droit De La Propriété Industrielle* (Daloz, Paris), 2006, p. 271, 282.
- 16 Genotype describes in general the genetic constitution of an organism i.e., the specific allelic makeup of an organism, usually with reference to a specific character under constitution.
- 17 T 49/83 Materiel of reproduction/Ciba-Geigy (1963), *Official Journal of European Patent Office*, 1984, p. 112.
- 18 G1/98 Novartis II (1999), *Official Journal of European Patent Office*, 2000, p. 111.
- 19 European Community Regulation on Community Plant Variety Rights, *Official Journal of the European Community*, 227 (1994) 1- 30.
- 20 T 356/93 Plant genetic systems N V et al./ Greenpeace Ltd (1995), *Official Journal of European Patent Office*, 1995, p. 545.
- 21 In general, it is also advisable to mention that regarding patentability evaluation of various plant products many arguments have already raised upon which this evaluation depends a priori on the concept of 'plant variety' to delimit the application field of the relevant exclusion of patentability according to some patent laws. Liewelyn M, La brevetabilité de la matière biologique: les contradictions et al confusion perdurent, *Bulletin de Droit de la Propriété Industrielle*, 707 (II) (2000) 158-160.
- 22 For example, the preamble of the Directive specify that, '(30) whereas 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; (31) 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'.
- 23 Fekete de vari Anne, La brevetabilité du vivant, *Europe Environnement*, 2001, 12-23.
- 24 Grubb Philip W, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (Oxford University Press, USA), 1999, p. 251.
- 25 Rapport de la Commission au Parlement et au Conseil, Evolution et implications du droit des brevets dans le domaine de la biotechnologie et du génie génétique. COM/2002/0545, 32.
- 26 Roberts T, Pourquoi ne pas breveter les plantes? (Why not patent plants?), *Bulletin de Droit de la Propriété Industrielle*, 687 (II) (1999) 177-178.
- 27 T 19/90 Harvard (1990), *Official Journal of European Patent Office*, 1990, p. 476.
- 28 G 3/95 The EBA decision of EPO (1995), *Official Journal of European Patent Office*, 1999, p. 169.
- 29 T 1054/96 Transgenic Plants/Novartis I (1997), *Official Journal of European Patent Office*, 1998, 511.
- 30 The same argument presented again by the EPO in T\_0149/98, *Bayer BioScience N V v Syngenta Participations AG* (2003), <http://legal.european-patent-office.org/dg3/biblio/t980149eu1.htm> (1 February 2009) and in T\_0179/01, *Monsanto v GreenPeace* (2005), <http://legal.european-patent-office.org/dg3/biblio/t010179eu1.htm> (1 February 2009).
- 31 Bijman Jos, Agracetus; Patenting all transgenic cotton, *Biotechnology and Development Monitor*, 21 (1994) 8 - 9.
- 32 Mestel R, Rich pickings for cotton's pioneers, *New Scientist*, 1994, 13-14.
- 33 Japanese Patent Examination Guidelines, VII, C2, 3.1.2 & VII, C2, 1.1.1. (4).
- 34 It is important to mention that India has also a *sui generis* plant variety rights system. In 2001, the Indian Parliament passed the Plant Variety Protection and Farmers' Rights (PVPFR) Act, which grants rights to new varieties of seeds.
- 35 T 320/87 Lubrizol (1988), *Official Journal of European Patent Office*, 1990, p. 71, 72.
- 36 For example, Plant Variety Protection Act (PVPA), 1970, in US, amended in 1994, offers protection for unique, sexually reproduced cultivars and inbred parents of hybrids based on 'novelty', 'uniformity', 'stability' and 'distinctiveness'. The 1994 amendments include changes in eligibility (sexually reproduced plants and tuber-reproduced plants), exclusions

- (not bacteria or fungi),... This Act is also similar to the French law concerning plant breeding whose protection exist in its national legal system since the law of the 11 June 1970. However, it is fact that some other countries had already adopted *sui generis* system for plant protection.
- 37 For example, Article 2(b) of the Convention of Strasbourg, 1963; Article 53(b) of the EPC and the other identical provisions stipulated in European national patent laws or those integrated later in the patent laws of some Middle East countries.
- 38 Watal J, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International, The Hague), 2000, p. 149.
- 39 *J E M Ag Supply v Pioneer Hi-Bred*, 122 S Ct 593, 49, *The United State Patents Quarterly*, 2001, 1815.
- 40 The Central American Free Trade Agreement (CAFTA) was entered into by US and five Central American countries, i.e., Costa Rica, Honduras, Nicaragua, El Salvador, and Guatemala on 28 May 2004 to establish a tariff-free area for the exchange of goods and services among those countries, [http://www.ustr.gov/Trade\\_Agreements/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Section_Index.html) (1 March 2009).
- 41 The US- Chile Free Trade Agreement is the first free trade agreement between US and a South American country which was approved by US Congress in 2003.
- 42 The Jordan Free Trade Agreement was signed on 24 October 2000, [http://www.ustr.gov/Trade\\_Agreements/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Section_Index.html) (1 March 2009).
- 43 <http://ec.europa.eu/world/agreements/default.home.do>.
- 44 OECD, *Regionalism and the Multilateral Trading System*, 2003, [www1.oecd.org/publications/e-book/2203031E.PDF](http://www1.oecd.org/publications/e-book/2203031E.PDF) (18 February 2007).
- 45 According to Rules 27 & 29 EPC technical character/technical effect are required to consider the matter for which protection is sought as 'invention'; <http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma2.html> (1 March 2009).
- 46 Article 6 of UPOV, 1991.
- 47 Lenben Markus, The overlap between patent and plant variety protection for transgenic plants: Problems and solutions, Institute of Commercial and Economic Law, University of Bonn, May 2006, [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=924343](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=924343) (17 January 2009), Forge Frédéric, *Intellectual Property Rights in Plants and the Farmer's Privilege*, *Canadian Parliamentary Information and Research Service*, Document PRB 05-33E, 2005, 2.
- 48 Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, *Official Journal*, 1998, L 213/13.
- 49 Parvin Mohammad Reza, *Les Aspects Juridiques De La Brevetabilité Des Inventions Biotechnologiques: Comparaison Internationale*, Ph D Thesis (University of panthéon Assas, Paris) 2007, p. 392.
- 50 Community plant variety rights (CPVR) was established by Council Regulation. (EC) N 2100/94 on 27 July 1994. This Community system provides European Union-wide intellectual property protection for new plant cultivars of all botanical genera and species, including *inter alia* hybrids between genera and species. This system is modelled on the UPOV, 1991.
- 51 Article 5(3) CPVR stipulates that 'a plant grouping consists of entire plants or parts of plants as far as such parts are capable of producing entire plants, both referred as 'variety constituents'.
- 52 It is important to remember that the European Community decided to maintain the prohibition of plant varieties patentability, although it has not been imposed by the UPOV since 1991.