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Plant Patents in the European Union: Recent Developments

La patentabilidad de las plantas en la Unión Europea: Desarrollos recientes

Mª Mercedes Curto Polo

Associate Professor of Business Law, Commercial Law Department

Spanish National University for Distance Learning (UNED)

Calle Obispo Trejo, nº 2

28040 Madrid, Spain

curtopom@der.uned.es

https://orcid.org/0000-0002-4125-0415

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ABSTRACT: Biotechnology has become one of the most promising and important technologies for the development of innovation in agriculture. The economic importance of the invested resources justifies that innovators ask for an adequate means of protection to compensate their efforts. There are two possible ways of protection of the developments in plant innovation: A *sui generis* system born in the middle of last century in order to protect the results of traditional breeding processes, on the one hand; and the patentability of plant inventions which normally are the result of biotechnological processes which operate at the cellular level. The coexistence of these two systems of protection in the European Union causes some frictions which have to be solved, not only by the legislator, but also by the courts and the patent offices when they apply the law to a constantly evolving reality.

KEY WORDS: Breeders' rights; Plant Patents; Biotechnological inventions; plant varieties; agricultural innovation.

RESUMEN: La biotecnología constituye una importante y prometedora tecnología para el desarrollo de la innovación agrícola. La importancia económica de los recursos invertidos explica que quienes innovan demanden una protección adecuada de los resultados logrados para compensar sus esfuerzos. Existen dos posibles vías de protección de los desarrollos relativos a la innovación agrícola: Un sistema sui generis de protección nacido hacia mediados del siglo pasado para proteger los resultados de los procedimientos tradicionales de innovación agrícola, que se adapta mal a las innovaciones logradas mediante la aplicación de la biotecnología; y la protección mediante patente de los resultados de los procedimientos biotecnológicos que operan al nivel celular de la planta. La coexistencia de ambos sistemas de protección en la Unión Europea origina algunas controversias que tienen que ser resueltas no sólo por el legislador, sino también por los tribunales y las oficinas de patentes cuando aplican el Derecho existente a una realidad en constante evolución.

PALABRAS CLAVE: Derechos del obtentor vegetal; patentes sobre plantas; invenciones biotecnológicas; variedades vegetales; innovación vegetal.

TABLE OF CONTENTS:

1. Introduction

Biotechnology has become one of the most promising and important technologies for the development of innovation in agriculture. An adequate regulation of the matter, fully respectful of environment and consumers' interests, but also with those of innovators, is necessary to ensure legal certainty. If this is true in relation with all the biotechnological inventions, this affirmation is more valid about improvements in agricultural techniques which result in direct products for human consumption.

One of the aspects of Plant Biotechnology that should be ruled relates to the protection of the innovations achieved in the field. There is no doubt that nowadays plant development industry is a very big business. Large international chemical companies invest huge amounts of money in sophisticated investigations to increase quality of agricultural products or to facilitate their production. The economic importance of the invested resources justifies that they ask for an adequate means of protection to compensate their efforts.

The existing legislation for the protection of plant innovations is complex and far from being uncontested. On the one hand we have a specific system of protection for plant innovation. National authorities realised in the middle of last century that an adequate system of protection had to be established to protect the new developments that had been achieved in the agricultural field. Since the middle of the last century, when Gregor Mendel laid down the foundations of experimental genetics in his theory of the laws of segregation and recombination, and Friedrich Miescher revealed that the main constituent of the cell nucleus is nucleoprotein[1], continuous improvements have been made in order to increase the quality and to facilitate the production of agricultural products, getting to extremely sophisticated methods, such as the recombinant DNA, of genetically transforming plants. These inventions were very easy to copy: The reproducible nature of these developments was such that once a small quantity of the new plant varieties was released, it was potentially available to all[2].

But they realised soon that the patent system did not constitute an adequate means of protection for these new inventions, even though some States as the USA established since 1930 a system of plant patents. There was an international attempt of extending this kind of protection at the Lisbon Diplomatic Conference to revise the Paris Convention for the Protection of Industrial Property in 1958. But the general opinion was that a special law was needed. It came on international level with the UPOV Convention, signed in 1961, which dealt specifically with the field of plant variety protection. In order to form part to this Convention, Member States had to adapt their national legislation to ensure the minimum standard of protection established by the international text is reached. Many of them did it by simply copying its provisions.

[1] A combination of basic proteins and nucleic acid (later established as deoxyribonucleic acid (DNA).
[2] BARRY GREENGRASS, "UPOV and the Protection of Plant Breeders- Past Developments, Future Perspectives", *IIC*, 1989, p. 622.

This Convention, binding since 10 August 1968, has been modified on three occasions to grant a more adequate protection to the continuous developments achieved in the field of biotechnological inventions, and to adapt this specific system of protection to the resolutions adopted by the patent offices on the field. The first revision was done by the Additional Act of 10 November 1972; the second one by the Additional Act of 23 October 1978 and the third one took place through the Additional Act of 19 March 1991.

On the other hand, we have the patent system as the general framework of protecting innovations. A lot of critics have arisen in respect of the patentability of innovations related to living matter. But the patentable subject-matter has been progressively extended thanks to an interpretation of the concept of "invention" adapted to the new technical developments. As far as plant innovations are concerned, even though a lot of criticism has arisen regarding the application of patent protection to the improvements on plant breeding, at the end some innovations have been considered patentable.

Therefore, the protection afforded by patent law to these inventions coexists with the specific one which was established in the middle of the last century considering the special characteristics of the innovations on plants[3].

The coexistence of these two systems of protection for plant innovations has been recognised at international level[4]. Article 27. 3. b) of the TRIPs Agreement states that "*Members may also exclude from patentability (…) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement*".

At the European level the principle to assure a pacific coexistence of both systems has been the prohibition of double protection, established in the UPOV Convention in 1961, and, although later abolished in the UPOV revision of 1991, maintained unaltered in the European legislation. According to Article 53 (b) of the European Patent Convention (EPC) of 1973, "*European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals*". Therefore, plant varieties and essentially biological processes for the production of plants are excluded from patentability. *Sensu contrario*, plants which do not consist in a plant variety and non-essentially biological processes (mainly microbiological processes) and the products thereof are patentable.

Even if the distinction between the protectable subject matter under the two systems of protection is clear in theory, in practice there is much controversy about it. The coexistence of both systems creates some problems of coordination which are not completely solved, not only at the European level, but also at the international one, mainly due to the technical

[3] MIREIA MARTÍNEZ BARRABÉS, *La patente biotecnológica y la OMC,* Madrid, Barcelona, Buenos Aires, Marcial Pons, 2014, p. 185.
[4] LAURENCE R. HELFER, *Intellectual Property Rights in plant varieties,* FAO, 2004, p. 60.

improvements in the field that were completely unforeseeable at the date of elaboration of legislation on patents. At European level two main efforts have been made to solve those frictions. One of them refers to the specific protection of breeders' rights and is legally binding upon Member States since 27 April 1995. In effect, Council Regulation Nº 2100/94 on protection of Plant Varieties[5] has been issued as an intent to avoid disparities of protection of plant varieties within the Community, derived from the fact that not all the Member States belong to the same version of the UPOV Convention[6]. The other one was a more general intent to adequate patent laws of the Member States to new biotechnological improvements, also ensuring a compatibility with the other specific system of protection. In 1998 the Directive on patentability of biotechnological inventions was approved[7], after a previous rejection of the European Parliament in 1995 due to the ethical implications of the matter.

But despite these legal initiatives, there is still some legal uncertainty concerning the patentability of some innovations related to plants and breeding processes. The object of this article is to analyse briefly the patentability of plant innovations and processes for obtain them, taking into account the exclusion of patentability contained in the European Patent Convention and the Directive on the patentability of Biotechnological inventions, as well as the recent practice of the European Patent Office in this regard. But before that a general overview about the patentability of biotechnological inventions in Europe will be addressed.

2. The patentability of biotechnological inventions

2.1. Preliminary remarks

It is obvious that the system of patent protection has been an important instrument of promoting technical innovation and industrial development. Patent systems of the OECD countries, having their roots in the 19th century, propose an adequate equilibrium between the general interest of society, which consists in the disclosure of inventions; and inventors' concerns, who receive an appropriate reward through the assignment of a monopoly right to exploit their innovations, during a limited period of time. The problem that patent system presents nowadays is that there are many areas of new technologies to which it is very difficult to apply the strict criteria of patentability, and which, nevertheless, constitute an important technological improvement that deserves a high degree of protection. Due to its traditional consideration as non-patentable subject-matter, protection of these inventions has had to be achieved by other means different from patent law; but sometimes they have been considered as not completely satisfactory and this has given rise to a lot of discussions

[5] Council Regulation (EC) Nº 2100/94 , of 1 September 1994, on Community plant varieties, O.J.L227/1.
[6] PAUL VAN DER KOOIPJ, *Introduction to the EC Regulation on Plant Variety Protection,* London, The Hague, Boston, Kluwer Law International, 1997, p. 11.
[7] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.1998, p. 13.

in the sectors concerned. The field of biotechnological inventions has been until recently the most prominent example of the existence of a considerable gap between the state of the art and the state of the law[8].

