

## CHAPTER XVIII

### VEGETABLE INVENTIONS AND PATENTS

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SUMMARY: 1. Exclusive rights in the food sector and international patents – 2. European legislation and the UPOV Convention on the protection of new varieties of plants – 3. Regulation No 2100/94 - 4. The farmer's right - 5. Fair remuneration and reutilization – 6. Patentability of GMO food.

#### **1. Exclusive rights in the food sector and international patents**

The exclusive rights in the food sector can be referred to three different situations: *(i)* patents concerning foods which have been totally or partially transformed as a result of the application of a new technological process (so called “novel foods”), *(ii)* exclusive rights granted with regard to varieties of plants; and, finally, *(iii)* patents concerning foods or biotechnological sowing seeds.

Patents concerning new kinds of food (novel foods)<sup>1</sup> are regulated according to the general rules and regulations which grant protection to new industrial inventions.

From an international and European standpoint, said rules and regulations can be outlined as follows.

At international level, the protection of the so called “international patents” has been granted by the Patent Cooperation Treaty (PCT), which is an international Treaty of 1970. PCT in-

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<sup>1</sup> See Chapter XXIII.

roduced a unified patent procedure whereby it can be possible to simultaneously file same application in a sizable number of Countries. The procedure set forth by PCT splits into two phases: the international (I phase) and the national (II phase) one. The international application shall be filed with the prescribed Receiving Office (in Italy, the Italian Patent and Trademark Office), which will check and process it. One copy of the international application shall be kept by the Receiving Office (“home copy”), one copy (“record copy”) shall be transmitted to the International Bureau, and another copy (“search copy”) shall be transmitted to the competent International Searching Authority – ISA referred to in Article 16 of PCT.

In the request form the applicant shall designate the contracting State or States in which protection for the invention is desired (so called “designated States”). Once the international application and the international search report – issued by ISA with the purpose of discovering the relevant prior art – have been published, the procedure proceeds at a national level within the designated States.

Therefore, though the PCT procedure introduces a standard patent application, it is the national relevant authority that finally grants the patent according to the national applicable law. In Italy, for example, there is not a precise national phase; therefore, the international application shall designate the European patent and Italy shall be designated during the EU regional phase.

In other words, the outcome of a PCT application is not the release of an “international patent”, since there is no such kind of patent according to the current international rules and regulations on intellectual property.

Besides the “international” process, inventors have the opportunity to receive protection for their invention also at European level. The European patent, indeed, has been granted by the Munich European Patent Convention of 1973 (the “Convention”).

The application for European patent (which shall mention the Countries, among those which are contracting parties of the Convention, in which the inventor is willing to obtain protection) is filed with the Chamber of Commerce of Rome, as well as with the Italian Patent and Trademark Office or, in case

of priority claiming of a precedent Italian application, with the European Patent Office located in Munich (EPO).

The release of a positive opinion upon said application shall pass through the evaluation of the patentability of the invention.

According to Article 52 of the Convention, in order to succeed in the release of the European patent, the invention shall be new, involve an inventive step and be susceptible of industrial application. Said requirements represent the basic rules concerning the patentability of inventions. To make the invention “patentable”, all the other requirements set forth by the Convention itself shall be met.

Once granted by the EPO, the European patent comes into existence effectively as a “bundle of national patents”, since the content of the exclusive granted rights is regulated by the national laws of those Countries in which the European patent is valid according to the validation procedure.

## **2. European legislation and the UPOV Convention on the protection of new varieties of plants**

The exclusive rights issue in the food sector is mainly connected with the objective to improve the available varieties of plants, with a view to ensuring larger and more advantageous productions for food consumers. Such activities consist in improving the traditional techniques of selection and hybridization in the traditional biotechnologies and in genetic engineering. The results are under protection.

