Stanford – Vienna
Transatlantic Technology Law Forum

A joint initiative of
Stanford Law School and the University of Vienna School of Law

TTLF Working Papers

No. 98

A Comparative Analysis of the EU and the US Approaches Towards Intellectual Property Rights for New Plant Varieties: Is There Space for Further Harmonization?

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2023

TTLF Working Papers

Editors: Siegfried Fina, Mark Lemley, and Roland Vogl

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Suggested Citation

This TTLF Working Paper should be cited as:
Nicolás Garnham Brandes, A Comparative Analysis of the EU and the US Approaches Towards Intellectual Property Rights for New Plant Varieties: Is There Space for Further Harmonization?, Stanford-Vienna TTLF Working Paper No. 98, http://ttlf.stanford.edu.

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Abstract

During the last decades, intellectual property rights related to agriculture have become increasingly important, mainly because scientific and technological innovations are everyday more used across the whole food chain, but also because there is growing awareness of the significant role that innovation in plant breeding will play to face some of the major challenges of the twenty-first century, such as food security concerns associated with climate change. This tendency, it seems, is only meant to continue in the future as intellectual property protection linked to agriculture progressively expands. However, whether plant varieties can be considered as a patentable subject matter remains as a threshold issue in which different jurisdictions have maintained divergent views.

Acknowledging this trend, this Master Thesis will perform a comparative analysis of the origins, consolidation, and state of the art of relevant intellectual property rights for agriculture in the European Union and the United States, with focus on the different methods available for the protection of new plant varieties, i.e., utility patents, plant breeder's rights, and other sui generis statutes. Furthermore, it will discuss the main features of the different approaches followed by these two jurisdictions and the possibilities for convergence between them, in an area that is today characterized by growing reliance of both public and private actors on formal protection by intellectual property rights to foster biological innovation, as well as for interests in reinforcement and international harmonization in these matters.

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LIST OF ABBREVIATIONS

ASSINSEL: International Association of Plant Breeders for the Protection of Plant Varieties

BPAI: Board of Patent Appeals and Interferences

CPVO: Community Plant Variety Office

CPVRs: Community Plant Variety Rights

EBA: Enlarged Board of Appeals

EPC: European Patent Convention

EPO: European Patent Office

EU: European Union

IP: Intellectual Property

IPRs: Intellectual Property Rights

MNEs: Multinational Enterprises

PBRs: Plant Breeder's Rights

PPA: Plant Patent Act

PVPA: Plant Variety Protection Act

PVPC: Plant Variety Protection Certificates

PVPO: Plant Variety Protection Office

PVRs: Plant Variety Rights

TRIPS: Trade-Related Aspects of Intellectual Property Rights Agreement

UPOV: International Union for the Protection of New Varieties of Plants

US: United States of America

USC: United States Code

USDA: United States Department of Agriculture

USPTO: United States Patent and Trademark Office

WTO: World Trade Organization

Chapter 1: Introduction

'Plant breeding, the art of improving the genetics of plants, has been around as long as man has planted and saved seeds of the best plants for the next year's crop'.[1] By means of traditional agricultural methods, farmers and early plant breeders selected and cultivated the most successful plant strains from plant varieties and then exchanged seed in informal markets, a tradition that remains in place until today in rural regions of several countries around the world.[2] Meanwhile, in modern agriculture science is constantly and increasingly been applied to the selection and improvement of crops in order to achieve high-yielding varieties and massive productivity gains, a practice that began in the late nineteenth century with the arrival of scientific breeding technologies in North America and Europe.[3] Following the appearance of a robust seed industry, during the first half of the twentieth century intellectual property rights (IPRs) were granted for the first time to plant and seed developers.[4]

Since then, intellectual property (IP) has played an important role in several areas of agriculture, from plant breeding to the development of farming machinery and through to the way produce is labelled and marketed. But despite this, the interaction between IP law and agriculture attracted comparatively little interest, a situation that only changed during the last decade due to different reasons. On one hand, there is growing

[1] Debra L Blair, 'Intellectual Property Protection and its Impact on the U.S. Seed Industry' (1999) 4 Drake Journal of Agricultural Law 297.
[2] Keith E Maskus, 'Intellectual Property Rights in Agriculture and the Interests of Asian-Pacific Economies' (2006) 29 (6) The World Economy 715 <https://onlinelibrary.wiley.com/doi/10.1111/j.1467-9701.2006.00817.x> accessed 1 July 2022.
[3] ibid.
[4] Emily Marden and R Nelson Godfrey, 'Intellectual Property and Sharing Regimes in Agricultural Genomics: Finding the Right Balance for Innovation' (2012) 17 25 Drake Journal of Agricultural Law 369.

awareness of the significant role that IP plays in fostering research and innovation in the breeding of new crops,[5] which in turn is key to help face some of the major challenges of the twenty-first century, for instance, food security concerns associated with the effects of climate change, as well as preventing the expansion of agricultural land while maintaining and increasing food production to cope with the demands of international markets.[6]

On the other hand, modern agriculture has become subject to considerable technological innovation. In fact, as pointed by Maskus, '[a]n important, and sometimes overlooked, feature of farm policy is that agriculture is a technologically dynamic sector'.[7] Proof of this is that during the last decades agriculture has experienced several technological revolutions, such as the use of crop genetics, and gene modification through recombinant DNA. Consequently, there is increasing product innovation through the development of new plant varieties, and, as a result, the agricultural industry has placed growing reliance on formal means for protecting new technologies, including IPRs, while relevant actors, such as large agribusinesses, research institutions and multinational enterprises (MNEs) have been pushing for further strengthening and international harmonization in this regard.[8]

The United States of America (US) and the European Union (EU) have led international efforts within the World Trade Organization (WTO) for its members to

[5] Susannah Chapman and Brad Sherman, 'Finding a Place for Agriculture in Intellectual Property Law' (2018) 49 IIC - International Review of Intellectual Property and Competition Law 759 <http://link.springer.com/10.1007/s40319-018-0753-8> accessed 1 May 2022.
[6] European Union Intellectual Property Office and Community Plant Variety Office, '*Impact of the Community Plant Variety Rights System on the EU Economy and the Environment'* (Publications Office of the European Union 2022) 3 <https://data.europa.eu/doi/10.2814/467391> accessed 16 August 2022.
[7] Maskus (n 2).
[8] ibid.

implement legislation providing some form of IP protection for new plant varieties. But even between these two jurisdictions there is a lack of consensus concerning the type of protection that should be granted.[9] Reflecting on this, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement calls WTO Members to 'provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof'[10] thus allowing them to act with broad discretion as to the type of protection to be granted. In consequence, major patenting jurisdictions have developed over the past several years a wide array of approaches towards IP protection for plants. This lack of uniformity is an important challenge for the increasingly globalized agricultural area, as MNEs and other relevant actors might find difficulties to determine their rights and potential market share on an international level.[11]

Currently, there are three forms of IPRs that are especially relevant for the agricultural sector: patents on life forms, plant breeder's rights (PBRs) and geographical indications.[12] Other forms of IP such as trade secrets and trademarks are also important, but do not raise distinctive issues when applied to agricultural undertakings.[13] On the contrary, a matter that has been subject of high controversy and debate is the patenting of life forms, including plants. While few countries consider

[9] Anne E Crocker, 'Will Plants Finally Grow Into Full Patent Protection on an International Level? A Look at the History of U.S. and International Patent Law Regarding Patent Protection for Plants and The Likely Changes After The U.S. Supreme Court's Decision in J.E.M. Ag Supply v. Pioneer Hi-Bred.' (2003) 8 44 Drake Journal of Agricultural Law 254.

[10] See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) Article 27.3(b) (TRIPS Agreement).

[11] Mark D Janis, 'Patenting Plants: A Comparative Synthesis' in Ruth L. Okediji and Margo A. Bagley (eds) '*Patent Law in Global Perspective*' (Oxford University Press, 2014).

[12] Maskus (n 2); Jayashree Watal, 'Intellectual Property Rights and Agriculture: Interests of Developing Countries' Paper prepared for the World Bank's Integrated Program of Research and Capacity Building to enhance participation of developing countries in the WTO 2000 Negotiations (Geneva, 1999) <http://web.worldbank.org/archive/website00667/WEB/PDF/WATAL.PDF> Accessed 24 July 2022.

[13] Watal (n 12).

plants as patentable subject matter, several others resist granting full patent protection for plants based on economical, ethical, and cultural reasons. Following this view, many of them have opted for other patent-like forms of protection, such as PBRs, while a few others offer little to no IP protection for plants.[14]

This Master Thesis aims to offer background and to comment the relevant issues regarding this international discussion, by performing a comparative analysis of the legal approaches followed by the EU and the US towards IP protection for new plant varieties. The focus is set on both jurisdictions for several reasons: the EU and the US are two of the major patenting dominions in the world,[15] and at the same time they represent two of the worlds' biggest markets for agricultural produce.[16] Furthermore, and following Janis' 'three paradigms' on patent eligibility of plants, the EU and the US embody different approaches that are worth examining: while the US has followed a *permissive approach* under which plants are considered patentable subject matter, the EU is characterized for having an *intermediate approach* according to which plants are excluded from patentability and instead are protected under a sui generis system that allows important exceptions to the exclusive rights over a protected plant variety.[17]

For such purpose, this thesis aims to answer the following questions: How did IPRs for plant varieties originated and evolved in the EU and the US up to its current stage? What are the main similarities and differences of the legal approaches followed by

[14] Crocker (n 9).
[15] Janis (n 11).
[16] FAO, *Fruit and vegetables – your dietary essentials. The International Year of Fruits and Vegetables, 2021, background paper* (Rome, 2020).
[17] See Janis (n 11). According to Janis, three approaches have emerged, with variations within each group, towards patent eligibility of plants: a permissive approach, followed by the United States, Japan, South Korea and Australia; a restrictive approach, followed by China, India and certain South American countries; and an approach or set of approaches that resist easy characterization, but may be referred to as intermediate approaches, followed, inter alia, by Europe and Canada.

these two jurisdictions towards IP protection for new plant varieties? And, within a context of growing interests for international harmonization in this matter, in what aspects may these approaches converge in the future?

Chapter 2 of this Master Thesis will provide a general framework of important notions in the matter, by describing the concepts of plant variety, patents and PBRs, addressing the particular nature of biological material as subject matter for IP protection, and providing a brief reference of to the relevant international treaties.

Chapter 3 will trace the origins and evolution of statutory law granting IP protection for plant varieties in the US. Then it will offer a brief analysis of relevant case law, which has played a fundamental role in determining the scope of application and interaction among the different statutes offering plant patent or patent-like protection in the US.

Chapter 4 will address the approach followed by the EU, describing the general framework for plant protection in the EU, together with the relevant case law, and how after changing criteria it has favored the EU sui generis system of protection for plants as an alternative to patents.

Chapter 5 will compare the main features of the EU and the US systems and will then conclude that further convergence between them seems unlikely in the near future, as both jurisdictions present structural differences in their views towards IP protection for new plant varieties.

Chapter 2: General Considerations Regarding IPRs for New Plant Varieties

IPRs can be defined in broad terms as 'a set of laws devised for the purpose of protecting or rewarding inventors or creators of new knowledge'. This laws recognize that 'because knowledge, unlike consumable goods, can be shared by any number of persons without being diminished, creators are dependent on legal protection to prevent direct copying or the utilization of the product or process they have invented without payment or compensation'.[18] Two important features of IPRs are that they are limited to a defined territory, and that they have historically been adapted to the needs and circumstances of different jurisdictions.[19] These are particularly important regarding IP protection for new plant varieties.