Many arguments have arisen against patentability of biotechnological inventions in general[9], and in the field of plant innovation in particular[10]. In order to explain them, we must take into account that the system of patent protection was exclusively conceived for technical innovations, without even imagining the new developments that are being achieved nowadays. The remarkable deepening of the scientific foundations of biotechnology over the past five decades has, indeed, caused a revolution in the whole field. On the one hand, a wide range of life processes at the molecular level has been clarified. On the other hand, new techniques generally known as "genetic engineering" have been developed and mastered.

Nevertheless, the system of patent protection was considered appropriate to apply to plant varieties in the USA as early as 1930[11]. Although at the beginning plants, even those artificially bred, were considered as products of nature and not patentable subject matter, in 1930 the Plant Patent Act (PPA) extended patent protection to *asexually* reproduced plant varieties. In order to face the problems that this change could provoke, the requirement of the enabling description was reduced[12]. As far as plant varieties *sexually* reproduced were concerned, a special title of protection was created by the Plant Variety Protection Act (PVPA) in 1970, which provides a system of protection very similar to that conferred by patent law[13]. The scope of the patentable subject-matter has also been extended by judicial authorities. Normal patents (*Utility patents*) were granted to micro-organisms in 1980 by the Supreme Court decision in the case *Chakrabarty v. Diamond*[14]. In this sense, the Board of Patent Appeals and Interferences held in 1985 in *Ex parte Hibberd et al*[15], a case in which the plaintiff claimed maize seeds, maize plants and maize tissue culture, that plants constitute patentable subject-matter within the meaning of 35 USC § 101, which is directed to the subject matter eligible for utility patent protection. It established that the PPA or PVPA were not intended to pre-empt utility patent protection of plants under 35 USC § 101 when the state of the art advanced to the point that utility patent protection became available.

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[8] FRIEDRICH-KARL BEIER, JOSEPH STRAUS, "Patents in a Time of Rapid Scientific and Technological Change: Inventions in Biotechnology", in FRIEDRICH-KARL BEIER, R. STEPHEN CRESPI, JOSEPH STRAUS J., *Biotechnology and Patent Protection - an International Review,* OCDE, 1985, p. 21.

[9] THE ROYAL SOCIETY, *Keeping SCIENCE open: the effects of intellectual property policy on the conduct of science,* Abril, 2003, disponible en https://royalsociety.org/topics-policy/publications/2003/keeping-science-open/

[10] HANS NEUMAIER, *Sortenschutz und/oder Patentschutz für Pflanzenzüchtungen,* Köln, Berlin, Bonn, München, Carl Heymanns Verlag KG, 1990, p. 67.

[11] For a general overview of the US Patent Law for the protection of biotechnological inventions, see ROBERT ARMITAGE, "The emerging US Patent Law for the Protection of Biotechnology Research Results", *EIPR,* 1989, p. 47.

[12] MARTIN ADELMAN/ RANDALL RADER /JOHN R. THOMAS, *Cases and Materials on Patent Law,* 3ª ed., West, St. Paul, 2009, p. 25; VIRGILIO D`ANTONIO, *Invenzioni biotechnologiche e modelli giuridichi: Europa e Stati Uniti,* Napoli, Jovene editore, 2004, pp. 289 y ss.

[13] JANICE MUELLER, *Patent Law,* 3. Ed., Austin, Boston, Chicago, New York, The Netherlands, Wolters Kluwer, 2009, pp. 287 y ss.

[14] (1980) 206 USPQ, 193. See MANUEL BOTANA AGRA, "El Tribunal Supremo Norteamericano se pronuncia a favor de la patentabilidad de los microorganismos", *ADI*, 1979-1980, p. 421.

[15] (1985) 227 USPQ 443. See NOEL BYRNE, "Patents for Plants, Seed and Tissue Cultures", *IIC,* 1986, p. 324.

Also in Germany a positive development of the jurisprudence towards the patentability of new inventions regarding plant varieties and animal breeding can be appreciated[16]. In its *Red Dove*[17] decision, the Supreme Court departed from the historical interpretation of the concept of patentable inventions, and gave a more dynamic definition, open for the future developments. It stated that "*Invention is a basic concept in the field of law having as its most important task encompassing the patentable results of the most recent states of science and of research. Therefore the intent of the Patent Act itself not only permits but even compels taking into account the latest state of scientific knowledge to interpret the concept of invention...".* However, while in theory the opportunity to patent animal matter was possible, the Court held in that case that every invention had to fulfil a "repeatability requirement", and this had not been fulfilled in this case[18]. As regards to plants it is important to take into account that patent protection is possible for those plant varieties that do not comply with the requirements of the Plant Variety Act, i.e. plant varieties that belong to a taxon of a higher rank than the variety, such as a specie, family, etc. In 1987, for example, the German Patent Office granted a patent for a "Tomoffel" ("Topatoe"), a plant created by means of a successful and repeatable fusion of tomato and potato protoplasts, on the grounds that it was a new plant genus.[19]

In the European legislation, the starting point is Article 52 EPC, which states in its first paragraph that "*European patents shall be granted for any inventions which are susceptible of industrial applications, which are new and which involve an inventive step".* Therefore, it opened the door for the patentability of biotechnological inventions.

As regards the patentability of plant innovations, Article 53 b) EPC excludes for patentability "*plants or animal varieties or essentially biological processes for the production of plants and animals*". But, after this general statement, it contains in its second clause an exception to that exclusion related to "*microbiological processes or the products thereof*".

The same solution was adopted by the Spanish legislator. Art.5.2 of the Spanish Patent Act of 1986[20] reproduced almost literally Art.53 of the EPC and it didn't contain a general prohibition of patentability of all plant varieties, but only for those that can be protected by the Plant Variety Protection Act of 12 March 1975, later replaced by the Plant Variety Protection Act 3/2000, of 7. January[21]. Article 5.2 of the new Spanish Patent Act of 24. July 2015[22] reproduces the same exclusion from patentability, but extended it to plant varieties of all genres as far as all are protected by the Plant Variety Law according to the UPOV 1991.

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[16] JOSEPH STRAUS, *Gewerblicher Rechtsschutz für biotechnologische Erfindungen,* op.cit., pp. 49 y ss.; RAINER MOUFANG, *Genetische Erfindungen im gewerblichen Rechtsschutz,* Köln, Berlin, Bonn, München, Carl Heymanns Verlag KG,1988, pp. 81 ff.
[17] Federal Supreme Court decision of March 27, 1969, *IIC,* 1970, p.136 ("Rote Taube" - Red Dove).
[18] ROBIN NOTT, "Patent Protection for Plants and Animals", *EIPR*, 1992, p. 79.
[19] Examined Patent Application Nº P 2.842.179.6. JOSEPH STRAUS, "The relationship between Plant Variety Protection and Patent Protection for Biotechnological Inventions from an International Viewpoint", *IIC,* 1987, p. 729.
[20] Ley 11/1986, de 20 de marzo. (BOE Nº 73, de 26 de marzo).
[21] Ley 3/2000, de 7 de enero, de régimen jurídico de la protección de las obtenciones vegetales (BOE núm. 8 de 10 de Enero de 2000).
[22] Ley 24/2015, de 24 de julio, de Patentes (BOE núm. 177 de 25 de Julio de 2015)

Notwithstanding these developments toward patent protection for the new inventions on living matter in general, and on plants in particular, different arguments have arisen against it. Criticism has been strong regarding the patentability of inventions on human elements, due to the ethical concerns on the matter[23]. But also the patentability of plant innovations has been sharply criticized[24]. The arguments against it can be summarised as follows:[25]

> a) Industrial property rights should not be granted to any life form whatsoever and, neither to plant varieties constituting an essential step in the food production process. Additionally, many people consider that it may result in the exploitation of developing countries which would proportionate the substantial material to have a new variety but, due to the lack of technical means, they would depend on foreign multinationals to profit from them[26].
>
> b) The process of selection of a plant variety addresses an obvious objective with known technology and does not represent an inventive step.
>
> c) The absence of an enabling disclosure. It is suggested that it is impossible to so describe a process of selection of a specific variety, that a person skilled in the art could repeat the selection of the same variety.
>
> d) Since plant varieties are frequently capable of self-replication, a patentee's rights would be exhausted after the first sale and would not extend to subsequent replication, so that a patent on a plant variety is an ineffective form of protection.

Notwithstanding these objections, at the international level Article 27 of the TRIPS Agreement states that "*…patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*".