The European legislation is based on Regulation No 2100/94<sup>2</sup> regarding exclusive rights over vegetable inventions (known as basic Regulation) and on Directive No 98/44<sup>3</sup> on biotechnological patents. The aforementioned provisions have set up a system of binary protection of vegetable “inventions”,

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<sup>2</sup> Regulation No 2100/94 of 27 July 1994, as amended by Regulations No 2506/95 of 25 October 1995, No 807/2003 of 14 April 2003, No 1650/2003 of 18 June 2003, and No 873/2004 of 29 April 2004.

<sup>3</sup> Directive No 98/44/EC of 6 July 1998. See Chapter XIX.

which recognizes a *ius excludendi alios* to a varying extent depending on the object of protection, with a view to protecting every vegetable type obtained through human intervention (Germanò 2002). Vegetable inventions are protected in two different and specific ways depending on whether they are based on hybridization or genetic manipulation. In particular, exclusive rights over vegetable inventions regard only one specific variety of plant which is characterized by its identity and capacity of being distinguished from those which already exist, so that it would lose protection should the said variety be modified and consequently differ from the protected variety in terms of even only one characteristic. While biotechnological patents do not only concern the product, but also the different ways and purposes in which and for which the product can be used, as well as the process through which it is obtained.

By Regulation No 2100/94 the European Community has allowed the protection of new plants obtained through an “essentially biological” process, where the “invention” consists in the distinguishability and individuality of the new variety for the entire genome with respect to other varieties, even presupposing a specific denomination by which it can be identified. By Directive No 98/44, the European Union has permitted the patentability of a “non-essentially biological” process and of the relevant result (i.e. of the biological products obtained through a process using a microbiological material and which implies an intervention on the microbiological material or which produces a microbiological material) which is not a new variety of plant, but rather a genetic modification that can be used in more than one variety of plant.

Regulation No 2100/94 was the result of the work of the International Union for the Protection of New Varieties of Plants (Upov - *Union pour la protection des obtentions végétales*) and of the relevant Convention for the protection of varieties of plants.

The Upov is an intergovernmental organization based in Genève. Its task is to facilitate the joining of new States and

ensure that the Convention is duly and correctly applied. The initiative, which sprung from the two diplomatic Paris Conferences of 1957<sup>4</sup> and 1961<sup>5</sup>, and was the work of the eight participant States (Belgium, Denmark, France, Italy, the Netherlands, the United Kingdom, the Federal Republic of Germany, and Switzerland), resulted in the drafting of the Convention for the protection of varieties of plants.

### **3. Regulation No 2100/94**

The UPOV Convention was not harmonized in the different member states; the different national legal systems had very different institutes both due to their having joined the UPOV at different times, thus adopting the text in force without subsequently updating the relevant legal provisions, and due to the wide margin of discretion allowed for the adoption of the convention texts.

To remedy such situation, the EU authorities harmonized the legal provisions at issue by adopting Regulation No 2100/94, based on the 1992 version of the Convention, whereby a system of EU patents for vegetable inventions was set up as the only type of European industrial property regarding varieties of plants (Van Der Kooji 1997).

The European legislation on exclusive rights grants “inventors” of new plant varieties (or their nominees) which are “distinct”, “homogeneous”, “stable”, “new” and designated by “original denominations”, a twenty-five-year exclusive right over the “invented” biodiversity, which includes the production, conditioning for multiplication purposes, offer for sale, marketing, exportation, importation, and storage for any of the aforesaid purposes (Mayr 2000).

In particular, exclusive rights may be granted with regard to the varieties of all botanic species and genera, including,

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<sup>4</sup> 7-11 May 1957.

<sup>5</sup> 21 November-2 December 1961.

without limitation, hybrids between genera and species that are clearly “distinguishable” in terms of genotype with respect to the known varieties, sufficiently “homogeneous” as regards their distinctive characteristics, “stable” in the expression of such characteristics, including in the subsequent generations, and “new”, i.e. not marketed or otherwise assigned for more than a year on the European territory (four years as regards species of trees and vines).