2.1. Patents and Plant Breeder's Rights

Patents (also called utility patents in the US) are the oldest and possibly the strongest form of IPRs.[20] It is a government-granted IP right over a new invention, one of its main features being that it provides the right to exclude others from making, using or selling the invention during the life of the patent, which typically lasts twenty years from when the patent application is filed.[21] Patents are a matter of national law and are

[18] Carline Brenner, 'Intellectual Property Rights and Technology Transfer in Developing Country Agriculture: Rhetoric and Reality' Research Programme on: Global Interdependence, Working Paper No. 133 (Formerly Technical Paper No. 133) (OECD Development Centre, 1998) 11.
[19] Watal (n 12).
[20] Matthew S Clancy and GianCarlo Moschini, 'Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture' (2017) 9 Annual Review of Resource Economics 53 <https://www.annualreviews.org/doi/10.1146/annurev-resource-100516-053524> accessed 1 May 2022.
[21] Jonathan S. Masur and Lisa Larrimore Ouellette, *Patent Law: Cases, Problems, and Materials* (2nd Edition 2022, CC 4.0) 10 < https://www.patentcasebook.org/> Accessed 10 September 2022.

granted by the correspondent designated authority; in the US patents are granted by the United States Patent and Trademark Office (USPTO), while in the EU they are issued by the European Patent Office (EPO), which although is not a EU institution, has been given, under the European Patent Convention (EPC), the faculty to issue patents with effect in all Member States of the EU (as well as in other non-EU members that are also signatories to the EPC).

The conditions for patentability are similar across jurisdictions: for a patent to be granted, the invention must consist of a patentable subject matter, must be industrially applicable (useful), must be new (novel), must exhibit an "inventive step" (be nonobvious) and the disclosure of information regarding the invention in the patent claim must comply with certain minimum standards.[22]

But even though there is international consensus about the patentability requirements, there are important differences as to what should be considered patentable subject matter, especially regarding plant and biological innovations. Some countries, the most notable case been the US, allow patent protection for plants. On the contrary, other jurisdictions, including the EU, preclude the patenting of new plant varieties and in turn have opted for PBRs systems.[23]

PBRs are a sui generis form of IP protection since they provide a special kind of safeguard for plant varieties, different than patents. They are considered to be weaker when compared to patents, because right holders of a PBR cannot prevent certain third parties from using the protected invention for specific purposes. More concretely, PBR

[22] Clancy and Moschini (n 20).
[23] ibid.

holders cannot impede farmers from saving seeds of a protected variety for the purpose of replanting them for their own use and cannot exclude other breeders from using the protected variety for the purposes of research and development of new varieties. These are the so-called "farmers' privilege" and the "breeder's exemption", respectively, and represent fundamental features of PBRs.[24]

Likewise, the requirements to grant PBRs are less strict than those for patents. To be protected by PBRs, new varieties must fulfil the three criteria known as DUS: they have to be distinct (D) from earlier varieties, they have to be uniform (U), meaning to display the same essential characteristics in every individual, and they have to be stable (S), i.e., retain the same essential characteristics over generations. Furthermore, a standard of novelty must also be met, which refers to commercialization only, and it must have a suitable denomination. Protection typically lasts 20-25 years depending on the plant species.[25]

2.2. Relevant International Treaties

2.2.1. The International Convention for the Protection of New Varieties of Plants

Since the middle of the twentieth-century European national authorities noted that there was an increasing need for legislation to protect the new developments that were being achieved in the agricultural field. Nonetheless, they considered that patent protection was not the most adequate mean to protect these innovations; instead '[t]he general opinion was that a special law was needed'. Following this line, PBRs

[24] European Union Intellectual Property Office and Community Plant Variety Office (n 6).
[25] Watal (n 12).

provisions were enacted in several countries across Europe: in 1942 the Netherlands passed a plant variety protection act, followed by Germany in 1953.[26]

The first international initiative for harmonizing and extending PBRs was undertaken by a group of European countries and took place at the 1956 congress in Austria of the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL), which then led to the formation of the International Union for the Protection of New Varieties of Plants (UPOV) adopted after the Convention for the Protection of New Varieties of Plants held in Paris in 1961.[27] It represents 'the culmination of a long-standing quest to secure intellectual property protection to breeders at a time when it was believed that their innovations were outside the statutory subject matter of utility patents'.[28] UPOV is today an intergovernmental organization with headquarters in Geneva, Switzerland. Its mission is to 'provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society'.[29] The Convention provides the basis for UPOV members to grant PBRs for breeders of new plant varieties.

The UPOV Convention has been subject to subsequent revisions in 1972, 1978 and 1991. The last revision extended the terms of species covered and the length of protection, which is currently 20 years for perennial crops and 25 years for trees and

[26] Geertrui Van Overwalle, 'Patent Protection for Plants: A Comparison of American And European Approaches' (1999) IDEA-Journal of Law and Technology, pp. 143-194, 1999 <https://ssrn.com/abstract=1718614> Accessed 24 July 2022.
[27] Brenner (n 18) 12.
[28] Clancy and Moschini (n 20).
[29] International Union for the Protection of New Varieties of Plants (UPOV), *Overview of UPOV* (Publication No. 437, November 3, 2021) < https://www.upov.int/edocs/pubdocs/en/upov_pub_437.pdf> Accessed 5 July 2022.

vines. It allows countries to include, at their own discretion, the farmer's privilege, while the breeder's exemption remains compulsory. Importantly, while the 1961 and 1972 versions have been replaced, UPOV 78 and UPOV 91 coexists. New members are bound to the 1991 version, while existing members are free to ratify the more restrictive 91' version or remain under UPOV 78. Unlike most patent regimes, there are no public disclosure requirements under UPOV; instead, the breeder must provide sufficient evidence to demonstrate the variety meets the protection criteria, or alternatively submit a physical sample to the national authority for their own inspection.[30]

Most countries and supranational organizations which have introduced a PBRs system have chosen to base their system on the UPOV Convention in order to provide an effective, internationally recognized system. Currently, UPOV has 78 members, including the EU, the US, as well as most of the world's largest agriculture and seed producing economies.[31]

2.2.2. The Agreement on Trade-Related Aspects of Intellectual Property Rights

By the 1990s only 14 states where members of UPOV. In this sense, the reach and impact of IP protection for plants articulated in UPOV was broadened with the advent of the TRIPS Agreement. Adopted on 1 January 1995, it is to date the most comprehensive multilateral agreement on IP, mandatory for the 164 members of the WTO. Its aim and main novelty are that it establishes minimum standards for IP protection within WTO members, together with providing mechanisms for the

[30] Marden and Godfrey (n 4).
[31] UPOV (n 29).

international enforcement of IPRs. It provides that patents shall be available for all new industrial products and processes that 'involve an inventive step and are capable of industrial application'.[32]

Especially relevant for agriculture and plant breeding is Article 27.3(b), which deals with the patentability or non-patentability of plant and animal inventions. It stipulates that plants and animals (other than microorganisms) may optionally be exempted from patentability, but specifically for plants it provides that WTO members 'shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by a combination thereof'. In this sense, the TRIPS provision mandates the enactment of some form of IP protection for all new plant varieties, weather in the form of patents, PBRs, or both.

There is consensus in that PBRs defined by UPOV meet TRIPS criteria. And even though states do not need to join UPOV to fulfil TRIPS requirements, several countries have followed this way, leading to an important increase in UPOV membership.[33] In this context, the US is the major jurisdiction that grants utility patents over plant varieties, although it has also become an accepted practice in Japan, South Korea and Australia.[34] Meanwhile, the EU has generally excluded plants from patentability and only grants them in very specific cases. Instead, the EU has opted for a sui generis protection system composed by the Community Plant Varieties Rights (CPVRs) at the Union level and national Plant Variety Rights (PVRs) at the Member States level.

[32] Marden and Godfrey (n 4).
[33] Clancy and Moschini (n 20).
[34] Janis (n 11).

2.3. Plant Variety Concept and the Particular Nature of Biological Subject Mater

For the purposes of this work, the definition of plant variety provided by the 1991 Act to the UPOV Convention will be used as a reference. According to its Article 1(vi):

"variety" means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged;[35]

As explained by the European Community Plant Variety Office (CPVO) to clarify the scope if this provision, 'the commonly used taxonomic ranks in the classification of plants are, in descending order, Kingdom, Division, Class, Order, Family, Genus, Species and Varieties. In other words, each variety belongs to a species, each species to a genus, each genus to a family, and so on'.[36]

Plant varieties present distinctive characteristics regarding IP protection when compared to other types of inventions. One common feature among the traditional

[35] For further guidance on the definition of "variety" see the Explanatory Notes on the Definition of Variety Under the 1991 Act of the UPOV Convention. International Union for the Protection of New Varieties of Plants, 'Explanatory Notes on the Definition of Variety Under the 1991 Act of the UPOV Convention' (Geneva, 2010) < https://www.upov.int/edocs/expndocs/en/upov_exn_var.pdf> Accessed 3 July 2022.
[36] European Union Intellectual Property Office and Community Plant Variety Office. (n 6).

categories of IP law (patents, copyright, trademark, and trade secrets) is that they all deal with intangibles, by regulating their creation, circulation, and use. This regulation is accomplished basically by separating the intangible and the tangible form of the subject matter.[37] In the case of patents, for example, this separation allows the invention to be reduced to a written description in the specification for the patent claim. And from that description third parties might repeat the invention. In contrast, this is not possible with biological inventions: third parties will only be able to reproduce them if they have material access to the physical form of the invention; in the case of new plant varieties, the seed, germplasm, cutting, or the plant itself.[38] Moreover, and in contrast to mechanical creations, a unique feature of biological subject matter is that the physical form of the invention might have an inherent capacity for reproduction.[39]

Acknowledging the relevance of the physical form of biological subject matter and its intrinsic capacity for reproduction is important to understand the way in which IP law interacts with plant breeding. For instance, an important reason to initially deny patent protection for plants was the difficulties for plant related inventions to fulfill the written description requirements of patent claims. In this sense, IP law has relied upon the material expression of the biological subject matter, whereas to have a physical representation of the intangible contribution of the invention, to give third parties the chance to reproduce the invention, or to have certainty about the identity of the protected subject matter.[40] As will be described in the next chapters, technological advances that made it possible to overcome the stringent written description

[37] Chapman and Sherman (n 5).
[38] ibid.
[39] Clancy and Moschini (n 20).
[40] Chapman and Sherman (n 5).

requirements of patent claims provided an alternative to the reliance on the material expression of biological subject matter.

Chapter 3: IP Protection for New Plant Varieties in the US

The US has pioneered the recognition and protection of IP over plants. First, with the enactment of statutes granting IPRs for new plant varieties, and second, through the interpretations given by the courts and patent agencies setting out the scope of these statutes.[41] This chapter will describe the origins and evolution of statutory law regarding plant IP protection in the US and then refer to the relevant case law in the matter, which has shaped the system up to its current state.

3.1. Statutory Law

Three sets of statutory law provide protection for new plant varieties and plant genetic resources in the US: the Plant Patent Act, the Plant Variety Protection Act, and the Utility Patent Act.