Therefore, the European legislator tried to adapt the patent system of the different Member States to the new developments in the field of biotechnology through a specific legal instrument, which finally was approved in 1998 as the Directive 98/44/EC of the European Parliament and of the Council, of 6 July 1998, on the legal protection of biotechnological inventions[27] [28].

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[23] NUFFIELD COUNCIL ON BIOETHICS, "The ethics on patenting DNA. A discussion paper", Nuffield Council on Bioethics, 2002; RAINER MOUFANG, "Patenting of Human Genes, Cells and Parts of the Body? The Ethical Dimensions of Patent Law", *IIC*, 4/1994, p. 487.

[24] HANS NEUMAIER, *Sortenschutz und/oder Patentschutz für Pflanzenzüchtungen,* Köln, Berlin, Bonn, München, Carl Heymanns Verlag KG, 1990, p. 67.

[25] SERGIO SERMON, *The impact of the UPVO 1991 Act upon seed and production and research,* Scotland, University of Edinburgh, 1995, p. 22. *Also* RAINER MOUFANG, "Protection for Plant Breeding and Plant Varieties- A Frontier of Patent Law"*, IIC,* 1992, p. 328.

[26] In this regard, it is considered that the seeds developed by new technology hold a great promise in agriculture for developing countries but they are more suited for developed market economy. It is an expensive technology, which has the potential of social and economic dislocation for developing countries by giving the monopoly rights over the propagating material to the breeder, leading to high prices. SITANSU KUMAR VERMA, "TRIPs and plant variety protection in developing countries", *EIPR*, 1995, p. 289.

[27] OJ L 213, 30.7.1998, pp. 13–21.

[28] The legal history of the Biotechnological Directive is a long and complicated one. Since the publication of the first Proposal in 1988, it was amended several times by the European Parliament and the Council, following the codecision procedure (Art.189B EC Treaty). The most controversial issues were the patentability of human genome and the ethical considerations involved in it. On 23 January 1995 an agreement was reached on this point by the Conciliation Committee: elements of the human body may not be patentable as such, but they can be patented when they form part of an industrial invention and are modified in such a way that they are no

In order to explain the provisions contained in the Directive, special attention should be paid to its recitals. They highlight the differences existing in the legal protection of biotechnological inventions offered by the laws and practices of the Member States and the necessity to assure them an adequate protection due to the economic importance of the matter. But they consider that the legal protection of biotechnological invention can be achieved by adaptation of the existing patent law in order to acknowledge the patentability of new technological developments which may involve biological material and fulfil the requirements for patentability.

Therefore, the Directive is conceived mainly as a bundle of guidelines that have to be used in order to interpret the traditional patent laws to include the protection for the biotechnological innovations.

It is important to highlight that, although it was not compulsory, the main principles contained in the Directive were included in the European Patent Convention system through the reform of its Implementing Regulations by the Decision of the Administrative Council of 16 June 1999[29]. According of Rule 26 (1) of these Implementing Regulations[30] "*for European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation*".

2.2. Patentable subject-matter: The concept of invention

The European Patent Convention does not define the concept of invention[31]. On the contrary, Article 52, in its second paragraph, establishes a non-exhaustive enumeration of matters that are not considered inventions, and it expressly excludes from patentability "*discoveries, scientific theories and mathematical methods*".

In this sense it has been argued that, as far as products to which new biotechnological techniques are applied, are already existing in nature, they cannot be the object of a monopoly right granted by a patent, because they are not inventions but mere discoveries. Therefore, a clear distinction between "invention" and "discovery" should be established to criticise this argument.

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longer directly linked to an individual. Nevertheless, the Proposal was surprisingly rejected by the European Parliament (with a clear majority of 240 votes against 188 in favour with 23 abstentions). A new proposal much stricter as regards patentability of human genome and ethical problems existing on the matter, was then summitted by the Commission to the Council on 13 December 1995 and it was finally approved in 1998. For further detail about the legislative history of the Rejected Proposal of Biotechnology Directive, see GERALD KAMSTRA/ MARK DÖRIGN/ NICK SCOTT-RAM/ ANDREW SHEARD/ HENRY WIXON, *Patents on Biotechnological Inventions: the EC Directive,* London, Sweet & Maxwell, 2002, pp. 2 ff.

[29] JO OEB 7/1999, p. 437.

[30] Last modified by Decision of the Administrative Council of 25 March 2015 approving amendments to the Rules of Procedure of the Enlarged Board of Appeal of the European Patent Office.

[31] JUSTINE PILA, *The Requirement for an Invention in Patent Law,* Oxford, Oxford University Press, 2010, p. 5.

Traditionally "*invention*" has been defined as a final resolution of a given problem by technical means, whereas "*discovery*" is the finding or knowledge of regularities, causal relations, characteristics or phenomena that were until then unknown but existed before in Nature. Therefore, *discovery is a pure knowledge whereas invention is an applied knowledge*[32]. But this distinction, even if theoretically clear, becomes problematic when it should be applied to each concrete case, because it is obvious that many inventions are founded on some acquired knowledge on nature[33].

It should be considered that the concept of patentable invention must be progressively adapted to new investigation techniques[34]. In the present state of the art the elaboration of new inventions requires a previous investigation process, long and expensive. This is particularly true in the case of biotechnology. Even if biological material exists in nature, its knowledge is achieved by expensive investigation processes. The question is, if this material can be considered as an invention that complies with the novelty requirement or as a mere discovery, and consequently not patentable. The increasing economic importance of the investments in the field of biotechnological research and the pressure of the sectors concerned have led to a positive approach about the question of patentability of such biological discoveries. The literal wording of the legal provisions has not changed but it is interpreted by the authorities as to grant protection to the new biological inventions trying to balance public interests and free availability on one hand and the fostering of developments in this field on the other. It is undeniable that the scope of protection afforded to products of nature depends, to a greater extent than in other technological fields, on how broadly or how narrowly the boundaries defining this field will be drawn by the courts.[35] In this regard the exam directives of the EPO admit the patentability not only of the process to obtain a substance but also of the substance as such if it is found in nature, the process to obtain it is established and is sufficiently characterised by its structure, the obtention process or by other parameters[36].

Taking into consideration this new approach of the concept of invention, the resolutions given as regard patentability of living matter by the USA and European Patent Offices become more understandable. In this regard, in Europe it is important to take into consideration some relevant cases such as the *Ciba-Geigy* case[37] in which some plant

[32] FRIEDRICH-KARL BEIER, "Resultados de la investigación, Derecho de patente e innovación", *ADI,* 1974, p. 14.
[33] PHILIP W.GRUBB, *Patents for Chemicals, Pharmaceuticals and Biotechnology. Fundamentals of Global Law, Practice and Strategy,* 5. Ed., Oxford University Press, 2010, p. 70.
[34] CHRISTINA GATES, "Patenting the Life Sciences at the European Patent Office", in SALIM MAMAJIWALLA/ ROCHELLE SEIDE (Eds), *Intellectual Property in Molecular Medicine,* New York, Cold Spring Harbor Laboratory Press, 2015, p. 37.
[35] JASPER UTERMANN, "Reflections on Patent Protection of Products of Nature- Part One", *IIC,*1978, p. 413.
[36] In parallel the Court of Appeals for the Federal Circuit decided in *In re Deuel* (Court of Appeals Federal Circuit decision 28 March 1995, USPQ 34, 1210) that newly retrieved DNA sequences from their correspondent amino acid sequence were non-obvious, regardless of the retrieval method used, and therefore it were considered as patentable. For a negative opinion about this decision, see PAUL DUCOR, "In re Deuel: Biotechnology Industry v Patent Law?", *EIPR,* 1996, p. 35. The author basically argues that while there are some policy grounds to afford legal protection to DNA sequences obtained from amino acid counterparts, there are other good policy reasons to award patents only to non-obvious subject-matter. The non-obviousness requirement has been very controversial in EEUU practice because different criteria have been established throughout the years. See JANICE MUELLER, *Patent Law,* cit., pp. 217 ff.
[37] T49/83 EPOR 3/1984,112. (*IIC*, 1986,123

innovations were considered as patentable subject-matter, or the problematic *Harvard/Onco Mouse*[38] decision in which a patent was granted for the protection of a process to produce trans genetic animals and for the own animal wearing a cancerigenous gen. More discussions undoubtedly have arisen in respect of the patentability of the human genome[39].