“Original denomination” means that the varieties of plants must be such as to define their own identity with respect to other known varieties. The denomination must not be misleading or confusing with regard to the characteristics and/or the identity of the inventor and must be different from all the others which designate the varieties of the same species of plant or of a close species in each Member State of the Upov.

The granting of exclusive rights and any related issues are the responsibility of the Community Plant Variety Office (CPVO) and is characterized by a peculiar regime of exceptions and limitations for the purposes of protection.

Firstly, the *ius excludendi alios* is subject to the limitation imposed on the use of plants for experimental purposes or for plans of development of new lines of plants which can then be marketed without the authorization of the holder of the basic invention (or, in the case of limited originality, by paying him a utilization “indemnity”). More precisely, the above exception allows competitors to generate a new variety by using the biodiversity of the protected plant, which can then be sold without infringing the exclusive rights, obtaining, in turn, the protection envisaged by the basic regulation upon fulfilling the legal requirements, provided that it does not essentially derive from the protected variety.

In the latter case, there is no absolute prohibition of protection. Pursuant to art. 13, paragraph 6, of the basic regulation, whoever “develops” a new variety of plant starting from an original variety is required to apply for the authorization of its inventor if the new variety “essentially” originates from the previ-

ous one, where “essentiality” means prevalent derivation, i.e. maintaining the essential characteristics of the genotype or of the combination of genotypes of the original variety.

Furthermore, the exclusive rights regime does not include any actions carried out as a private party and for non-commercial purposes and is limited for reasons of public interest. In such cases and upon request by a Member State, by the Commission or by any other body recognized by the Commission, a “compulsory license” may be granted to a *category* of individuals (or to certain individuals) to permit, the utilization of the invention without the authorization of the holder against the payment of a fee.

#### **4. The farmer’s right**

Finally, the legislation on exclusive rights here at issue contemplates the so-called “farmer’s right”. This is an exception to the *ius excludendi alios*, whereby the holder of the exclusive right cannot prevent the farmer who purchases the propagation material (of the protected variety) from reusing on his farm the sowing seeds of the subsequent generations of plants obtained from the seeds initially purchased from him. More precisely, by defining the first sowing of the vegetable invention purchased from the holder as *utilization* and subsequent sowings as *reutilization*, in order to safeguard agricultural production which the system of protection of the varieties of plants could jeopardize, the farmer is granted the right to *reuse*, without authorization, the vegetable invention purchased from the holder and *used* on the individual farm.

From this perspective, the farmer’s right serves the purpose of reconciling conflicting interests, i.e. the interest in protecting the exclusive rights of the individual inventors of a new variety of plant exploiting biodiversity, and the interest in protecting the “weak” party in the agricultural market, namely the farmer. These interests can be safeguarded only through their reason-

able balance or through the existence of proportionality between the purpose of the respective condition and the actual effect of their observance. The balance, envisaged by the basic regulation and implemented by Regulation No 1768/95<sup>6</sup> (so-called Implementation Regulation<sup>7</sup>), implies a control over production cost, which, in the case of “small farmers” (i.e. those who, in the case of forage production, limit cultivation to an area not large than that necessary to produce 92 tons of cereals per crop, or, in the case of different species of plants, cultivate surface areas comparable to the aforementioned criterion), means the annulment of *reutilization* expenses, while, for “non-small” farmers expenses are limited to so-called “fair remuneration”, i.e. an indemnity paid to the holder of the exclusive right, calculated on the *reused* quantities of the protected variety.

## 5. Fair remuneration and reutilization

Farmer’s right and fair remuneration pose an issue regarding the application of the legal provisions concerning the exercise of the right in the case of non- payment of the fair remuneration. In such a case, the lawful exercise of the farmer’s right would be impeded and the farmer would be liable for cultivating “without authorization”, i.e. in breach of Article 13(2), of the basic regulation, and as a consequence a prohibition action could be brought against him to order him to interrupt the utilization of the invention, as well as an action to seek payment of damages.