3.1.1. The Townsend-Purnell Plant Patent Act of 1930

Until 1930, plants were not patentable in the US. They were excluded from patent law for two reasons: '[f]irst, plants are products of nature. Second, plants were not thought to be amenable to the written description requirement of patent law'.[42] Nevertheless, as modern agriculture and plant breeding developed, during the late nineteenth-century breeders and seed producers began pressing for IP protection and ownership of their creations. Following the International Convention for the Protection of Industrial

[41] Crocker (n 9) 256.
[42] Blair (n 1) 310.

Property, commonly known as the Paris Convention of 1883, breeders and seed producers in the US demanded for the equivalent of patents in plant protection, arguing that their contribution to society should be recognized in the same way as the contribution of industrial inventors.[43] As Representative of Indiana, Fred Purnell (whose name was then given in part to the Plant Patent Act), argued before the United States House of Representatives: '[w]hy should a man who invents a mouse trap or a jazz song have protection and enjoy the privileges that the patent system gives him, and a man like Luther Burbank[44], who spent his life developing new plants, get nothing?'.[45]

The granting of patent rights over plant inventions was further supported by well-respected inventors of the time, such as Thomas Edison who stated that '[n]othing that Congress could do to help farming would be of greater value and permanence than to give the plant breeder the same status as the mechanical and chemical inventors now have through the patent law'.[46]

As a result, the Townsend-Purnell Plant Patent Act (PPA) of 1930 was enacted. This statutory law was the first of its kind not only in the US but in the entire world.[47] It covered biological material explicitly by providing patent protection for new varieties

[43] Brenner (n 18) 12.
[44] Luther Burbank was a famous American plant breeder and botanist whose production of new varieties of fruits, flowers, vegetables, and grasses encouraged the development of plant breeding into a modern science. See Encyclopedia Britannica, 'Luther Burbank: American Plant Breeder' <https://www.britannica.com/biography/Luther-Burbank> Accessed 08 August 2022.
[45] United States House of Representatives: History, Art & Archives, Historical Highlights 'Plant Patent Act of 1930' <https://history.house.gov/Historical-Highlights/1901-1950/1930_05_13_Plant_Patent/#:~:text=On%20this%20date%2C%20the%20House,%2C%20flowers%2C%20and%20other%20flora.> Accessed 25 July 2022.
[46] Crocker (n 9) 258.
[47] ibid.

of domesticated plants such as apple, pear, rose, and other species that are multiplied asexually[48] for the commercial market.[49]

Initially encompassed under the utility patents provisions of 35 USC Section 101, in 1952 the US Congress moved the PPA statute to Section 161 of the USC. The PPA provides the patent holder with the right to prevent third parties from making, selling, or reproducing a patented variety, and it lasts for a period of twenty years. To be eligible for PPA protection a plant breeder must demonstrate that a plant with novel and unique features was obtained, and which can be asexually reproduced resulting in a new plant that possess the exact same novel and unique characteristics.[50]

An important feature to highlight is that the PPA offered, for the first time, an alternative to the written description requirements needed to obtain a utility patent, by accepting instead a deposit of the exact specimen of the plant in order to receive patent-like protection. Before the PPA, one of the main reasons innovations in plant breeding were denied substantive protection was because it was almost impossible to satisfy the stringent written description requirement of utility patents found in Title 35 USC § 112, even though these developments could easily be seen with the naked eye. The new regulation corrected this issue and hence, for the first time in the history of IP law, granted plant breeders with patent-like protection. The guarantee of exclusivity rights to the production and sale over their patented varieties, in turn, fostered an

[48] Asexually reproduced plants are those that are propagated by means other than seeds, for example, layering, budding, and other horticultural techniques.
[49] Cary Fowler, 'The Plant Patent Act of 1930: a Sociological History of Its Creation' Journal of the Patent and Trademark Office Society 82, no. 9 (2000) 621.
[50] Crocker (n 9) 257-58.

increase in research on asexual plant reproduction and development of new varieties by breeders and agribusinesses.[51]

Nonetheless, the protection provided by the PPA turned out to be very limited in practice, since it only covered asexually reproducing plants, leaving with no protection to those that reproduce sexually, which are the vast majority of plants used in agriculture.[52] Sexually reproduced plants were not covered by the PPA due to their particular feature of evolving and modifying over generations, which make it difficult to determine what was originally patented.[53] As a consequence, 'researchers realized that any developments of new varieties of sexually reproducing plants would be unprotected and that they would never be able to recoup the time, money and resources required to create and perfect a new variety'.[54] Thus, the exclusion of sexually reproducing and other categories of plants (such as tubbers) created the conditions for the enactment of future legislation that was necessary to fulfill this important gap.

3.1.2. The Plant Variety Protection Act of 1970

Two elements can be considered as the main incentives for the enactment of a new plant protection act in the US after the PPA. On one hand, farmers, plant breeders and newly emerged seed companies lobbied for a way to protect their investments in new sexually reproduced plants. On the other hand, on December 2, 1961, the UPOV Convention was adopted by a group of European countries with the aim of providing uniform protection for plant breeders of new varieties. Even though the US initially did

[51] ibid 258.
[52] ibid.
[53] Brenner (n 18) 12.
[54] Crocker (n 9).

not took part in UPOV and only became a member of the Convention in 1981, it was certainly an incentive for the enactment of a new plant variety protection mechanism in the country.[55] As a result, the Plant Variety Protection Act of 1970 (PVPA) was passed with the purpose of encouraging 'the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promoting progress in agriculture in the public interest'.[56]

In this way, UPOV was implemented in the US by the 1970 PVPA. It provides patent-like protection to plant breeders of new varieties of sexually reproduced plants and tuber propagated plants (e.g., potato varieties) through the issuance of Plant Variety Protection Certificates (PVPC) for a term of twenty years for most crops, or twenty-five years for vine and trees. PVPC provide certificate owners with the rights to, inter alia, exclude others from marketing and selling their varieties, manage the use of their varieties by other breeders, and enjoy legal protection of their work. The certificates are recognized worldwide and allow faster filing of plant variety protection in other countries. The PVPA is currently administered by the Plant Variety Protection Office (PVPO) of the United States Department of Agriculture (USDA).[57]

To be entitled to PVPA protection, the variety must meet certain conditions and requirements: certificates are warranted to breeders who create novel and distinct varieties, that may be replicated through sexual reproduction provided the variety breeds *true-to-type* over several generations. This means that the new variety must

[55] Blair (n 1) 311.
[56] ibid.
[57] U.S. Department of Agriculture (USDA), 'Plant Variety Protection' Agricultural Marketing Service <https://www.ams.usda.gov/services/plant-variety-protection> Accessed 26 July 2022.

generate the same novel and distinct characteristics when reproduced over various generations. The only variations allowed are those that are predictable, commercially acceptable, and have reasonable stability. In this sense, the requirements are different from those of the PPA, which only requires a variety to be new and distinct. However, the PVPA follows the innovation contained in the PPA regarding the exemption of the written description requirements for patent protection, as it allows the deposit of seed as an alternative to providing a detailed written description of the invention.[58]

Furthermore, and following the line of PBRs, a noteworthy feature of the PVPA is that it considers two major exemptions to the protection given to a PVPC holder: (a) the "farmer's exemption" and (b) the "research exemption".[59]

i. The Farmer's Exemption

Based on the long-standing tradition of farmers who save seeds from their best crop in order to replant those seeds for a good crop in future years, the PVPA considers an exemption under which farmers are allowed to save a limited amount of a PVPA protected variety's seeds from year to year, as long as the farmers' primary occupation is growing crops to be sold for purposes other than seed quality.[60] This exemption has received great amount of attention in the US, primarily in cases in which Monsanto has sued farmers who have allegedly saved and replanted soybean seed containing the Roundup Ready gene.[61]

[58] Crocker (n 9) 260.
[59] Blair (n 1) 312.
[60] Crocker (n 9) 260.
[61] Janis (n 11) 236.

Formerly, this exemption allowed saving seeds from year to year and selling it to others with no further special requirements. This was then amended in 1994 to bring the PVPA into conformity with the 1991 version of UPOV. These amendments included, inter alia, that the sale of protected seed would only be possible with the prior permission of the certificate holder. Thus, the Farmer's Exemption was drastically narrowed, and as a result, farmers are now allowed only to save seed for their own crops.[62]

ii. The Research Exemption

Under this exemption, also known as the Breeder's Exemption, the use of a PVPA protected variety without the certificate holder's authorization is permitted for the purposes of bona fide research study and reproduction, allowing scientists to use protected varieties as stepping-stones to develop new varieties and advance agricultural biotechnology through research.[63] This achievement of these positive effect is the ultimate purpose of the research exemption.

On the other hand, the research exemption can hinder the interests of legitimate right holders as it allows, for example, a plant breeder to purchase a commercially available soybean variety protected under a PVPC and use it to develop a new variety, which in turn can be sold by the breeder, who then can even apply for PVPA protection of its own as long as it is fulfills the eligibility requirements for protection. As noted by Blair

[62] Crocker (n 9) 261.
[63] ibid.

'[t]his has the ultimate effect of allowing company *A* to purchase seed from company *B* to utilize in company's *A* breeding program'.[64]

3.1.3. Utility Patents

Even though the PPA and the PVPA provided considerable legal protection for plant inventions, there was still a gap in legislation that needed to be filled regarding the interests of breeders, researchers, and seed companies, who pursued a stronger form of IP protection that did not allowed exclusions such as the breeder's exemption.[65]

In this sense, Title 35 USC §101: Inventions Patentable, provides that '[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title'. The name *utility patents* after which these patents are commonly known derives from the specific requirement that a patentable invention must be "useful". They are issued for a 20-year term and grant the patent holder with the right to exclude others from making, using, or selling the patented invention in the US. [66] They are distinct from "design patents", which are issued under 35 USC §171 and "plant patents" which, as mentioned before, are issued under 35 U.S.C. §161.

[64] Blair (n 1) 313.
[65] ibid 315.
[66] James A Toupin and others, 'Brief for The United States as Amicus Curiae Supporting Respondent' in *J.E.M. AG Supply, Inc., v Pioneer Hi-Bred International., Inc.*, Supreme Court of the United States No. 99-1996 38.

Utility patents offer the greatest protection for plants when compared to plant patents provided by the PPA and to PVPA certificates. For instance, they allow the breeder or patent holder to claim rights over the multiple, individual components of a new variety, such as the DNA sequence, genes, or a specific plant part, as opposed to being entitled to just one claim over the entire plant as set out under the PPA and the PVPA. In addition, there are no exemptions to the patent holder's rights such as those considered by the PVPA. Furthermore, methods to use a new variety to produce other new varieties or hybrids, and the resulting new varieties or hybrids, are likewise patentable. This, in turn, allows the licensing of new components or uses. All these features, considered together with the fact there is a much bigger and patent-holder friendly body of case law for utility patents than for PPA patents and PVPA certificates, offers a robust form of protection and enforcement of utility patents for plants.[67]

To receive utility patent protection, an invention must be new, novel, non-obvious, and described with enough detail and specificity to meet the written description requirement of 35 USC §112. As reviewed earlier, meeting the written description requirements was one of the main impediments for granting utility patent protection to plants, since it was almost impossible to satisfy them with the available technical means. But advances in genetic engineering for both plants and seeds made it possible for breeders to accurately identify and distinguish between varieties based upon a seed's genetic composition, which would otherwise be undistinguishable to the naked eye, and in that way meet the demanding written description provision of §112.[68]

[67] Crocker (n 9) 262.
[68] ibid.