Patentability of living matter has been expressly affirmed in the Directive on Biotechnological Inventions. Article 3 of the Directive states that "*1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. 2. 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 it defines '*biological material*' as "*any material containing genetic information and capable of reproducing itself or being reproduced in a biological system*" (Article 2.1 a) Biotech Directive)

On the other hand, several ethical considerations are presented against the patentability of living matter. In this regard it has been argued that patents on living material is clearly contrary to the "*ordre public*" and morality, and they cannot be granted based on Article 53(a) EPC[40]. It is said that living material forms part of the common heritage of mankind and they should be freely available and not owned by any individual or group. Aligned with this argument is the contention that patenting living material would have the effect of depleting biological diversity and this would be contrary to the principle of moral responsibility. The EPO had to face especially these kinds of arguments in the *Harvard/Onco mouse* case. It solved the question by stating that a balance must be made to grant a patent on living matter between the benefit that can result for mankind by protecting the technological inventions that encourage further investigations in the field, and the detriment caused to the environment by granting the patent. In the *Greenpeace v Plant Genetic Systems NV*[41] case, the Technical Board of Appeal concreted these affirmations. On the one hand it expressed that the concept of morality that must be taken into consideration is not a national but a European one. Therefore, the question whether man should be allowed to own life has to be assessed according to acceptable European moral norms. On the other hand, it stated that to do the balance benefit/detriment, only a seriously prejudice to the environment must be taken into consideration.

[38] 1990 EPOR 501. (*IIC*, 1991, 74).
[39] Considering that the purpose of this paper is the analysis of the legal protection provided for plant varieties, we will concentrate our efforts on the determination of the scope of the prohibition about them. To have a general overview of the practice of the EPO as regards patentability of microorganisms, see HANS REINER JAENICHEN/ JÜRGEN MEIER/ LESLIE A. MCDONELL/ JAMES F. HARLEY JR./ YOSHINORI HASODA, *From Clones to Claims,* 6 ed., Carl Heymanns Verlag, 2016, pp. 2 ff; HAROLD C. WEGNER, "Patenting Nature's Secrets- Microorganisms", *IIC*, 1976, p. 235 and MANUEL BOTANA AGRA, "La patentabilidad de las invenciones microbiológicas", *ADI*, 1979-1980, p. 29.
[40] OLIVER MILLS, *Biotechnological Inventions: Moral Restraints and Patent Law,* Ashgate, Aldershot, 2005, pp. 19 ff.; MANUEL BOTANA AGRA, "Buenas costumbres y Derecho de patentes", in AAVV, *Estudios sobre Derecho Industrial. Homenaje a H. Baylos,* Grupo español de la AIPPI, Barcelona, 1992, p. 86.
[41] T356/93 (1995) EPOR 357.

3. The patentability of plant innovations

3.1. Non-patentability of plant varieties "*per se*"

As far as the patentability of plant varieties is concerned, the starting point is the legal prohibition contained in Article 53(b) EPC. As already pointed out, in its first clause this article excludes from patentability "*plants or animal varieties or essentially biological processes for the production of plants and animals*". After this general statement, it contains, in its second clause, an exception to that exclusion related to "*microbiological processes or the products thereof*".

In order to define the scope of this exclusion of patentability a precise definition of the "plant variety" seems appropriate.

a) The concept of plant variety

There is a lot of uncertainty about the concept of "*plant variety*". In common use it is understood as a kind or type of a concrete plant. But to scientific sectors it has a more specialised and complex meaning.

Although it would have been advisable to have a strict definition of the term in order to be applied in its specific system of protection, legislators at all levels, national and international, did not paid much attention to the question when the specific protection for breeders' rights was first issued. This can easily be explained if one thinks that it is not a legislator's competence to give a scientific definition, which would moreover be very difficult for him due to the normal lack of adequate knowledge. Another reason can be that at the date of elaboration of the law about plant varieties there was a common understanding about what should be understood under plant variety and it was considered enough to refer to it.

Article 2(2) of the original version of the UPOV Convention stated that "*For the purposes of this Convention, the word "variety" applies to any cultivar*[42]*, clone*[43]*, line*[44]*, stock or hybrid*[45] *which is capable of cultivation and which satisfies the provisions of sub-paragraphs 1(c) and*

[42] The "cultivar": It is the more fundamental taxonomic unity. It consists of a group of cultivated plants that present certain characteristics (morphologic, physiologic, cytological, chemical or others) different from the others and that whenever reproduced (by sexual or vegetative reproduction) maintain such special characteristics. The sexual reproduction consists in the fusion of two reproduction cellules (gametes) in order to form a single one (zygote). Each gamete brings its own genetic chromosomic material that are homologue, which means that each gene brought by a gamete male has its correspondent gene brought by the gamete female. If in each cellule these two genes are equal the individual is said to be homozygous. If they are different, the individual is called heterozygous.
[43] The "clone": It is the genetically homogeny group of individuals heterozygous born from a single individual (plant or part of a plant) by asexual reproduction. The asexual reproduction consists in the division of one cell in two of the same size and containing the same structural elements and chromosomic material.
[44] The "strain": This is the group of descendants of one plant autofecunded. A cultivar can consist in one or more similar lines of individuals.
[45] The "hybrid": The variety consists of the group of individuals born from the same parental lines fixed and stable and following a controlled process of fabrication.

1(d) of Art.2[46]*"* (These sub-paragraphs dealt with homogeneity and stability)[47]. The words used did not give certainty of scope, but it was considered enough at that moment. The important criteria for operation of the plant variety right system were those of distinctness, uniformity, and stability (DUS), and whatever could be shown to have DUS would be the precise subject of legal protection[48].

This paragraph was in force when the European Patent Convention (EPC) came into being in 1973. In Article 53(b) plant varieties as such were excluded from patentability and it seemed that in principle no problems would arise: Plant Varieties as such couldn´t be protected by patents, but if they comply with the requirements of distinctness, uniformity and stability they could be protected under Plant Variety Law. On the other hand, "*innovations which cannot be given the protection afforded to varieties are still patentable if the general prerequisites are met"*[49]*.* No definition of Plant Variety is contained in the EPC because it was clearly determined by reference to the concept stated in the UPOV Convention.

But new developments in biotechnology innovation have shown that this pragmatical approach is no longer valid and that there can be cases in which an effort of interpretation is required by the concerned authorities to settle if a plant innovation is excluded from patentability because it is a plant variety[50].

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[46] The "synthetic varieties": They are born from selected lines or clones, genetically different but morphologically equal, that are planted together and that are fecunded inter se. The identity of the variety is preserved by limiting the number of generation multiplication.
-The "population varieties": they are species of crossed fecundation, whose characteristics are achieved by a selected manipulation of the environmental means.

[47] This definition of UPOV Convention of 1961 was followed by most of national acts that established same system of protection for plant varieties at national level. In this sense, Art.2 of the Spanish Act 12/75 of 12 March 1975 is almost a literal copy of Art.2 (2) quoted. According to it Art.2: *"In order to apply the present Act, "plant variety" is to be understood as any commercial variety (internationally known as "cultivar"), clone, line, stock or hybrid that complies with the conditions established in the present act".*

[48] R. STEPHEN CRESPI, "Patents and Plant Variety Rights: Is there an Interface Problem?", *IIC*, 1992, 169 at 173.

[49] In the *Ciba-Geigy* case (T49/83 EPOR 3/1984, 112. (*IIC*, 1986, 123)), examined below, the Technical Board of Appeals held that *"Art. 53(b) prohibited only patenting of plants or their propagating material in genetically fixed form of the plant variety*", and that *"The skilled person understands the term "plant varieties" to mean a multiplicity of plants which are largely same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle (...) Plant varieties in this sense are all cultivated varieties, clones, lines, strains and hybrids which can be grown in such a way that they are clearly distinguishable from other varieties, sufficiently homogeneous, and stable in their essential characteristics (Art. 2(2) in conjunction with Art. 6 (1) (a), (c) and (d)). The legislator did not wish to afford patent protection under the European Patent Convention to plant varieties of this kind, whether in the form of propagating material or of plant itself. (...) it is perfectly sufficient for the exclusion* (from patentability) *to be left restricted, in conformity with its wording, to cases in which plants are characterised precisely by genetically determined peculiarities of their natural phenotype. In this respect there is no conflict between areas reserved for national protection of varieties and field of application of the EPC. On the other hand, innovations which cannot be given the protection afforded to varieties are still patentable if the general prerequisites are met".*

[50] There are different possibilities of innovations related to the processes and products as regard to plants. A distinction should be made between developments that affect the whole plant, that essentially correspond to the traditional breeding processes, and those that are applied to the vegetal cells, that are the modern innovations.
Among the processes that affect the whole plant, it is important to consider:
— Treatment techniques: These are the different methods of treatment applied to the plant or to the means in which they are developed, in order to stimulate their growing, to increase their efficiency, but without intervening at genetical level. These are, for example, culture processes, treatment with pesticides and therapeutical, cosmetic and chirurgical treatment applied to plants.
— Multiplication techniques that consist of the fragmentation of the plant in parts that will form a new plant by its own or in combination with parts of another plant. These are techniques of bouturage, marcotte or greffage.
-Selection techniques that consist of selection of those plants that present the searched characteristics and elimination of those that are further away from the ideal type. These operations are repeated during several generations in order to get the specific variety that is looked for.
— Hybridisation techniques: They consist of crossing of different plants by greffage or by artificial fecundation.