In fact, the EU Court of Justice has specified that «the farmer who fails to pay the holder a fair remuneration upon using the product of the crop obtained by cultivating material of multiplication of a protected plant variety cannot invoke the application of art. 14, no. 1, of regulation no. 2100/94 and must therefore be deemed to have carried out, without authorization,

<sup>6</sup> Commission Regulation No 1768/95 of 24 July 1995.

<sup>7</sup> As amended by Commission Regulation No 2605/98 of 3 December 1998.



one of the acts specified in art. 13, no. 2, of the aforesaid regulation»<sup>8</sup>.

This interpretation cannot be shared. With respect to the entire set of provisions regulating the farmer's right, the above interpretation does not seem to take into due account the fact that the farmer's right is not a right under a condition precedent, nor can the fair remuneration be regarded as the equivalent of the authorization provided for by Article 13 for the lawful utilization of the protected invention. Instead, Article 14 seems to present the farmer's right as a right immediately effective as a departure from the general provisions, the exercise of which only occasionally (i.e. when the farmer is not "small") gives rise to an obligation to pay the fair remuneration («the farmer's personal obligation to pay the fair remuneration arises when (the farmer) actually uses the product of the crop for multiplication purposes»: Article 6 of the implementation regulation). This is a "derivative" relationship that seems autonomous and independent from its source and as such is unable to change the legal nature of the *reutilization* undertaken, from the exercise of a right to the infringement of an exclusive right, as non-payment of the fair remuneration does not nullify the exception regime of Article 13, but is exclusively a breach of contract that results in autonomous pecuniary liability.

These special legal provisions apply only to certain specific species of plants (classified in four groups: fodder plants, cereals, potatoes and oil and fiber plants), and the exemption applies without quantitative restrictions at farm level.

In any case, *reutilization* gives rise to a series of obligations to be fulfilled by the parties involved; such obligations consist in: (i) the payment by the farmers of the specified fair remuneration; (ii) the supply of information regarding the *reutilization* of the protected variety; (iii) the safeguarding of the identity of the product of the crop subject to treatment with that which results from the processing; and (iv) surveillance to ensure respect

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<sup>8</sup> ECJ, 10 April 2003, Case C-305/00, *Schulin v. Saatgut-Treuhandverwaltungs*, (para 71).

of the conditions for the application of the exception. The last mentioned activity is the responsibility of the holder of the exclusive right, who may approach the individual farmers to gather the necessary information.

However, such exclusive right vis-à-vis the individual farmers is not absolute; it is related to the availability of certain leads on the fact that, for the purposes of multiplication in the fields of their farms, farmers have presumably used or reused, or are in the condition to do so, the product of the crop obtained by cultivating material of multiplication of the protected variety (Florida 2001).

In this respect, in the aforementioned *Schulin* case the Court of Justice stated, in principle, that the holder of an exclusive right cannot ask an individual farmer questions if he has adequate evidence against him to prove the *reutilization* of the protected invention. The difficulty in establishing whether a plant has been obtained after *reutilization* or *utilization* of the seeds purchased and the necessity to safeguard, in any case, the legitimate interests of the inventor in obtaining the fair remuneration that the production of such evidence jeopardizes, lead to limit the incidence of such a rule to the existence of “suitable and sufficient leads”, and not to prove the actual *reutilization*, and to rather believe that such *reutilization* is probable.

Considering that the exercise of the farmer’s right presupposes the purchase of the protected variety, the proof of this purchase by the farmer is considered a “suitable and sufficient lead”<sup>9</sup>. Regardless of the length of his invention’s distribution chain, the holder of an exclusive right can easily gather such evidence through the due organization<sup>10</sup>, as he is able to control the distribution phases of his product in that he is allowed, «pursuant to art. 13, no. 2, second paragraph, of regulation no. 2100/94... [to] require from his authorized supplier to register the name and domicile of the farmers who purchase the material

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<sup>9</sup> Para. 63 to 66 of the judgment.

<sup>10</sup> Para. 70.

of multiplication of any of his varieties of plants»<sup>11</sup>. The *Schulin* decision was shared and confirmed by the EU Court of Justice in the subsequent judgment of 11 March 2004<sup>12</sup> (Benozzo 2004).