Nonetheless, despite technological improvements that allowed to fulfill the written description requirements and the fact that utility patent is the oldest of the three types of IP protection available for plants in the US, plants were not recognized as patentable subject matter under §101 until the US Supreme Court clarified the issue, through a series of rulings starting with *Diamond v. Chakrabarty* in 1980, and settling the matter in *J.E.M. Ag Supply v. Pioneer Hi-Bred,* in 2001.

3.2. Statutory Interpretations

Case law from the US courts and the USPTO has played a fundamental role in the interpretation of the different statutes offering IP protection for plants, in particular to define their scope and compatibility, and to recognize plants as patentable subject matter. In this sense, three major cases must be considered to understand the current state of IPRs available for plants in the US.

3.2.1. Diamond v. Chakrabarty

Interestingly, the first advance towards utility patent protection for plants came from the area of genetic engineering, rather than from plant breeders or the seed industry.[69] In 1972 respondent Chakrabarty, a microbiologist who developed a genetically engineered bacterium capable of breaking down crude oil - a property which is possessed by no naturally occurring bacteria - filed a patent application before the USPTO for his human-made invention. The application involved three types of claims: first, a claim for the method for producing the bacteria; second, a claim for the

[69] Blair (n 1) 315.

inoculum that contained the bacteria; and third, a claim for the bacteria themself. The patent examiner allowed the first two claims but rejected the third. 'His decision rested on two grounds: (1) that microorganisms are "products of nature", and (2) that, as living things, they are not patentable subject matter under 35 USC § 101'.[70] Following Chakrabarty's appeal, the decision was affirmed by the Patent Office Board of Appeals, which relying on the legislative history of the 1930 PPA concluded that '§ 101 was not intended to cover living things such as these laboratory created micro-organisms'.[71] This decision was then reversed by the Court of Customs and Patent Appeals, who considered that the fact that microorganism are living things was 'without legal significance'[72] for the purposes of patent law. After this, the Acting Commissioner of Patents and Trademarks, Diamond, sought *certiorari* before the US Supreme Court.[73]

In the appeal before the Supreme Court, 'the issue was a question of statutory interpretation of 35 USC § 101 and whether or not Chakrabarty's "microorganism constitute[d] a "manufacture" or "composition of matter" within the meaning of the statute". If so, then the microorganism would in fact be available for utility patent protection'.[74]

On its approach towards the case the Supreme Court first considered the language of the statute as well as the ordinary dictionary meaning of the words "manufacture" and "composition of matter", and found that 'Congress plainly contemplated that the patent

[70] *Diamond v. Chakrabarty* [1980] U.S. Supreme Court 447, 305-306 (1980).
[71] Ibid 306
[72] Ibid (citing In re Bergy 563 F.2d 1031, 1038 (1977))
[73]Ibid 307
[74] Crocker (n 9) 264.

laws would be given wide scope'.[75] Furthermore, the Court took consideration of the legislative history of § 101 and held, quoting the Committee Reports accompanying the Patent Act of 1952, that 'Congress intended statutory subject matter to include *anything under the sun that is made by man'*.[76] In light of this broad interpretation of the scope of patent eligibility, together with consideration for the ordinary meaning of words used in § 101, the Court concluded that Chakrabarty's human-made bacteria was in fact patentable subject matter since microorganisms fell within the definition of "manufacture".[77]

The Court then assessed the two arguments that were presented by Diamond to support that microorganism such as Chakrabarty's oil-eating bacteria could not be considered as patentable subject matter under § 101. First, the fact that the Congress had already enacted the PPA and PVPA as special statutes addressing patent and patent-like protection for plants, separately from the utility patent statute, confirmed that Congress never intended living things to be eligible for utility patent protection, since if intended otherwise these statutes would have not been necessary. Second, there was no express direction form the Congress to provide utility patent protection for human-made microorganisms because genetic alterations were unforeseen when the statute was enacted.

The Court dismissed both arguments. The first, on the basis that there was no evidence of congressional intent contradicting the ordinary meaning of the words in § 101. The

[75] *Diamond v. Chakrabarty* [1980] U.S. Supreme Court 447, 305-306 (1980).
[76] Ibid 309
[77] Crocker (n 9) 264.

second, by concluding that the Congress used a broad language in § 101 precisely because inventions, such as engineered microorganisms, are often unforeseeable.[78]

In its ruling, the Supreme Court held for the first time that a living organism was patentable under a utility patent. Nevertheless, 'a major issue remained unclear in regard to plant materials, that is: are sexually reproduced, "man-made" plants patentable subject matter under 35 U.S.C. § 101?'.[79] Furthermore, since the PPA applied only to asexually reproducing plants, and the PVPA extended protection to sexually-reproduced plants but did not confer a total protection from use by others as it considered the research and the breeder's exemptions, after *Diamond v. Chakrabarty* 'there continued to be uncertainty as to how the protections afforded by the Plant Patent Act and the PVPA, and now utility patents would merge or overlap. This uncertainty was exacerbated by the initial indecision within the [Patent and Trademark Office (PTO)] as to the application of Chakrabarty to plants.'[80]

3.2.2. Ex parte Hibberd

Even though *Ex parte Hibberd* was a decision from the USPTO Board of Patent Appeals and Interferences (BPAI) and not a court decision, it constitutes an important landmark towards widening the scope of patent protection for plants.[81] This case specifically addressed the question of patentability for sexually reproduced, man-made plants under 35 U.S.C. § 101.

[78] ibid.
[79] Blair (n 1) 316.
[80] ibid.
[81] Crocker (n 9) 266.

In 1985, five years after *Chakrabarty*, the USPTO denied a utility patent claim for maize plant technologies, including seeds, plants, and tissue cultures. The patent examiner rejected the application on the basis that the PPA and the PVPA were the only protections available for plants. The decision was appealed before the BPAI, which overturned the examiner's rejection and held that the claimed subject matter was patentable. The issue on appeal, then, was 'whether subject matter such as plants and seeds that are protectable under the PVPA or subject matter such as tissue culture that are protectable under the PPA of 1930 are also protectable under 35 U.S.C. Section 101'.[82] The Board relied on the Supreme Court's analysis in *Chakrabarty* according to which Section 101 includes man-made life forms, including plant life, and that neither the PPA nor the PVPA restricts or limits the scope of patentable subject matter under § 101. Furthermore, the BPAI held that protecting plants under § 101 did not createed irreconcilable practical conflicts with the PPA or PVPA.[83]

Thus, Ex parte Hibberd opened the door for breeders of transgenically modified plants to file utility patent claims for their inventions. But there was still no certainty on whether plants and seeds could be considered as proper patentable subject matter under Section 101. 'In essence, although Hibb[e]rd held that protection is available to plants under the utility patent, it did not automatically mean that they will receive that protection, due to the written description requirements of § 112, which plant breeders had yet to overcome at that time'.[84]

[82] Blair (n 1) 317.
[83] Toupin and others (n 65) 6.
[84] Crocker (n 9) 267.

3.2.3. J.E.M. Ag. Supply Inc. v. Pioneer Hi-Bred International, Inc.

After *Hibberd* decision there where important matters regarding patent protection for plants that needed to be settled, especially if the courts would confirm the view that Congress intended plants to be eligible for patent protection under the utility patent provisions, considering that it had already enacted two statutes, the PPA and the PVPA, specifically addressing plant patent protection. Breeders and seed companies where still looking for a stronger form of plant protection, and the fast development and adoption of biotechnology by large agribusinesses in the US and other countries added extra pressure for this issue to be clarified.[85] 'The stage for resolving this question was set when the United States Supreme Court granted certiorari to hear J.E.M. Ag Supply v. Pioneer Hi-Bred'.[86]

Pioneer Hi-Bred, a company that hold 17 utility patents covering the manufacture, use, sale, and offer for sale of its inbred and hybrid corn seed products, filed an action for patent infringement against J.E.M. Ag. Supply, a small dealer of agriculture supplies that was reselling bags of Pioneer Hi-Bred's patented hybrid seeds of corn.

The accusation was denied by J.E.M. Ag. Supply, who filed a patent invalidity counterclaim arguing that sexually reproducing plants, such as Pioneer's corn plants, were not patentable subject matter under 35 U.S.C. Section 101. J.E.M.'s main argument was that the 1930 PPA and the 1970 PVPA contained the only valid statutory provisions for protecting plant life, because they were more specific than

[85] ibid 270.
[86] ibid.

Section 101, and thus these statutes carved out subject matter from Section 101 for special treatment.[87]

The District Court, relying on the Supreme Court's broad interpretation in *Diamond v. Chakrabarty*, held that Section 101 'clearly covers plant life', and added that by enacting the PPA and the PVPA the Congress neither expressly nor implicitly removed plants from Section 101's subject matter, noting in particular that by passing the more specific PVPA the Congress did not implicitly repeal Section 101 as there was no irreconcilable conflict between the two statutes. The United States Court of Appeals for the Federal Circuit confirmed the decision. [88]

J.E.M. then filed a petition for *certiorari* before the Supreme Court. The issue was whether utility patents may be issued for plants pursuant to 35 U.S.C. Section 101.[89] Instead of focusing the case on whether Pioneer's corn plants met the requirements for utility patent protection, J.E.M. argued that plants in general were not subject matter for utility patent because the exclusive statutory means for obtaining plant patent protection where the PPA and the PVPA.[90]

Following this line, J.E.M. presented three arguments to support that the PPA excluded utility patent protection for plants: first, that utility patent protection was not available for plants before the enactment of the PPA in 1930; second, the fact that the PPA protects only asexually reproducing plants evidences that the Congress did not intended to grant utility patent protection for sexually reproducing plants; and third, if

[87] *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.,* [1996] 534 U.S. 124 [2001]
[88] Ibid
[89] Ibid 130.
[90] Crocker (n 9) 271.

Congress intended plants to be eligible for utility patent protection it would have not enacted other statutes for this specific subject.

Furthermore, regarding the alleged PVPA preclusion of utility patents protection for plants, J.E.M. added two arguments: first, the legislative history of the PPA and PVPA shows that the congressional intent was to preclude plants from the broader protection available under utility patents; and second, the PVPA altered the subject matter coverage of §101 by implication.[91]

Concerning the PPA question, the Court dismissed J.E.M.'s arguments on the following basis:

(i) *Utility patent protection was not available for plants before the 1930 PPA.* The Court noted that Congress enacted the PPA precisely to acknowledge and protect the efforts of plant breeders who could not meet the rigorous written requirements of utility patents, but that did not mean that plants where precluded form ever meeting these requirements in the future.[92] The Court said that 'plants have always had the *potential* to fall within the general subject matter of § 101, which is a dynamic provision designed to encompass new and unforeseen inventions' and added that '[d]enying patent protection under §101 simply because such coverage was thought technologically infeasible in 1930 (…) would be inconsistent with the forward looking perspective of the utility patent statute'.[93]

[91] ibid. 271-74.
[92] ibid. 272.
[93] Ibid 273.

(ii) *The fact that the PPA protects only asexually reproducing plants evidence that the Congress did not intend to grant utility patent protection for sexually reproducing plants.* The Court noted that the 1930 PPA was enacted at a time when the primary way to breed plants that would preserve their desirable, patentable features from specimen to specimen was only by asexual reproduction, but that limited understating of plant breeding as well as the state of patent law in 1930 did not show a congressional intent towards limiting patent protection exclusively for asexually reproduced plants.[94]

(iii) *If Congress intended plants to be eligible for utility patent protection it would have not enacted other statutes for this specific subject.* What J.E.M. reasoned here was that when moving PPA protection away from utility patent protection in 1952, Congress intended the PPA to be the only protection available for plants, and not an alternative to utility patent protection.[95] But the Court held instead that 'this negative inference simply does not support carving out subject matter that otherwise fits comfortably within the expansive language of § 101, especially when §101 can protect different attributes and has more stringent requirements than does §161.'[96]

Then, J.E.M.'s arguments for the PVPA prevention of plant patent protection under § 101 were rejected by the Court as follows:

[94] ibid.
[95] ibid.
[96] ibid.