Legislators have tried to be more precise regarding the concept of plant variety. Art.1 of the UPOV Convention, as revised in Geneva on 19 March 1991, after establishing that protection extends to all genera and species[51], gives a more complete definition of "plant variety". It states that *"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:*

> *— defined by the expression of characteristics that results from a given genotype or combination of genotypes,*
>
> *— distinguished from any other plant grouping by expression of at least one of the said characteristics,*
>
> *—considered as a unit with regard to its suitability for being propagating unchanged".*

This definition was later taken in Council Regulation (EC) Nº 2100/94, of 1 September 1994, on Community plant varieties. It is without doubt more scientifically precise. The change is very important and it is possible that patent case law of the European Patent Office has provided a great deal of motivation for this move.

Nevertheless, it is considered by some authors that to equate the term "variety" with "UPOV-protectable variety" was not a good solution and that it cannot avoid the problem of clearly defining the limits of both systems of protection. As some authors affirm, "(…) *an incipient variety which had not reached the DUS standard and would not qualify for UPOV type protection might be presented for patent protection and, on case law, could presumably not be refused. But plants which do not fully meet criteria necessary for plant breeders' rights do not* ipso facto *become protectable by patent. Failure to meet plant breeders' rights criteria is a purely negative factor which has nothing to do with positive requirements of inventive step and other criteria of patent law. It was a groundless fear that attempts could be made to patent "*failed*" varieties in order to dominate fully-fledged varieties which are later developed from these precursors and which then qualify for plant breeders' rights*"[52].

— Artificial mutations: When some mutagens agents (natural or chemical substances) are applied to grains, grains of pollen or to the whole plant some hereditary variations can be achieved.
At cellular level, some very new techniques are used in order to affect the reproduction process:
—Techniques without genetical modifications:
In vitro clonage
In vitro fertilisation
Culture of embryos
— Techniques of genetic manipulation:
Protoplasm fusion
Recombinant DNA
They all consist in manipulation of plant cells or plant tissues in order to modify the phenotypic and genotypic characteristics of the whole plant in a previously determined manner and to obtain varieties more resistant to certain diseases, hybrids, reproduction achieved in shorter time, etc. These processes are, without doubt much more complicated than traditional breeding processes and require the creation of very sophisticated installations and therefore great investments. It has been argued that these processes, and the products resulted from them, require another kind of protection than that conferred traditionally to breeding processes and resulting plant varieties.

[51] At the beginning the Plant Protection Acts were applied exclusively to certain species that were enumerated in the corresponding Annexes.

[52] R. STEPHEN CRESPI, "Patents and Plant Variety Rights…", *op.cit.*, p.176.

In order to define the plant variety some technical remarks should be made in this part, notwithstanding that we won't go into very deep detail[53].

We must work on the basis that there can be genetic variations among members of the same species that means a population of organisms that present a genetic "lien". A distinction has to be made between genetic variations (hereditary) and variations achieved during the existence of an organism under the influence of some external factors; in this case the characters achieved only correspond to variations in the expression of potentialities of the organism and they are not transmitted to following generations, except in case of stable mutations.

On the other hand we should distinguish between variations that affect the appearance of an individual in all aspects (anatomic, physiologic, psychic) and which constitute the *phenotype* of the individual, that results from a co-operation between all chromosomic genes, the extra chromosomic genetic material and the environment in which the organism is established; and variations that affect the genetic material of the individual that constitutes the *genotype.*

All members that belong to the same species and present the same variations, temporary or hereditary, phenotypical or genotypical, will constitute a variety of the specie, which means a taxon much lower than the specie[54]. Consequently, a plant variety, independently on the fact that it can be protected because it complies with the requirements to get legal protection or not, will be a group of plants of the same species that present the same characteristics. But in order to get protection under the special title of Plant Variety Protection, external expression of the genetical modifications that results in the variation of their natural phenotype and a certain degree of stability, uniformity and distinctness are required[55].

b) The exclusion of plant varieties from patentability in European Patent Law

The general analysis of the practice of the EPO in this sense leads to the conclusion that the concept of plant variety considered in order to apply the exclusion from patentability is that expressed in the UPOV Convention and, as far as the claimed material does not satisfy the requirements expressed in this Convention, there are no obstacles to be protected by a patent when the requirements for patentability are fulfilled[56].

[53] See BENHARD BERGMANS, *La protection des innovations biologiques. Une étude de Droit Comparé*, Brussels, Maison Larcier, 1991, p. 31.
[54] Taxon is each unit used by the Science of Classification or Taxonomy. Traditionally seven different taxons have been used: regnum, division, class, order, family, genre and species.
[55] Art.5 of Council Regulation (EC) Nº 2100/94
[56] M. MERCEDES CURTO POLO, "La protección de las invenciones biotecnológicas (Especial referencia a la coexistencia de patentes y títulos específicos en relación con las obtenciones vegetales)", *RGD,* nº 642, 1998, p. 146.

In the *Ciba-Geigy* case in 1983 the Technical Board of Appeals stated that Article 53(b) EPC prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety. In this case claims were related to "*propagating material for cultivated plants treated with an oxime derivative according to an expressed formula*" (Claim 13) and to "*propagating material according to claim 13 characterised in that it consists of seed*" (Claim 14). The Board held that "*propagating material from such cultivated plants comprises all reproductive plant components, including plants and plantings, which have begun to be germinated, but particularly seeds. Even if certain known varieties of wheat, millet and barley are mentioned in the example in connection with oxime treatment, the subject matter of claims 13 and 14 is not an individual variety of plant distinguishable from any other variety, but the claims relate to any cultivated plants in the form of their propagating material which have been chemically treated in a certain way"*. Therefore, the Board granted a patent to propagating material, in particular seeds, of cultivated plants treated with a chemical process in order to make it resistant to agricultural chemicals, because it did not consider such propagating material as a plant variety defined in Art.2(2) of the UPOV Convention.

But it is important to consider that in this case there was no claim of the plant treated by chemical agents, but only of the propagating material. On the contrary in the *Lubrizol* case[57] the claim contained not only a method to produce hybrid seeds, but also the seeds and the plants derived from them. The Board considered the concept of "*plant varieties*" and supported the decision of the Technical Board of Appeal in the *Ciba-Geigy* case. It considered that a multiplicity of plants which are largely the same in their characteristics (homogeneity) and remain the same within specific tolerances after every propagation cycle (stability) would be a prerequisite for a "*plant variety*". When at least one of the parent plants used as a source for the whole processes was heterozygous[58], and it would never breed true, it appeared that the claimed hybrid seeds or plants, considered as a whole generation population, was not stable in the sense of the above definition and therefore could not be considered as a "variety". Accordingly, the claimed material was not a "variety" and the patent was granted.

In the *Plant Genetic System* case in 1995[59] the claim was referred to a plant which had been genetically modified in order to make it resistant to the Herbicide "Basta". This genetic modification remained unaltered after successive reproductions. The question was if this plant was a plant variety. The EPO considered it was so, as far as "*…in the Board's judgement, the concept of "plant variety" under Article 53 b) EPC, first half-sentence, refers to any plant grouping within a single botanical taxon of the lowest-known rank which, irrespective of whether it would be eligible for protection under the UPOV Convention, is*

[57] T 320/87 EPOR 3/1990, 71. (*IIC*, 1990, 361).
[58] The sexual reproduction consists in the fusion of two reproduction cellules (gametes) in order to form a single one (zygote). Each gamete brings its own genetic chromosomic material that are homologue, which means that each gene brought by a gamete male has its correspondent gene brought by the gamete female. If in each cellule these two genes are equal the individual is said to be homozygous. If they are different, the individual is called heterozygous.
[59] T356/93, Plant cells, 21. February 1995.

characterised by at least one single transmissible characteristic distinguishing it form other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics…".

This decision was very much criticised as long as it is generally acknowledged that a plant variety cannot be characterised by only one gene, even if stable after reproduction, but by all the whole genome which determines its phenotype. Therefore, a plant grouping characterised by having only one gene in common should be a patentable invention if it complies with the patentability requirements.