Therefore, utilization and reutilization give rise to a series of rights and obligations for the inventor and the farmer, the exercise and fulfilment of which inevitably lead to the reconciliation/clash of conflicting interests of both parties. Therefore, upon exploiting the varieties of plants, the farmer's right appears, with respect to such subjective positions, as a clearing house with respect to which it is necessary to establish a point of balance between the purpose of the respective positions and the actual effect of their observance. The Court of Justice established a point of balance by limiting to the farmers who consciously had some kind of relationship with the holder of the invention the identification of the addressees of the information right, and excluding rights of the inventor against the farmers not involved in a contractual relation. The above provides a system of protection of both positions (inventor's and farmer's), by proportionately limiting one position in favour of the other, and assigning to the relevant legal provisions a well-defined political and economic function, i.e. to allow an agricultural economy with insufficient funds to save on costs not always necessary for the protection of subjective interests. Should this not be the case, that which is necessary to safeguard the reciprocal lawful interests of the inventor and the farmer would be exceeded and the farmer would be required to bear an unjustifiable burden, even if he were not a voluntary party to the contractual case of exploitation of the protected biodiversity.

## 6. Patentability of GMO food

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<sup>11</sup> Para. 68.

<sup>12</sup> ECJ, 11 March 2004, Case C-182/01, *Saatgut-Treuhandverwaltungs v. Jäger*.

Patentability of genetically modified products destined to the food market is regulated by Directive No 98/44<sup>13</sup>, which was challenged by the Netherlands, upheld by Italy and Norway, and found lawful by the Court of Justice<sup>14</sup> (Albisinni 2006). The aforesaid judgment put an end to a nearly ten-year-long debate, on the possible experimentation and application of advanced biotechnologies on an industrial scale.

The first proposed directive dates back to 1988. The text, examined and amended several times, reached the conciliation phase in 1995, but failed to be approved, partly due to the opposition to inserting the prohibition of patentability of the human body, only in one Recital. However, the text rejected by the Parliament was a useful springboard, as the Commission drew from its content and supplemented its provisions with the different positions expressed by the opponents during the relevant debate. The new text was submitted once again to the Council for further evaluation; on that occasion, the conciliation phase was completed positively and the directive was definitively approved.

In Directive No 98/44, the Union acknowledged the increasingly important role of genetic engineering in the future development of the food industry. The legislator was forced to stimulate the activity of the food sector through adequate protective measures, the only ones capable of ensuring adequate returns on the huge investments made in machinery, facilities and personnel that research in such a sector required.

However, in an attempt to limit, as much as possible, the impact on the internal legal systems of the new “concession” to industries, the European legislator expressly stated that biotechnological inventions did not require a special set of provisions and regulations, but should be protected within each legal system by merely adjusting the national legislation on industrial inventions already in force.

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<sup>13</sup> Directive No 98/44/EC of 6 July 1998.

<sup>14</sup> ECJ, 9 October 2001, in Case C-377/98, *Netherlands v. Council and Parliament of European Union*.

The aforementioned directive recognizes two different types of biotechnological patents depending on the object of the invention: *product* patents and *process* patents. A *product patent* is granted when the invention consists of a biological material, which contains genetic information and is self-reproducible or capable of reproducing itself in a biological system, while a *process patent* protects the process through which the biological material is produced, processed or used.

In order for a patent to be granted, the invention must meet the requisites of the traditional patents, i.e. the invention must be: (i) *new*, i.e. not in the state of the art, (ii) the result of an *inventive activity*, (iii) *lawful*, and (iv) suitable for *industrial application*.

The last requisite implies that the patent application must contain a detailed description of the invention, with specific indication of the protein (or the partial protein) produced and of the function performed, so as to permit its *industrial repeatability* by an expert.