(i) *The legislative history of the PPA and PVPA shows that the congressional intent was to preclude plants from the broader protection available under utility patents.* J.E.M. argued that by authorizing limited patent-like protection for some sexually reproduced plants the Congress intend to deny broader utility patent protection for such plants. The Court dismissed the argument for two reasons. 'First, nowhere does the PVPA purport to provide the exclusive statutory means of protecting sexually reproduced plants. Second, the PVPA and §101 can easily be reconciled. Because it is harder to qualify for a utility patent than for a Plant Variety Protection (PVP) certificate, it only makes sense that utility patents would confer a greater scope of protection.'[97]

(ii) *The PVPA altered the subject matter coverage of § 101 by implication.* The Court referred to past decisions when a statute is repealed by implication, noting that significant evidence to support the finding of irreconcilable conflict between the earlier and the later statute is needed. In this case, although there are differences in the requirements and level of protection offered by the PVPA and §101, these are not irreconcilable conflicts but rather features of a 'parallel relationship between the obligations and the level of protection under each statute' and so, both were compatible.[98]

Finally, in a 5-2 decision, the Supreme Court held that 'newly developed plant breeds fall within the terms of §101, and that neither the PPA nor the PVPA limits the scope of §101's coverage', adding that '[a]s in Chakrabarty, we decline to narrow the reach

[97] Ibid.
[98] Crocker (n 9) 275.

of § 101 where Congress has given us no indication that it intends this result'.[99] Thus, the Court confirmed that plants are proper subject matter for utility patent protection under 35 USC § 101, and that it is compatible with the provisions of the PPA of 1930 and the PVPA of 1970.

[99] *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.,* [1996] 534 U.S. 124 [2001].

Chapter 4: IP Protection for New Plant Varieties in the EU

Legislation in the EU regarding IP protection for new plant varieties is complex and far from been debated, as it has been subject of several disputes regarding the eligibility of plants as subject matter for patent protection.[100] Today, IPRs over plant varieties are granted under the EU's Community Plant Variety Rights (CPVR) or under the Member States' national Plant Variety Rights (PVR). Until recently though, plants were also patentable under the European patent system, but after a series of highly debated decisions by the EPO the general rule today is that, except for some specific exceptions, plants are not patentable.

In this sense, two schemes coexist: the specific systems for the protection of plant varieties at the EU and the Member State's level, and the European patent system as a general framework to protect innovation.[101] This chapter will describe the history, functioning, and scope of the legal bodies that form the EU's structure for IP protection of plant varieties, and how they interact with each other. Also, a brief analysis of the most important decisions of the EPO will be undertaken in order to understand the different factors that led to the EU's current approach towards plant patentability.

[100] María Mercedes Curto Polo, 'Plant Patents in the European Union: Recent Developments' (2019) Revista Electrónica de Direito 43 <https://cije.up.pt//client/files/0000000001/3-m-mercedes-curto-polo_928.pdf> accessed 17 August 2022.
[101] ibid.

4.1. The European Patent Convention

After the UPOV 1961 Convention, which set the basis for a harmonized PBRs system within the European countries, the next relevant event regarding IP plant protection in Europe came with the adoption of the European Patent Convention (EPC). Also known as the Convention on the Grant of European Patents, it was adopted in 1973 and last revised in 2000. The EPC is a regional patent treaty providing a single application and examination procedure to protect inventions in its contracting parties.[102] Currently 38 states have ratified the EPC, including all EU Member States.[103] The EPC provides the legal foundations for the existence of the European Patent Organization, which is composed of two organs responsible for granting European patents: the EPO and the Administrative Council.

It should be noted at the outset that the EPO is not part of the EU, and therefore it is not subject to its laws nor to the jurisprudence of the Court of Justice of the European Union, the higher judicial authority in the EU and which, in that role, has the last word regarding the interpretation of EU law. Instead, the EPO has its own quasi-judicial bodies: the Boards of Appeals, and the Enlarged Board of Appeals (this last one being the higher instance within the EPO). Both are only bound by the EPC provisions and, to a certain extent, by their own jurisprudence.[104] This is relevant since the EPO has played a fundamental role in interpreting the scope of the EPC regarding plant patent protection, thus shaping the EU's position in the matter.

[102] Overwalle (n 30).
[103] European Patent Office, *Member States of the European Patent Organization - Updated 22 February 2022* <https://www.epo.org/about-us/foundation/member-states.html> accessed 19 August 2022.
[104] Franz-Josef Zimmer and Markus Grammel, 'Plant Patents in Europe' (2015) 34 Biotechnology Law Report 121 <http://www.liebertpub.com/doi/10.1089/blr.2015.29006.fjz> accessed 18 August 2022.

Regarding patentable inventions, Article 52(1) EPC states that 'European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application'. This broad and all-encompassing approach would appear to include new plant varieties as patentable subject matter as long as they fulfill the patentability requirements; however, it is offset by Article 53 EPC which lists the exceptions to patentability.[105] Letter (b) of Article 53 EPC provides that European patents shall not be granted in respect of 'plant or animal varieties, or essentially biological processes for the production of plants or animals' and then adds a counter exception by providing that 'this provision shall not apply to microbiological processes or the products thereof'.

In this way, the EPC outlines which inventions related to vegetable living matter are out of its scope of protection, by excluding both "plant varieties" and "essentially biological processes for the production of plants". Thus, according to Article 53(b) EPC a patent claim cannot be made for a plant variety or an essentially biological process for the production of a plant. However, the rest of living vegetable matter, as well as production processes which are not essentially biological, and the products obtained thereof, are patentable.

The EPC is complemented by the Implementing Regulations to the EPC, which in its Chapter V, Rules 26 to 34, addresses the patentability of biotechnological inventions in different areas, including that of vegetable matter. Through these rules, the Implementing Regulation offers further guidance on the EPC's provisions concerning

[105] ibid 123.

the protection of plant varieties. For instance, the Implementing Regulations provides key definitions in the subject: Rule 26(4) defines the concept of "plant variety" by following almost literally the definitions given in the UPOV Convention as revised in 1991[106] and in the EC Regulation on Community plant variety rights.[107] Furthermore, Rule 26(5) clarifies what should be understood by "essentially biological process for the production of plants" by stating that a processes for the production of plants 'is essentially biological if it consists entirely of natural phenomena such as crossing or selection', reproducing the definition of Article 2(2) of the EU Biotech Directive 98/44.

Importantly, according to the Implementing Regulations, biotechnological inventions are in general patent eligible, in line with the basic legal principle of Article 52(1) EPC under which any invention that fulfils the patentability requirements shall be patentable. More specifically, Rule 27(b) provides that biotechnological inventions that concern plants shall be patentable as long as the technical feasibility of the invention is not confined to a particular plant variety.

But even though the EPC and its Implementing Rules determines in a clear way which plant related inventions are patentable, experience has shown that the EPO has had a 'more mixed normative commitment to excluding plant innovation' from the European patent system.[108] The scope of the exclusion of "plant varieties" and "essentially biological processes for the production of plants" from patentability, as provided under

[106] See International Convention for the Protection of New Varieties of Plants of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991, Article 1 (vi) <https://www.upov.int/edocs/pubdocs/en/upov_pub_221.pdf> Accessed 23 August 2022.
[107] Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [1994] OJ L 227, 1.9.1994, p.1 Article 5(2).
[108] Janis (n 11) 220.

the exception of Article 53(b) EPC, has been subject of high controversy and debate over several years, not only within the European patent community, but also among other interested actors such as farmer's associations, NGOs, and the general public.[109]

4.1.1. Case Law of the EPO Regarding Plant Patentability

The first patent claims for plants and the respective decisions of the EPO came in hand with the advances in the field of biotechnology. Since large amounts of capital were needed for research and development in biotechnology, investors were looking for the strongest type of protection available for their innovations and that appeared to be patents.[110] Over the last decade, the EPO's Enlarged Board of Appeals has changed several times its approach towards the patentability of plants produced by essentially biological processes. According to the most recent, and perhaps definitive, opinion of the Enlarged Board of Appeals in the so-called "Pepper" case (G3/19), plants and plant products are not patentable in Europe if they are exclusively obtained by means of an essentially biological process.

However, this opinion is the last one in a long running series of case law, which will be briefly described in the following lines in order to explain how the EPO arrived at its current view. For a better understanding, the issue can be divided into three separate points of law: i) the scope of the "plant varieties" exclusion, ii) the scope of the "essentially biological process" exclusion, and iii) whether plant products (i.e., products of plant origin, such as vegetables, fruits, cereals, flowers, leaves, and others) are excluded or not from patentability.

[109] Zimmer and Grammel (n 103).
[110] ibid.

i. The Plant Varieties Exclusion

The EPO's decision in G 1/98 (Transgenic plant/NOVARTIS II) of 20 December 1999 remains as the primary case concerning the scope and interpretation of Article 53(b) EPC's exclusion of patentability for plant varieties.[111] Novartis had claimed a patent over, inter alia, transgenic plants comprising in their genomes specific foreign genes, but did not identify any particular plant as the new plant variety over which the claim was filed. The application was denied by the examining division of the EPO on the grounds of non-compliance with Article 53(b) EPC, based on its earlier decision in the *Plant Cells* case (T-356/93). According to *Plant Cells* decision, 'a claim is not allowable if the grant of a patent in respect of the invention defined in said claim is conducive to an evasion of a provision of the EPC establishing an exception to patentability'[112]. The Technical Board of Appeal of the EPO confirmed this view, and further argued that accepting that the exemption of Article 53(b) EPC could be avoided simply by filing a broad and generic claim encompassing the explicitly excluded plant varieties, would not comply with the normal rules of logic.

Novartis appealed this decision, and so the Technical Board referred a series of questions to the Enlarged Board of Appeal of the EPO. The main issue was whether a claim that relates to plants in broad generic terms and in which the specific plant varieties are not individually claimed, would *ipso facto* avoid the prohibition of patenting based on Article 53(b) EPC. The Technical Board, as well as a various third

[111] Janis (n 11) 221.
[112] Case T0365/93 *Plant Cells* [1995] OJ 1995,545.

parties submitting *amici curiae,* believed that if a single potential embodiment in the claim was a plant variety, then it was not patentable.[113]

Nonetheless, the Enlarged Board took a different approach by ruling that '[i]n the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is not directed to a plant variety or varieties within the meaning of Article 53(b) EPC'.[114] In consequence, even though a claim directed to a plant variety is *per se* excluded from patentability, a claim which may encompass a multiplicity of varieties and where particular plant varieties are not individually claimed, is not excluded under Article 53(b) EPC.[115]

Regarding the opinion that such a criterion was not logical, the Enlarged Board held that it was not something to be resolved by 'arithmetic logic' but rather to be addressed as a policy issue towards innovation in plant biotechnology. Since transgenic biotechnology had the capacity to be applied across a wide array of plants, protecting the resulting products only under plant variety protection regimes would not provide adequate incentives for innovation because they granted rights only over individual plant varieties. Instead, patents would provide a broader and more suitable protection.