This Decision was later overruled by the Enlarged Board of Appeal in the *Novartis/ Transgenic Plants* case[60]. According to this Decision, "*The definitions in Article 5(2) of the EC Regulation on Community Plant Variety Rights as well as under Rule 23b (4) EPC, which entered into force on 1 September 1999, are identical in substance. The reference to the expression of the characteristics that results from a given genotype or combination of genotypes is a reference to the entire constitution of a plant or a set of genetic information (…).In contrast, a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed (…). It is not a concrete living being or grouping of concrete living beings but an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part. As described in more detail in the referring decision, the claimed transgenic plants in the application in suit are defined by certain characteristics allowing the plants to inhibit the growth of plant pathogens (Reasons, point 11, Annex I, point 8). The taxonomic category within the traditional classification of the plant kingdom to which the claimed plants belong is not specified, let alone the further characteristics necessary to assess the homogeneity and stability of varieties within a given species. Hence, it would appear that the claimed invention neither expressly nor implicitly defines a single variety, whether according to the definition of "plant variety" in Article 1(vi) of the UPOV Convention 1991, or according to any of the other definitions of "plant variety" mentioned above. This also means that it does not define a multiplicity of varieties which necessarily consists of several individual varieties. In the absence of the identification of specific varieties in the product claims, the subject-matter of the claimed invention is neither limited nor even directed to a variety or varieties*"[61] [62].

[60] G 1/98, *Transgenic Plants/ Novartis II*, 20 December 1999.

[61] And it states also that "*(…) the subject-matter of a claim covering but not identifying plant varieties is not a claim to a variety or varieties (see above point 3.1). It follows that such an invention cannot be protected by a plant breeders' right which is concerned with plant groupings defined by their whole genome but not by individual characteristics (Greengrass, Recent Phenomena in the Protection of Industrial Property, Plant Variety Protection No. 57, 1989, page 28, at page 57). Whereas in the case of a plant variety, the breeder has to develop a plant grouping fulfilling in particular the requirements of homogeneity and stability, this is not the case with a typical genetic engineering invention in a claim such as that referred to in question 2. The inventor in the latter case aims at providing tools whereby a desired property can be bestowed on plants by inserting a gene into the genome of those plants. Providing these tools is a step which precedes the further step of introducing the gene into a specific plant. Nevertheless, it is the contribution of the inventor in the genetic field which makes it possible to take the second step and insert the gene into the genome of any appropriate plant or plant variety. Choosing a suitable plant for this purpose and arriving at a specific, marketable product, which will mostly be a plant variety, is a matter of routine breeding steps which may be rewarded by a plant breeders' right. The inventor in the genetic engineering field would not obtain appropriate protection if he were restricted*

Some conclusions can be extracted from these cases as regard the interpretation given by the EPO to the content of the prohibition of art.53 (b) in respect of plant varieties:

> — The legal concept of "plant variety" in art.53 (b) is the concept established in the UPOV Convention, because the aim of the exclusion was to avoid double protection by patent and plant breeders' rights of certain innovations.
>
> — The UPOV concept includes those plants that have equal characteristics (homogeneity) that remain invariable after each reproduction cycle (stability) and which derive from the whole genotype or combinations of genotypes.
>
> — Therefore, if a plant does not comply with these requirements it is patentable if all the requirements for patentability are fulfilled.

These conclusions have been codified in the Directive on the patentability of Biotechnological inventions. On the one hand, it expressly refers to the concept of "plant variety" established in the Plant Variety Protection System. In this regard, Article 2.3. of the Directive states that "*the concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94*". On the other hand, article 4 of the Biotech Directive, after excluding from patentability plant and animal varieties, and essentially biological processes for the production of plants or animals, affirms the patentability of "*inventions which concern plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety*" and "*inventions which concern a microbiological or other technical process or a product obtained by means of such a process*".

Furthermore, in Recital 29 the Directive states that "*(…) inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety*". And in Recital 31 explains that "*(…) a plant grouping which is characterised 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*".

Therefore, it is clear that the exclusion of patentability of plant varieties should be understood in a strict sense. Only claims referred to the patentability of plant varieties should be rejected, but not when the claim refers to a plant grouping, of a higher taxon, even if it comprises one or more plant varieties, or to a plant innovation which is the result of a microbiological process. Nevertheless, in this case some problems of coexistence of patents

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to specific varieties for two reasons: first, the development of specific varieties will often not be in his field of activity and, second, he would always be limited to a few varieties even though he had provided the means for inserting the gene into all appropriate plants".

[62] ANDREAS HÜBEL, "The Limits of Patentability: Plant Biosciences", in ANDREAS HÜBEL/ ULRICH STORZ/ ALOYS HÜTTERMANN, *Limits of Patentability,* Heidelberg, New York, Dordrecht, London, Springer, 2013, p. 3.

and breeders' rights could arise. The Directive has tried to overcome them through a system of compulsory licences[63].

3.2. Non-patentability of essentially biological processes

In the *Lubrizol Case* the question of the patentability of essentially biological processes was also dealt with. Claim 1 was for "*a process for rapidly developing hybrids and commercially producing hybrid seeds, comprising:*

> *(a) selecting a first heterozygous parent plant and selecting a second parent plant;*
>
> *(b) crossing said first parent plant with said second parent plant to obtain original-parent-derived hybrids that are phenotypically uniform;*
>
> *(c) cloning said first parent plant to produce a first cloned parental line;*
>
> *(d) crossing plants of said first cloned parental line with said second parent plant or with a second parental line produced therefrom to obtain hybrid seeds which yield hybrids that are phenotypically uniform, provided that when said second parent plant is heterozygous and a second parental line produced therefrom is used in the crossing of step (d), said second parental line must be produced by cloning; and*
>
> *(e) repeating steps (c) and (d) as required to obtain hybrid seed that yields phenotypically uniform plants from seed*".

The Technical Board of Appeal confirmed that the words "*essentially biological*" in art.53(b) EPC had to be narrowly construed and had to "*be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved*". Traditionally, in order to measure this intervention, quantitative and qualitative criteria were taken into consideration. But the Board considered that it was not enough to know the quantitative or qualitative aspects of the human intervention, but that attention should be paid to the essence of the invention, considering the effects of human intervention in the result achieved. This can easily be explained if we consider that even though the human intervention is quantitatively important (as in the classical methods of plant breeding), or qualitatively relevant (as in the new biotechnological innovations), the process will be essentially biological if the technical rule depends on biological factors that human beings cannot control[64].

In that case the Board considered that the human intervention in relation with the very essence of the invention was relevant and patentable: *"In the present case, which presents a multi-step process, each single step as such may be characterised as biological in a scientific*

[63] See Article 12 of the Directive.
[64] JOSÉ ANTONIO GÓMEZ SEGADE, "La falta de patentabilidad de los procedimientos esencialmente bilógicos", *Cuadernos CEFI*, Nº7, p. 13.

sense. However, instead of the traditional approach of creating a single new crossing first and trying to propagate the individual result afterwards, the specific arrangement of the steps provides a process with a reversed sequence; (...) This arrangement of steps is decisive for the invention and permits the desired control of the special result in spite of the fact that at least one of the parents is heterozygous. The facts of the present case under appeal clearly indicate that the claimed processes 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 in the present case show important technological character"[65].

In the *Plant Genetic System* case, the Board of Appeal affirmed that "*a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result (…) does not fall under the exceptions to patentability under Article 53 b) EPC, first half-sentence*"[66].

It can be stated that the purpose of the EPC legislator was to exclude from patentability the traditional processes for the breeding of plants, but not other technical processes, included microbiological processes, that are inventive and new, and therefore that could be patented[67].

The distinction between microbiological processes that are patentable (Art.53 (b) EPC) and essentially biological processes, not patentable, is dealt with in Article 2 of the Directive on Biotechnological inventions. Article 2.1. b) defines the '*microbiological process*' as "*any process involving or performed upon or resulting in microbiological material*"[68]. On the other hand, it states that "*A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection*" (Article 2.2. of the Directive).

The same provision is contained in Rule 26 (5) of the Implementing Regulations of the EPC, according to which "*a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection*".

This definition of "*essentially biological processes*" has caused a great controversy in recent times, due to the fact that nowadays it is quite usual that processes for innovation in plants combine molecular techniques and traditional breeding practices. In fact, the use of

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[65] BEGOÑA CERRO PRADA/ NURIA URQUÍA FERNÁNDEZ, "En torno a la patentabilidad de los híbridos vegetales: el caso Lubrizol", *RGD*, 1992, p. 1855. Also CARLOS LEMA DEVESA, "El Convenio Europeo de Munich ante la protección de nuevas tecnologías", *AC*, 1993, p. 605. ROBIN NOTT, "Patent Protection for Plants and Animals", *EIPR,* 1992, p. 79.

[66] LI WESTERLUND, *Equivalence and Exclusions under European and U.S. Patent Law,* The Hague, London, New York, Kluwer Law International, 2002, p. 311; GERALD KAMSTRA/ MARK DÖRIGN/ NICK SCOTT-RAM/ ANDREW SHEARD/ HENRY WIXON, *Patents on Biotechnological Inventions: the EC Directive,* London, Sweet & Maxwell, 2002, p. 30.