If the invention regards a biological material which is not accessible to the public and which cannot be described in the patent application in such a manner as to permit its repetition easily, the description must be supplemented with the lodgement of the biological material with the lodgement entity authorized pursuant to Article 7 of the Budapest Treaty of 28 April 1977; the said biological material must also be made accessible through the free supply of a sample.

The requisite of lawfulness is considered fulfilled only when the invention does not contrast with the public order, as the expression of the ethical principles, and with morality, as the expression of the moral principles, and when it is not identifiable with any of the four inventions expressly prohibited by art. 6 of the measure or with those specified by Article 5 on patentability of the human body, with regard to which the enactment of a specific measure failed in the past.

The former prohibitions consist of: (i) cloning processes and processes of modification of the germinal genetic identity

of the human body; (ii) utilization of human embryos for industrial or commercial purposes, with the exception of inventions for therapeutic or diagnostic purposes; and (iii) processes of modification of the genetic identity of animals for non-medical purposes.

In particular, the legislator has set up a general regime and a series of exceptions with regard to the prohibitions concerning the human body. Pursuant to the first paragraph of Article 5, the human body and its components are not and can never be the object of a patent. However, paragraph 2 of Article 5 provides an exception to the general prohibition, in that it states that an isolated component of the human body (including the sequence, even partial, of a gene) may be a patentable invention if it has been separated from its natural environment or otherwise produced through a technical process (Pizzoferrato 2002). This exception allows the patenting of individual components of the human body as a departure from the general prohibition. The legislator has justified his choice, on the one hand, with a legal fiction, and, on the other hand, with new awareness.

More precisely, firstly, the legislator has stated that the individual components of the human being, albeit parts of a human being, must be considered no longer as such, but rather as true inventions, as the isolation of individual components is the result of technical processes of identification, purification, characterization, and multiplication, which only the human intellect is capable of performing, and which nature *per se* is unable to perform.

Secondly, the European legislator has justified the exception regime by stating that the isolation activities, albeit involving components of the human body, permit «decisive advances in the treatment of diseases», which, for such purposes, the Community has the obligation to encourage.

Furthermore, just like the general rule regarding the human body, animal breeds are not patentable if the technical implementation of the invention is limited to one breed only (Ricolfi 1995).

The patent obtained grants the patent holder a *ius excludendi alios* to use the invention to varying extents depending on the type of patent.

If it is a *product patent*, then the patent holder extends his exclusive right to the patented biological material, as well as to all the biological material for reproduction or multiplication purposes, deriving from the original material, provided that it maintains the same characteristics as the original material.

If it is a *process patent*, the patent holder is granted an exclusive right over the process object of his invention, over the biological material produced through such a process, and over the biological material for reproduction or multiplication purposes, deriving from the original material, provided that as a result of the invention, the material obtained has specific properties that can ascribe it the requisite of novelty.

Just like exclusive rights over varieties of plants, the legal protection of such inventions regarding both types of patents, is subject to some limitations arising from both industrial patent law and the special laws on biotechnological patents.

Pursuant to industrial patent law, the holder of a patent for a genetically modified organism cannot impede the use of his invention or claim compensation, when it is used for experimental or for private, non-commercial purposes. Subject to such limitations, the European legislator has also extended the specific exceptions regarding exclusive rights over varieties of plants to biotechnological patents in favour of the farmers, limiting the holder's exclusive rights over the future generations of the biological material (either patented or resulting from the patented process).

In short, the legal provisions and regulations on patents for living material contemplate the same farmer's right provided for the plant varieties protected by Regulation No 2100/94: the farmer has the right to use the product of the biotechnological crop that he has obtained by planting the seeds purchased from the patent holder in subsequent phases of sowing on his farm, without having to obtain the latter's authorization.

In addition to the farmer's right, the legislator has also contemplated a breeder's right in relation to animal "inventions", by virtue of which a farmer has the right to use the animals purchased from the patent holder for agricultural purposes, where the expression "agricultural purposes" also includes the animals' sexual reproduction to obtain brood to be used in the same agricultural activity.