Thus, as noted by Zimmer and Grammel, '[b]y interpreting Article 53(b) EPC as a simple delimitation statute vis-à-vis the plant variety rights (…) the Enlarged Board arrived at a very patentee friendly ruling (…). As long as the claimed subject matter is not directed to an individualized plant variety (or multiple plant varieties as individual

[113] Zimmer and Grammel (n 103) 124.
[114] Case G0001/98 *Transgenic plant/NOVARTIS II* [1999] OJ 2000,111.
[115] Janis (n 11) 221.

options), it does not fall under the plant variety exclusion of Article 53(b) EPC.'[116] The EPO has maintained this approach until today.

ii. The Essentially Biological Processes Exclusion

As mentioned, Article 53(b) EPC also excludes from patentability the "essentially biological processes for the production of plants", although the article itself, nor other parts of the EPC, describe what should be understood by this concept. In turn, this is clarified by Rule 26(5) of the Implementing Regulations of the EPC, according to which '[a] process for the production of plants (…) is essentially biological if it consists entirely of natural phenomena such as crossing or selection'. Additionally, the second part of Article 53(b) EPC provides that the exemption 'shall not apply to microbiological processes or the products thereof'. Again, the Implementing Regulations to the EPC gives further light in the matter by stating in Rule 26(6) that a microbiological process 'means any process involving or performed upon or resulting in microbiological material'.

Plants that have been deliberately modified to carry a certain quality, such as enhanced yield or resistance to droughts, are known as genetically modified (GM) plants. They are generally considered to be patentable since these innovations are usually introduced by genetic engineering techniques or other "technical" processes for the production of plants. On contrary, new plant varieties obtained by traditional breeding methods consisting of a non-technical and random process of crossing promising plants and selecting the new ones that carry the desired trait or characteristic, are not

[116] Zimmer and Grammel (n 103).

patentable, as these are essentially biological processes for the production of plants.[117] Until there the issue appears to be clear, but when breeding methods involve both traditional breeding techniques of crossing and selection together with technical methods, it becomes more complex to draw the line between which plant inventions are patentable and which are not.

The issue regarding the extent of the exclusion of essentially biological processes for the production of plants was addressed by the EPO some years after Novartis case. In consolidated decisions G1/08 (Tomatoes/STATE OF ISRAEL) and G2/07 (Broccoli/PLANT BIOSCIENCE), the so-called "Tomato I" and "Broccoli I" decisions of 2010, the Enlarged Board of Appeal 'appeared to conclude that method claims to many conventional breeding techniques would be excluded under Article 53(b)'.[118] Both cases began in the mid-2000's when two independent claims regarding marker-assisted methods of breeding went into appeal before the Technical Board. These methods involved the traditional steps of crossing individuals and then selecting the ones with the desired characteristics, together with other steps of a technical nature.

After reviewing relevant case law and its compatibility with the definition of essentially biological process for the production of plants provided in Rule 26(5) of the Implementing Regulations to the EPC, the Technical Board found inconsistencies between them, and so decided to refer questions of law to the Enlarged Board of Appeals. The fundamental question was if a non-microbiological process for the

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[117] European Patent Office, *Biotechnology Patents at the EPO* <https://www.epo.org/news-events/in-focus/biotechnology-patents.html> Accessed 11 September 2022.

[118] Janis (n 11) 222.

production of plants based on crossing and selection, but which also included further technical steps, would fall under the exclusion of Article 53(b) EPC, and if not, what would be the relevant criteria to draw the line between excluded and non-excluded processes?[119]

The Enlarged Board concluded that a non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing whole genomes of plants and then subsequently selecting plants is "essentially biological" within the meaning of Article 53(b) EPC, and thus excluded from patentability. It further noted that such a process does not escape the exclusion of Article 53(b) merely because it contains a step of technical nature that serves to enable or assist the performance of the traditional steps (such as marker-assisted methods of breeding). However, the Enlarged Board of Appeals added that if the process contains a technical step that by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, and this is not the result of crossing and selection, such a process is technical and in consequence patentable.[120]

In conclusion, a breeding process which combines crossing and selection with advanced techniques that are used to *assist* the process, is not patentable; but if the technical step *by itself* modifies the genome, then such process is patentable. This approach is currently applied by the EPO.

[119] Zimmer and Grammel (n 103).
[120] See joint cases G 0001/08 *Tomatoes/STATE OF ISRAEL* [2010] OJ EPO 2012, 206 and G 0002/07 *Broccoli/PLANT BIOSCIENCE* [2010] OJ EPO 2012, 130.

But whether the exclusion of Article 53(b) extended to product claims directed to plants obtained by an essentially biological process remained an open question.

iii. The Exclusion of Product Claims Over Plant Varieties Obtained by Essentially Biological Processes

After the decisions on Tomato I and Broccoli I, the Technical Board was of the opinion that the Enlarged Board of Appeals did not gave a clear answer regarding product claims over plants obtained by essentially biological processes, since it only stated that methods themselves were not patentable. In this sense, the problem for the Technical Board was that it was not clear if, for example, a tomato obtained by a new and inventive but essentially biological process, would be patentable. In consequence, in little more than a year the Technical Board referred new questions of law to the Enlarged Board of Appeals under the same proceedings. This was the first time in the history of the EPO where two different referrals were made in the same appeals[121], giving way to the G 2/12 (Tomatoes II) and G 2/13 (Broccoli II) decisions of 2015.

The referred question in both cases was in essence the same: if the exclusion of essentially biological processes for the production of plants under Article 53(b) EPC could have a negative effect on the allowability of a product claim directed to plants, in particular when the product is obtained by an essentially biological process. The Enlarged Board issued consolidated decisions, noting that the exclusion of said

[121] Zimmer and Grammel (n 103).

processes for the production of plants does not have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit.[122]

In consequence, the Enlarged Board arrived to an interpretation of Article 53(b) EPC according to which plant products that have been obtained by an essentially biological process are patentable. There was no reason in the Board's opinion to interpret the process exclusion so broadly that it would also include products under any circumstances, independent of how the product was described in the claim.[123]

However, this decision proved to be highly controversial. The European Commission intervened in November 2016 with a Notice setting out that, according to its view, the intention of the legislator in the EU Biotech Directive 98/44, which is incorporated into the EPO's legal framework, was that plants produced by non-technical processes such as crossing and selection should not be patentable.[124] Although the interpretations of the EC are not binding for the EPO, in an effort to harmonize European patent law the EPO amended its Implementing Regulations by introducing Rule 28(2), so as to not grant patents on products obtained by means of essentially biological processes.[125] But the EPO's Technical Board of Appeals rejected this amendment on the basis that it conflicted with the EPC, which takes precedence over the EPO's Implementing Regulations.

[122] See joint cases G 0002/12 [2015] OJ EPO 2016, A27 (Tomatoes II) and G0002/13 [2015] OJ EPO 2016, A28 (Broccoli II).
[123] Zimmer and Grammel (n 103).
[124] European Commission Notice C/2016/6997 on Certain Articles of Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions [2016] OJ C 411/3.
[125] Zimmer and Grammel (n 103).

Furthermore, in September 2019 the European Parliament intervened in the matter by adopting a non-legislative resolution stating that fruits and vegetables obtained from conventional breeding processes should not become patentable, since open access to breeding material is essential for innovation, food security and the environment, and calling the European Commission to do its utmost to convince the EPO not to grant patents to products obtained through these processes.[126]

The issue was finally (or at least for now) settled in the so-called Pepper (G3/19) decision of 14 May 2020. In April 2019, the President of the EPO submitted two questions to the Enlarged Board of Appeals, considering the previous developments regarding plant patentability in Europe and with the purpose of establishing a uniform application and certainty of the law. The Enlarged Board rephrased both questions into one, essentially asking whether the interpretation of the scope of the exception to patentability under Article 53(b) EPC could have a negative effect on the allowability of product claims directed to plants, if the claimed product is exclusively obtained by means of an essentially biological process.[127]

The Enlarged Board of Appeal noted, in first place, that 'developments after decisions G 2/12 and G 2/13 of the Enlarged Board of Appeals have been taken into account', acknowledging that this was not only a technical matter but also an issue of policy in which the EU sought to influence with its position against plant patentability. Next, the Enlarged Board held that 'the exception to patentability of essentially biological

[126] European Parliament Press Releases 'No Patents on Naturally Obtained Plants and Seeds' Ref.:20190912IPR60934 <https://www.europarl.europa.eu/news/en/press-room/20190912IPR60934/no-patents-on-naturally-obtained-plants-and-seeds> Accessed 12 September 2022.
[127] See G0003/19 *Pepper (Follow-up to "Tomatoes II" and "BRoccoli II")* [Opinion of the Enlarged Board of Appeal of the EPO of 14 May 2020].

processes for the production of plants (…) has a negative effect on the allowability of product claims directed to plants [and] plant material, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process'.[128]

Thus, overturning earlier decisions in Broccoli II and Tomato II of 2015, the EPO established in Pepper that plants and plant material with a new trait that is exclusively the result of traditional breeding methods are not patentable in Europe. In contrast, a process will not fall under the exclusion from patentability of Article 53(b) EPC, and therefore will be patentable, if it contains an additional step of a technical nature that by itself modifies the genetic characteristics of the plant. Importantly, the opinion has no retroactive effect on European patents granted before 1 July 2017, as well as on pending applications filed before that date, in accordance with the day when the corresponding amendments to the Implementing Rules of the EPC entered into force.

4.1.2. What plant-related inventions are patentable in the EU?

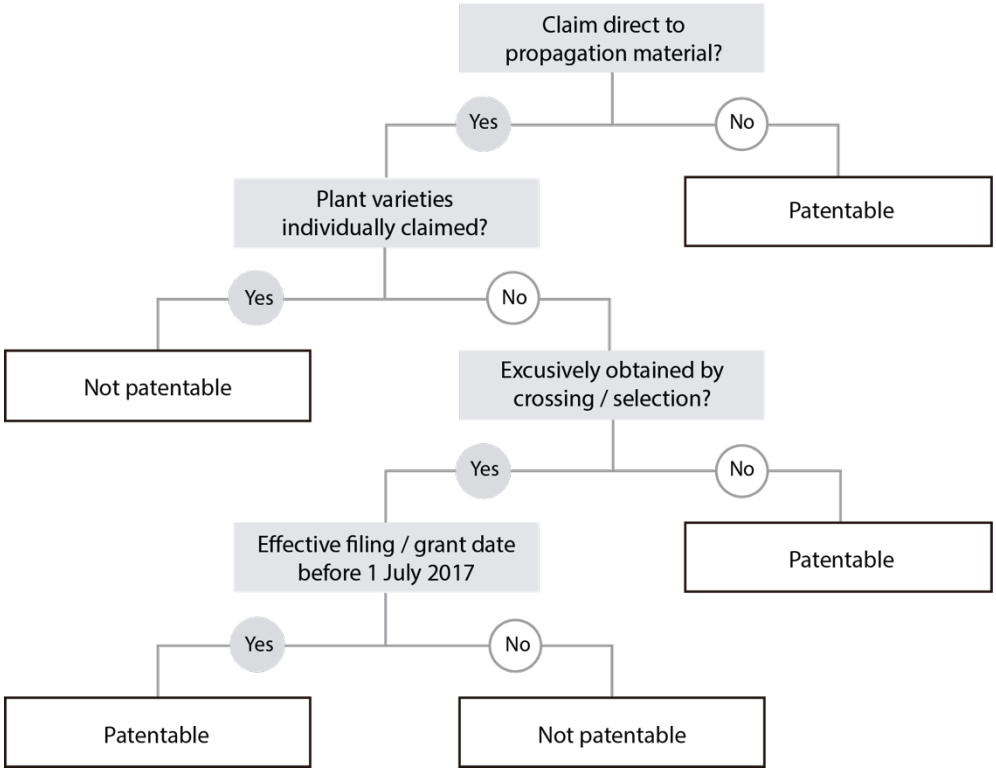
Following a complex regulation and the changes in criteria by the EPO, the question arises as to what is patentable for plant breeders in the EU after all? Currently, only plants and plant products obtained through a process that involves a technical step which by itself leads to a modification of the genome of the plant, are patentable. It is important to highlight that this technical step must not be a mere aid or assistance within a traditional breeding process; if the new plant variety is exclusively the result of crossing and selection, with no direct technical intervention, then it is not

[128] ibid.

patentable. The EPO's interpretation of the terms "essentially biological process", i.e., crossing and selection, and "step of technical nature", i.e., exceeding crossing and selection, are key elements in this regard.