[67] FRANZ-JOSEPH ZIMMER/ STEVEN M. ZEMAN/ JENS HAMMER/ KLARA GOLDBACH/ BERND ALLEKOTTE, *Protecting and Enforcing Life Sciences Inventions in Europe under EPC and EU Laws,* 2. Ed., München, C.H.Beck, 2015, p. 245.

[68] The Directive reflects a broad interpretation of the concept of "micro-organism" so that to include all micro-biological entities capable of replication such as bacteria, fungi, viruses and cells. It therefore covers all microscopic living matter as well as more familiar micro-organisms. Using a plant cell, or using genetic engineering techniques on it, will all therefore be eligible for patent protection, if industrial applicability and the other conditions of patentability are satisfied. HANS REINER JAENICHEN/ JÜRGEN MEIER/ LESLIE A. MCDONELL/ JAMES F. HARLEY JR./ YOSHINORI HASODA, *From Clones to Claims,* 6 ed., cit., p. 2.

"technical" devices (e.g. the use of a particular type of instrument in a grafting process, or of a special greenhouse for growing a plant) in a traditional breeding process is not new. Precisely, the use of the term "essentially" in the EPC is explained by the fact that it was evident that the exclusion should be extended to cover processes which were fundamentally biological, even if, as a secondary feature, "technical" devices were involved, it being understood that while such technical devices may perfectly well be patented themselves the biological process in which they are used may not.

Therefore, it seems clear that the legislator's intention was to exclude from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time. These conventional methods included in particular those based on the sexual crossing of plants (i.e. of their whole genomes) deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired traits. The application of technical means or other forms of human intervention in such processes which helped to perform them was already common. Nevertheless, the said processes were characterised by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis. If, on the contrary, these traits or characteristics were the result of the technical step controlled by the human intervention, the process could be patented.

Contrarily to this practice, according to the wording of the Directive, as far as a technical step is involved, the entire breeding process could be patented because it wouldn't consist entirely of natural phenomena, regardless of the impact of this technical step in the whole invention[69].

The European Patent Office faced this problem in some recent cases. In its Decisions G 2/07 (PLANT BIOSCIENCE/ BROCCOLI), and G 1/ 08 (State of Israel/ TOMATOES), of 9 December 2010, the Enlarged Board of Appeal decided that the wording of the Directive was ambiguous and contradictory. And "*the consequence of the self-contradictory wording of Article 2(2) Biotech Directive having been transposed verbatim into Rule 26(5) EPC is, regrettably, that Rule 26(5) EPC does not give any useful guidance on how to interpret the term "essentially biological process for the production of plants" in Article 53(b) EPC and therefore that term must be interpreted on its own authority. This is for the Enlarged Board to do*".

It considered that "*Rule 26(5) EPC was not meant as a(n exhaustive) definition of when a process is essentially biological within the meaning of Article 53(b) EPC but was only meant to serve as a reference, i.e. as an illustrative example of one of the kind of cases covered by the exclusion*".

And it concluded that "*Hence, in more general terms, the conclusion to be drawn is that a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process*

[69] SVEN BOSTYN, *Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering,* European Commission, May 2016, p. 23.

steps, remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC.

However, if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability. Therefore, such a process is not excluded from patentability under Article 53(b) EPC but qualifies as a potentially patentable technical teaching.

The above applies only where such additional step is performed within the steps of sexually crossing and selection, independently from their number of repetitions. Otherwise the exclusion of sexual crossing and selection processes from patentability under Article 53(b) EPC could be circumvented simply by adding steps which do not properly pertain to the crossing and selection process, being either upstream steps dealing with the preparation of the plant(s) to be crossed or downstream steps dealing with the further treatment of the plant resulting from such crossing and selection process. Any such additional technical steps which are performed either before or after the process of crossing and selection should therefore be ignored when determining whether or not the process is excluded from patentability under Article 53(b) EPC. For the previous or subsequent steps per se patent protection is available. This is the case, for example, for genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant (cf T 356/93 supra). However, in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process. As a result this means that, while the presence in a claim of one feature which could be characterised as biological does not necessarily result in the claimed process as a whole being excluded from patentability under Article 53(b) EPC (see 6.2 above), this does not apply where the process includes sexual crossing and selection".

Therefore, to determine if a process for the production of plants is "essentially biological", human intervention and its effects on the result must be taken into account, following in this regard the solution set by the Technical Board of Appeal in the *Lubrizol* case.

Even if the question related to the patentability of processes for the production of plants was more or less solved, a further problem arose regarding the patentability of the direct product resulted from essentially biological processes of breeding. In its Decisions G 2/12 (TOMATO II) and G 2/13 (BROCCOLI II), of 25 March 2015, the Enlarged Board of Appeal affirmed the patentability of plants derived from these processes, as far as there was no express exclusion of patentability provided for these plants.

These Decisions provoked a huge controversy, due to the absolute protection conferred under patent law to the patented products, which in the case determined a circumvention of the exclusion of the patentability of essentially biological processes ("*legal erosion*")[70].

Considering these critics, on 8. November 2016 the Commission issued a Communication explaining that the intention of the European legislator when drafting the European Directive on Biotech patents was to exclude from the patentability the products obtained by essentially biological processes.

The Administrative Council of the European Patent Convention amended the Rule 28 of the Implementing Regulation on 29.06.2017 and it included a paragraph 2, according to which "*Under Article 53 (b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process*". It entered into force on 01.07.2017.

On 22. March 2018 the Examining Division of the European Patent Office refused the European patent application entitled "*New pepper plants and fruits with improved nutritional valued*", filed by Syngenta Participations AG, on the basis of the Rule 28 (2), as added by the Administrative Council on 29.06.2017. The Examining Division reasoned that the European Commission, in its Notice of November 2016 had clarified the intentions of the EU legislator when adopting the exclusion of essentially biological processes in Article 4 of the EU Biotechnology Directive and that Rule 28(2) EPC therefore constituted a lawful clarification of the scope of Article 53(b) EPC. Consequently, the claimed subject-matter fell within the exception to patentability according to Article 53(b) and Rule 28(2) EPC (i.e. plants exclusively obtained by means of an essentially biological process) and the patent should be refused.

The applicant appealed this Decision on different basis. First of all, the view of the European Commission set out in the Notice was not legally binding, as only the Court of Justice of the European Union was competent to issue a binding interpretation of the Directive. Second, he reasoned that Article 53 (b) EPC had been interpreted by the Enlarged Board of Appeal in Decisions G 2/12 and G 2/13 in the sense that this legal provision did not exclude plants from patentability, even if they are obtained through an essentially biological process. Rule 28(2) of the Implementing Regulations was therefore in conflict with the previous interpretation of Article 53 (b) of the Enlarged Board of Appeal. And, having regard that Article 53 (b) EPC as interpreted by the EBA prevailed, Rule 28(2) must be held invalid or, alternatively, must be interpreted in line with the Decisions of the EBA.

On 5.12.2018 the Board of Appeal of the European Patent Office agreed with the appellant's reasoning and held that Rule 28(2) EPC was in conflict with Article 53(b) EPC as interpreted by the Enlarged Board of Appeal in decisions G 2/12 and G 2/13[71]. The Board referred to Article 164(2) EPC, according to which the provisions of the Convention prevail in case of

[70] RAIMUND LUTZ, *Patentschutz im Bereich der Biotechnologie,* München, Nomos-C.H.Beck, 2013, p. 22.
[71] T 1063/18.

conflict with the Implementing Regulations, and decided to set the decision under appeal aside and to remit the case to the Examining Division for further prosecution.

On 20 February 2019 in the meeting of the Committee on Patent Law, the Office and the representatives of the 38 EPO Contracting States, together with the European Commission as observer, had a first exchange of views on possible next steps following this Decision. The Committee addressed different potential options for the way forward and particularly supported measures to obtain an opinion from the Enlarged Board of Appeal on the matter.

On 29 March 2019 in the 159th meeting of the Administrative Council, the representatives of the 38 EPO Contracting States together with the European Patent Office discussed the need to find a solution in the short term following the Decision T 1063/18. The Contracting States expressed their concerns with regard to the legal uncertainty caused by decision T 1063/18. The President of the EPO expressed his view that a President's referral of the case to the Enlarged Board of Appeal was justified and necessary. The aim would be to obtain an opinion from the Enlarged Board of Appeal on the patentability of plants exclusively obtained by essentially biological processes, hereby considering recent legal developments.

On 5 April 2019, pursuant to article 112(1)(b) EPC, the President of the EPO submitted questions to the Enlarged Board of Appeal which relate to the patentability of plants exclusively obtained by essentially biological processes and to Decision T 1063/18 of a Technical Board of Appeal of December 2018. In the referral the President of the EPO seeks the Enlarged Board of Appeal to clarify the applicable legal framework.

Therefore we should wait for the Decision of the Enlarged Board of Appeal to clarify the question of the patentability of plants exclusively obtained by means of an essentially biological process.

4. Conclusions

Even if some legislative efforts have been made at European level in order to assure the pacific coexistence of Breeders' Rights and Patent Protection for Plant Innovations, the standing evolution of the technology in the field creates some frictions between both systems of protection and some legal uncertainty as regards the patentable subject-matter which are completely undesirable in order to promote the investments in the field of plant breeding.

Furthermore, the development of new techniques of breeding demand a more precise definition of the "essentially biological processes" in order to determine the scope of the exclusion of their patentability, as recognised in European legislation.

In recent times a new problem of interpretation has arisen concerning the exclusion from patentability of the products resulting from essentially biological processes, which was not expressly provided for in European legislation.

Bibliography

ADELMAN, MARTIN J. / RADER, RANDALL R./THOMAS, JOHN R., *Cases and Materials on Patent Law,* 3ª ed., West, St. Paul, 2009

ARMITAGE, ROBERT A., "The emerging US Patent Law for the Protection of Biotechnology Research Results", *EIPR,* 1989, pp. 47 ff.

BEIER, FRIEDRICH-KARL, "Resultados de la investigación, Derecho de patente e innovación", *ADI,* 1974, pp. 14 ff.

BEIER, FRIEDRICH-KARL, STRAUS JOSEPH, "Patents in a Time of Rapid Scientific and Technological Change: Inventions in Biotechnology", in BEIER FRIEDRICH-KARL, CRESPI R. STEPHEN, STRAUS JOSEPH, *Biotechnology and Patent Protection - an International Review,* OCDE, 1985, pp. 21 ff.

BERGMANS, BENHARD, *La protection des innovations biologiques. Une étude de Droit Comparé*, Brussels, Maison Larcier, 1991

BOSTYN, SVEN, *Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering,* European Commission, May 2016

BOTANA AGRA, MANUEL, "Buenas costumbres y Derecho de patentes", in AAVV, *Estudios sobre Derecho Industrial. Homenaje a H. Baylos,* Barcelona, Grupo español de la AIPPI, 1992, pp. 86 ff.

BOTANA AGRA, MANUEL, "El Tribunal Supremo Norteamericano se pronuncia a favor de la patentabilidad de los microorganismos", *ADI*, 1979-1980, pp. 421 ff.

BOTANA AGRA, MANUEL, "La patentabilidad de las invenciones microbiológicas", *ADI*, 1979-1980, pp. 29 ff.

BYRNE, NOEL J., "Patents for Plants, Seed and Tissue Cultures", *IIC,* 1986, pp. 324 ff.

CERRO PRADA, BEGOÑA / URQUÍA FERNÁNDEZ, NURIA, "En torno a la patentabilidad de los híbridos vegetales: el caso Lubrizol", *RGD*, 1992, pp. 1855 ff.

CRESPI, R. STEPHEN, "Patents and Plant Variety Rights: Is there an Interface Problem?", *IIC*, 1992, pp. 169 ff.

CURTO POLO, M. MERCEDES, "La protección de las invenciones biotecnológicas (Especial referencia a la coexistencia de patentes y títulos específicos en relación con las obtenciones vegetales)", *RGD,* nº 642, 1998, pp. 146 ff.

D`ANTONIO, VIRGILIO, *Invenzioni biotechnologiche e modelli giuridichi: Europa e Stati Uniti,* Napoli, Jovene editore, 2004, pp. 289 ff.

GATES, CHRISTINA, "Patenting the Life Sciences at the European Patent Office", en MAMAMJIWALLA SALIM/ SEIDE ROCHELLE (Eds), *Intellectual Property in Molecular Medicine,* New York, Cold Spring Harbor Laboratory Press, 2015, pp. 37 ff.

GÓMEZ SEGADE, JOSÉ ANTONIO, "La falta de patentabilidad de los procedimientos esencialmente biólogicos", *Cuadernos CEFI*, Nº7, pp. 13 ff.

GREENGRASS, BARRY, "UPOV and the Protection of Plant Breeders- Past Developments, Future Perspectives", *IIC*, 1989, pp. 622 ff.

GRUBB, PHILIP W., *Patents for Chemicals, Pharmaceuticals and Biotechnology. Fundamentals of Global Law, Practice and Strategy,* 5. Ed., Oxford University Press, 2010

HELFER, LAURENCE, *Intellectual Property Rights in plant varieties,* FAO, 2004

HÜBEL, ANDREAS, "The Limits of Patentability: Plant Biosciences", en HÜBEL, ANDREAS/ STORZ, ULRICH/ HÜTTERMANN, ALOYS, *Limits of Patentability,* Heidelberg, New York, Dordrecht, London, Springer, 2013, pp. 3 ff.

JAENICHEN, HANS-REINER / MEIER, JÜRGEN / MCDONELL, LESLIE A. / HARLEY JR., JAMES F. / HASODA, YOSHINORI, *From Clones to Claims,* 6 ed., Carl Heymanns Verlag, 2016

KAMSTRA, GERALD/ DÖRIGN, MARK / SCOTT-RAM, NICK / SHEARD, ANDREW/ WIXON, HENRY, *Patents on Biotechnological Inventions: the EC Directive,* London, Sweet & Maxwell, 2002

LEMA DEVESA, CARLOS, "El Convenio Europeo de Munich ante la protección de nuevas tecnologías", *AC*, 1993, pp. 605 ff.

LUTZ, RAIMUND, *Patentschutz im Bereich der Biotechnologie,* München, Nomos-C.H. Beck, 2013

MARTÍNEZ BARRABÉS, MIREIA, *La patente biotecnológica y la OMC,* Madrid, Barcelona, Buenos Aires, Marcial Pons, 2014

MILLS, OLIVER, *Biotechnological Inventions: Moral Restraints and Patent Law,* Ashgate, Aldershot, 2005

MOUFANG, RAINER, "Patenting of Human Genes, Cells and Parts of the Body? The Ethical Dimensions of Patent Law", *IIC*, 4/1994, pp. 487 ff.

MOUFANG, RAINER, "Protection for Plant Breeding and Plant Varieties- A Frontier of Patent Law", *IIC,* 1992, pp. 328 ff.

MOUFANG, RAINER, *Genetische Erfindungen im gewerblichen Rechtsschutz,* Köln, Berlin, Bonn, München, Carl Heymanns Verlag KG, 1988

MUELLER, JANICE M., *Patent Law,* 3. Ed., Austin, Boston, Chicago, New York, The Netherlands, Wolters Kluwer, 2009

NEUMEIER, HANS, *Sortenschutz und/oder Patentschutz für Pflanzenzüchtungen,* Köln, Berlin, Bonn, München, Carl Heymanns Verlag KG, 1990

NOTT, ROBIN, "Patent Protection for Plants and Animals", *EIPR*, 1992, pp. 79 ff.

NUFFIELD COUNCIL ON BIOETHICS, "The ethics on patenting DNA. A discussion paper", Nuffield Council on Bioethics, 2002

PILA, JUSTINE, *The Requirement for an Invention in Patent Law,* Oxford, Oxford University Press, 2010

SERMON, SERGIO, *The impact of the UPVO 1991 Act upon seed and production and research,* Scotland, University of Edimburg, 1995

STRAUS, JOSEPH, *Gewerblicher Rechtsschutz für biotechnologische Erfindungen,* Köln, Berlin, Bonn, München, Carl Heymanns Verlag KG, 1987

STRAUS, JOSEPH, "The relationship between Plant Variety Protection and Patent Protection for Biotechnological Inventions from an International Viewpoint", *IIC,* 1987, pp. 729 ff.

THE ROYAL SOCIETY, *Keeping science open: the effects of intellectual property policy on the conduct of science,* Abril, 2003, disponible en https://royalsociety.org/topics-policy/publications/2003/keeping-science-open/

UTERMANN, JASPER, "Reflections on Patent Protection of Products of Nature- Part One", *IIC,* 1978, pp. 413 ff.

VAN DER KOOIJ, PAUL, *Introduction to the EC Regulation on Plant Variety Protection,* London, The Hague, Boston, Kluwer Law International, 1997

VERMA, SITANSU KUMAR, "TRIPs and plant variety protection in developing countries", *EIPR*, 1995, pp. 289 ff.

WEGNER, HAROLD C., "Patenting Nature's Secrets- Microorganisms", *IIC*, 1976, pp. 235 ff.

WESTERLUND, LI, *Equivalence and Exclusions under European and U.S. Patent Law,* Kluwer Law International, The Hague, London, New York, 2002

ZIMMER, FRANZ-JOSEPH / ZEMAN, STEVEN M./ HAMMER, JENS / GOLDBACH, KLARA / ALLEKOTTE, BERND, *Protecting and Enforcing Life Sciences Inventions in Europe under EPC and EU Laws,* 2. Ed., München, C.H.Beck, 2015

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