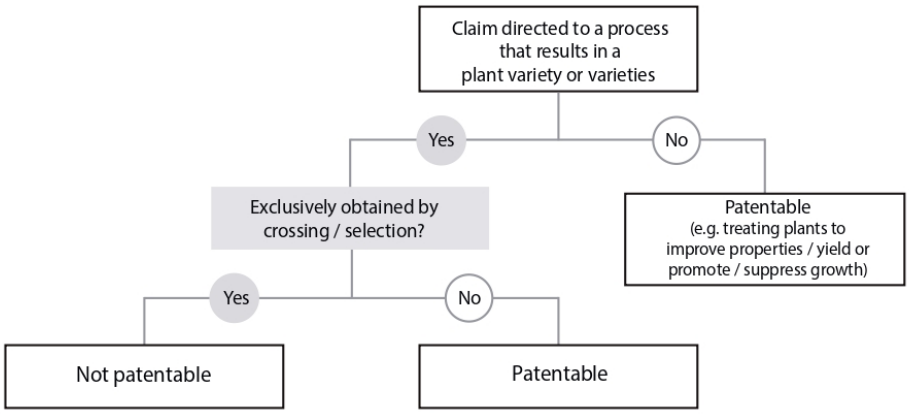
Since the overall picture can be hard to see, the following figures aim to provide light on the status of plant and plant products patentability in the EU:

Figure 1: Claims directed to plant products. [129]



[129] See Cooley LLP, *EPO: Plants and Plant Materials Not Patentable if Exclusively Obtained by Essentially Biological Process* (2020) <https://www.cooley.com/news/insight/2020/2020-05-29-epo-plants-and-plant-materials-not-patentable-if-exclusively-obtained> Accessed 23 September 2022.

Figure 2: Claims directed to methods relating to plants. [130]



4.2. Community Plant Variety Rights

Even though after the UPOV Convention of 1961 some minimum standards of protection for plant varieties were introduced within the European countries that where part to the agreement, IP protection regimes for plants continued to be regulated by the national legislation of the Member States, the content of which was not uniform. In such circumstances, the European authorities considered it was appropriate to create a Community regime that allowed the grant of IPRs over plants with validity throughout all its territory, which would coexist with national regimes.[131] In consequence, Council Regulation (EC) No 2100/94 of 27 July 1994 on "Community Plant Variety Rights", also known as the "Basic Regulation", was enacted. An essential feature of the CPVR is that it is not a patent system, but rather a *sui generis* system for IP protection of new plant varieties, adopted in compliance with Article 27(3)(b) of the TRIPS Agreement.

[130] ibid.
[131] Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [1994] OJ L 227, 1.9.1994, p.1.

The substantive part of the Basic Regulation models on the UPOV Convention as revised in 1991, to which the EU joined in 2005 as a supranational organization. In consequence, as from that date the UPOV Convention is an integral part of EU law. Pursuant to the *General Provisions* of the Basic Regulation, the CPVR is established as the sole and exclusive form of Community industrial property rights for plant varieties, which shall have uniform effect within its territory, and without prejudice to the right of the Member States to grant national property rights for plant varieties.[132]

Thus, the CPVR establishes a protection system at the EU level that coexists with each of the national PVR systems of the 23 EU Member States that currently have such a system. The CPVR is enforceable throughout all the EU and plant breeders can choose which protection to benefit from. However, cumulative protection of a plant variety, i.e., the simultaneous protection under the CPVR and under a national PVR, is prohibited.[133] In this regard, Article 92(1) of the Basic Regulation reads as follows: *'Any variety which is the subject matter of a Community plant variety rights shall not be the subject of a national variety right or any patent for that variety. Any rights granted contrary to the first sentence shall be ineffective'*.

The CPVR system is administered by an official and decentralized agency of the EU, the Community Plant Variety Office (CPVO), having its seat in Angers, France. Its mission is 'to deliver and promote an efficient Intellectual Property Rights system that supports the creation of new plant varieties for the benefit of Society'. Pursuant to Article 2 of the Basic Regulation and based on the Principle of Unitary Character, with one single application before the CPVO, one examination procedure, and one technical

[132] European Union Intellectual Property Office and Community Plant Variety Office. (n 6).
[133] ibid.

examination, the CPVO delivers a sole decision on whether a CPVR can be granted, and if that is the case, the CPVR will be valid and enforceable throughout the whole EU. This has been noted as one of the most advantageous features of the CPVR system.

Currently, six pieces of legislation regulate the CPVR system. Together with the already mentioned Basic Regulation, other specific aspects of its functioning, such as proceedings before the Community Plant Variety Office (CPVO) or fees payable to the CPVO, are regulated in detail by further CPVR-related legislation.[134]

4.2.1. Subject Matter of CPVR

As set out in Article 5(2) of the Basic Regulation, '[v]arieties of all botanical genera and species, including, *inter alia*, hybrids between genera or species, may form the object of Community plant variety rights.' Modeling on the UPOV Convention, paragraph 2 of said article adds that the term "variety" means 'a plant grouping within a single botanical taxon of the lowest known rank'.

As explained by the CPVO to clarify the scope if this provision, 'the commonly used taxonomic ranks in the classification of plants are, in descending order, Kingdom, Division, Class, Order, Family, Genus, Species and Varieties. In other words, each variety belongs to a species, each species to a genus, each genus to a family, and so

[134] ibid.

on'.[135] Thus, the Basic Regulation provides a broad scope of protection under which varieties of all botanical types might be protected by a CPVR.

4.2.2. Requirements for CPVR Protection

CPVR shall be granted for varieties that are: a) distinct, b) uniform, c) stable (the DUS criteria set out by the UPOV Convention), and d) new. Furthermore, the variety must be designated by a suitable denomination, meaning there is no impediment against it according to the criteria set out in Article 63 of the Basic Regulation.[136]

After an application for CPVR protection is filed, the CPVO will undertake a triple-fold examination to verify that the formal, substantive, and technical requirements are met. Once this has been confirmed, the CPVR will be granted and a certificate of the CPVR will be issued to the right holder, together with an official variety description of the specific features of the now-protected variety.[137]

4.2.3. Characteristics and enforcement of CPVR

As described in Article 13 of the Basic Regulation, the holder of a CPVR is granted the exclusive right to authorize or prohibit the following acts, in respect of a protected variety constituents or harvested material of the protected variety:

a) Production or reproduction (multiplication)

b) Conditioning for the purpose of propagation

[135] ibid.
[136] Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [1994] OJ L 227, 1.9.1994, p.1. Article 6 (n 129).
[137] European Union Intellectual Property Office and Community Plant Variety Office (n 6).

c) Offering for sale

d) Selling or other marketing

e) Exporting from the Community

f) Importing to the Community

g) Stocking for any of the purposes mentioned above

The term of a CPVR runs until the end of the 25th year, or the 30th year in the case of varieties of vine and tree species, following the year of grant. They can also be terminated by nullity or cancelation under the special cases foreseen in Articles 20 and 21 of the Basic Regulation.

It is important to highlight that one of the main features that differentiates the CPVR from a patent system is the fact that the exclusive right of the CPVR holder is subject to two major exemptions: the derogation established in Article 14 and the limitations set out in Article 15 of the Basic Regulation.

i. The Agricultural Exemption

Derogation under Article 14 is also known as the "agricultural exemption", "farmer's privilege", or "farm-saved seed concept".[138] It has been established 'for the purposes of safeguarding agricultural production', and provides that 'farmers are authorized to use for propagating purposes in the field, on their own holding[,] the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety' that is covered by a

[138] ibid.

CPVR. This exemption, however, shall only apply only to the 21 agricultural plant species listed in paragraph 2 of Article 14.

As the CPVO explains, '[i]n practice, under the agricultural exemption, farmers must pay an equitable remuneration significantly lower than the amount charged for the licensed production of propagation material, and small farmers are not required to pay any remuneration at all'. It further notes that '[t]he agricultural exemption is aimed at establishing a reasonable balance between the interest of CPVR holders (or breeders, more generally) and those of farmers.[139]

ii. The Breeder's Exemption and other Limitations Listed in Article 15

The so-called "breeder's exemption" allows anybody to use a CPVR protected variety for the purpose of breeding, or discovering and developing other varieties, without the CPVR holder's consent. It is considered as a cornerstone of the CPVR system, because it promotes innovation in plant breeding by encouraging the development of new varieties through the use of a CPVR protected one.[140] Other limitations set out in Article 15 of the Basic Regulation include 'acts done privately and for non-commercial purposes' and 'acts done for experimental purposes.'

In conclusion, the CPVR system establishes a single and uniform regime for the protection of plant varieties within the EU that solved the problems regarding unharmonized criteria of the different PVR systems of Member States. And even though it coexists with national PVR systems, it is reasonable to say that a breeder who

[139] ibid.
[140] ibid.

seeks protection in two or more Member States will file one single application for CPVR rather than different applications for each PVR.[141] Furthermore, in a similar way to the US PVPA, which was also enacted modeling the UPOV, the CPVR system contains exemptions and limitations that represent important differences with patent protection. Currently, CPVR are the only available form of IP protection in the EU for plant varieties obtained by traditional breeding methods.

4.3. The EU Biotech Directive

The patentability of biotechnological inventions in the EU is regulated by Directive 98/44EC of the European Parliament and of the Council of 6 July 1998 on the "legal protection of biotechnological invention", also known as the Biotech Directive. It was established with the aim of harmonizing the differences between the laws and practices of the different Member States, considering that such differences could lead to barriers to trade and impede the proper functioning of the Internal Market. The EU legislator considered that the legal protection of biotechnological inventions could be achieved by the granting of patents, and thus the existing patent law was amended so that new technological developments that might involve biological material could fulfill the requirements for patentability.[142]

In this sense, Article 3(1) of the Directive provides as a general rule that inventions will be patentable if they are new, involve an inventive step and are susceptible of industrial application 'even if they concern a product consisting of or containing

[141] ibid.
[142] Curto Polo (n 99) 51.

biological material or a process by means of which biological material is produced, processed or used'.

Regarding plants, and following the line of the EPC, Article 4 of the Biotech Directive establishes that plant varieties and essentially biological processes for the production of plants shall not be patentable. To outline what should be understood by "plant variety", Article 2(3) of the Directive refers to the concept provided in Article 5 of the CPVR Basic Regulation, which, as previously noted, adopted the definition of plant variety contained in the UPOV Convention as revised in 1991.

In line with the criteria set by the EPO, under the Biotech Directive plants are patentable as long as 'the technical feasibility of the invention is not confined to a particular plant (…) variety and if said plant (…) [is] not exclusively obtained by means of an essentially biological process'. Furthermore, inventions concerning plants may be patented 'provided that the application of the invention is not technically confined to a single plant (…) variety. However, said plants (…) must not be exclusively obtained by means of an essentially biological process'.[143]

In this way, the Biotech Directive follows the approach of the EPC and the EPO towards plant patentability. In consequence, it excludes plant varieties and essentially biological process for the production of plants as patentable subject matter, and only allows patentability under the particular circumstances described above.

[143] See Guidelines for Examination in the European Patent Office [2022] Part G. Chapter II.5. Exclusions and exceptions for biotechnological inventions <https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_2.htm> Accessed 15 September 2022.

Chapter 5: Conclusions

After reviewing the origins, development, and current state of IPRs available for the protection of new plant varieties in the US and the EU, several features of both systems can be highlighted and contrasted.

IP protection for plants in the US present the following main characteristics:

1. The three statutes offering IP protection for plant breeders, i.e., the 1930 PPA, the 1970 PVPA, and utility patents under 35 USC § 101, provide clear and strong IPRs over plants.
2. These statutes do not exclude each other but are rather complementary. In fact, there is no legal provision establishing that one statute shall prevail over the others, and the Supreme Court determined that they interact in such a way that simultaneous protection is possible. It is then up to the breeder to determine which statutes suits better its needs and therefore apply for the corresponding protection.
3. Case law in the US has followed a straightforward path regarding plant patentability, progressively expanding the scope of utility patent protection for living matter, and specifically for plant varieties. In *Diamond v. Chakrabarty* the Supreme Court declared that biological material could qualify as patentable subject matter under 35 USC § 101. Then, in *Ex parte Hibberd* the Board of Appeals and Interferences of the USPTO held that patent claims to conventionally bred maize seed having certain special characteristics where patentable, setting the legal basis for the USPTO to issue utility patents on plants. Finally, in *J.E.M. Ag. Supply v. Pioneer Hi-Bred* the Supreme Court confirmed the USPTO practice, settling the issue of plant patentability.

4. In consequence, plant entitlement for utility patent protection is well established and undisputed in the US. Furthermore, not only new plants themself, but also specific plant parts, seeds and other plant products are patentable. As noted by Janis, 'United States' patents directed to plant innovation frequently include claims directed to the plant itself, the seed of the plant, and various plant parts. All of these constitute patent-eligible compositions of matter under existing law; there is no serious challenge to eligibility'.[144]
5. Since utility patents do not contemplate any kind of exception to the exclusivity rights granted to the patent holder, breeders can obtain in the US the strongest form of IPRs available for new plant varieties. The application must comply with the patentability requirements: 1) novelty; 2) non-obviousness; 3) usefulness, and 4) written description. Patent protection lasts for a 20-year term and grants the patent holder with the right to exclude others from making, using, or selling the patented invention in the US.

On its part, the EU's approach can be described by the following main features:

1. The European legal framework is complex and considers several case-specific rules. Currently, it is composed by the following pieces of legislation:
    a) The EPC, which provides the general framework for the patenting of inventions in Europe, but under Article 53(b) specifically excludes plant varieties from patentability as well as essentially biological processes for the production of plants.
    b) The CPVR system (Council Regulation No 2100/94), which modeling on the UPOV Convention as revised in 1991 establishes a sui generis protection

[144] Janis (n 11) 216.

system for plant varieties that came to harmonize the different national PVRs of the Member States. In this sense, the CPVR provides a single protection mechanism with effect through the entire territory of the EU. It contains important limitations to the exclusivity rights granted to a CPVR holder, such as the "agricultural exemption" and the "breeder's exemption", differentiating in that way from patent protection.

c) National PVRs. Although not reviewed in detail as it would escape the scope of this work, it is nonetheless necessary to note that national PVRs are part of the EU's protection system for plant varieties, providing protection at the Member State's level. Currently, there are 23 EU Member States that have enacted a PVR system.[145] But as already mentioned, in practice they are not used often since CPVR prohibits cumulative protection, and so any breeder who aims to protect its plant variety in more than one Member State will certainly apply for CPVR protection rather than for several PVRs.

d) The EU Biotech Directive, which following the line of the EPO excludes plant varieties and essentially biological processes for the production of plants as patentable subject matter, and only allows the patentability of inventions where the technical feasibility is not limited to a particular plant variety which is not exclusively obtained by means of an essentially biological process. It also authorizes patenting inventions concerning plants when the application of the invention is not technically confined to a single plant variety.

2. These pieces of legislation exclude each other, meaning that protection under more than one of them is not possible. The Basic Regulation expressly prohibits cumulative protection of a plant variety under CPVRs, PVRs and any patent.

[145] European Union Intellectual Property Office and Community Plant Variety Office (n 6).

3. The EPO has been ambivalent in its criteria regarding the patentability of plants and plant products, issuing changing decisions that denote a strong conflict between expanding or restricting the scope of patent protection over plants. *Pepper* is currently the last decision in a long line of cases dealing with this controversial issue, where the EPO established that plants are not patentable in Europe if they are exclusively obtained by means of an essentially biological process, such as the crossing and selection of desired individuals. In consequence, plant varieties as defined under the UPOV Convention are not patentable in the EU. In what proved to be not only a technical issue but also a matter of public policy, the EU has opted to grant patents for plant inventions only in very specific cases, as it has been reflected in the EPO's latest decisions.
4. In turn, only plants and plant products obtained by means of a process that includes a technical step that leads, by itself, to a change in the plant's genome, are patentable in Europe. If the technical step is just a mere aid or assistance within a traditional breeding process, the resulting variety or products are not patentable.
5. Nonetheless, plant varieties are subject of appropriate sui generis protection under the CPVR system at the EU level, or under national PVRs at the Member States level. The EU's system of CPVRs considers important exceptions to the exclusivity rights granted to the right holder: the farmer's privilege and the research exemption. This is, in fact, a cornerstone of the EU's approach in the matter. To be eligible for protection the new variety must comply with the DUS criteria: distinctiveness from earlier varieties(D); uniformity (U); and stability (S). Protection under CPVR lasts 25 or 30 years depending on the plant species.

Initially, there was broad consensus in the EU and the US about the ineligibility of biological material as patentable subject matter. During the early to mid-twentieth century the US and certain European countries enacted the first pieces of legislation providing IP protection for plant varieties, a process that came in hand with the advent of modern breeding techniques in agriculture and the growth of newly emerged seed companies. The US was pioneer in granting IPRs for plants under the 1930 PPA, followed by the first European countries that enacted PBRs statutes, leading then to the UPOV Convention of 1961. In this sense, legislation in the US and Europe initially took a similar approach towards IP protection for plants since both considered them as non-patentable subject matter. This view prevailed during most of the twentieth century. However, after increasing pressures from agribusinesses and other relevant actors in the agricultural sector and the biotech industry to obtain full patent protection, together with technological advances that made it possible to fulfill the written description requirements in patent claims over plants and plant related inventions, the US and the EU took different roads.

One of the biggest strengths of the US system today is that it provides great clarity and certainty regarding both the patentability of new plant varieties and the exclusivity rights granted to the patent holder. This might be considered as a desirable feature in a context where research has shifted from the public to the private sector and where significant amounts of resources are being invested in the development of new varieties. Nonetheless, several voices have argued that this could have a negative effect, as 'IPRs can also provide private-firms with temporary monopolies of a welfare-reducing nature that may limit small-scale, resource-poor farmers' access to

technical solutions that increase on-farming productivity, improve household food security, and reduce poverty'.[146]

This matter has been a long-lasting concern in Europe, and since the times of ASSINSEL and UPOV the statutes granting PBRs have considered alternatives to allow third party access to protected breeding material under certain circumstances. Differently to the US, the farmer's privilege and the research exemption are one of the foundations of the EU's system of IP protection for plant varieties. Although the US PVPA considers these exemptions, in practice they have little practical effect when a new sexually reproducing or tubber propagated variety can be also protected under utility patents. In this way, the EU has been successful in pursuing and achieving, through CPVRs, a unitary system that equilibrates the different interests at stake in IP protection of plants: those of large agribusinesses and MNEs, as well as those of small farmers and society in general. However, the high complexity of the European legislation in this area and the changing criteria of the EPO towards plant patentability remain as important weaknesses of the EU's system.

Case law has played a major role in shaping the US permissive approach and the EU intermediate approach, by defining the scope of the statues offering IP protection for new plant varieties and especially regarding their patentability. As it has been discussed, the most notable difference between the two systems is related to the threshold issue of whether plants can be considered as patentable subject matter: while plants are patentable in the US, they are, in general, not patentable in the EU.

[146] David J. Spielman and Xingliang Ma, 'Intellectual Property Rights, Technology Diffusion, and Agricultural Development: Cross-Country Evidence' (International Food Policy Research Institute, 2014) 1 < https://ebrary.ifpri.org/utils/getfile/collection/p15738coll2/id/128141/filename/128352.pdf > Accessed 15 September 2022.

Despite these differences, it is possible to point out that the EU and the US converge in recognizing the importance of effective IP protection to foster innovation in plant breeding, and in consequence both have enacted several pieces of legislation addressing this issue. Moreover, both have led international efforts to extend international recognition of IPRs for new plant varieties, especially among members of the WTO. MNEs, research institutions, agribusinesses, and other relevant actors will find suitable IP protection for new plant varieties in the US as well as in the EU. Nonetheless, it should be noted that protection under PBRs has been described as 'weaker than patent protection' since right holders will find important limitations to their exclusionary rights under the farmer's privilege and the research exemption. Likewise, 'the criteria used to grant such protection is also somewhat weaker than that used for patents' mainly because the DUS requirements are less stringent and there is no need to provide a written description of the invention.[147]

The main divergence and underlying cause of the different approaches that the EU and the US have taken appears to be open access to breeding material: the EU considers it to be essential for innovation, food security and the environment, and thus has rejected plant patentability, opting instead for CPVR as these contain important exceptions to the right holder's exclusivity rights over the protected variety; meanwhile, the US Supreme Court considers that there are no compelling reasons to limit the scope of utility patent protection with respect to plant varieties and thus grants them full patent protection.

[147] Watal (n 12).

Consequently, it is unlikely that both models will tend to converge in the future, mainly because their points of disagreement are structural: they present divergent political priorities. This was revealed after the interventions of the European Parliament and the European Commission to reverse the EPO's decision that recognized the patentability of plants in Europe. Today, the US and the EU systems have fundamental differences regarding core issues of eligibility and scope. Furthermore, this divergence is allowed under TRIPS and UPOV, and there is a lack of any instruction in international treaties to harmonize these differences.

Consistent with the fact that one of the main arguments in Europe against plant patents is that it does not allow free access to plant material for the purposes of innovation and food security, the planned European Unitary Patent foresees a limited breeder's exemption that will allow free use of patented plant material for breeding, with a license from the patent owner required to commercialize new varieties bearing the patented trait. This exemption will take effect in the EU once the Unitary Patent comes into force.[148] In this way, even though the upcoming patent legislation will include protection for new plant varieties, by considering a limited breeder's exemption the IPR to be granted will really consist on a form of PBR rather than a patent, thus confirming that despite growing interests for international harmonization, the different approaches followed by the US and the EU towards IPRs for new plant varieties are likely to persist.

[148] European Patent Office (n 117)

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