

PATENTING OF PLANTS AND EXCEPTIONS TO EXCLUSIVE RIGHTS: LESSONS FROM EUROPEAN LAW

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ABSTRACT

Biotechnology has increased the use of patent law to protect the outcomes of plant breeding. While the TRIPS Agreement allows countries to exclude the patentability of plants and essentially biological processes to obtain them, many developing countries are granting patents on plants and plant components, such as seeds, cells, and genes. These patents can limit access to plant materials for further research and breeding and prevent farmers from saving and re-using seeds that incorporate patented materials. This study shows how European legislation has sought to strike a balance between the protection of plant-related inventions and the rights of breeders and farmers through the introduction of specific exceptions to patent rights and discusses what lessons can be drawn for developing countries.

La biotecnología ha incrementado el uso de la ley de patentes para proteger los resultados del fitomejoramiento vegetal. Aunque el Acuerdo sobre los ADPIC permite a los países excluir la patentabilidad de las plantas y los procesos esencialmente biológicos para obtenerlas, muchos países en desarrollo están concediendo patentes sobre plantas y componentes vegetales, como semillas, células y genes. Estas patentes pueden limitar el acceso a los materiales vegetales para su posterior investigación y mejora e impedir que los agricultores guarden y reutilicen las semillas que incorporan materiales patentados. Este estudio muestra cómo la legislación europea ha tratado de encontrar un equilibrio entre la protección de las invenciones relacionadas con las plantas y los derechos de los obtentores y los agricultores mediante la introducción de excepciones específicas a los derechos de patente, y analiza qué lecciones se pueden extraer para los países en desarrollo.

La biotechnologie a entraîné un recours accru au droit des brevets pour la protection des résultats de sélection végétale. Alors que l'accord sur les ADPIC permet aux pays d'exclure la brevetabilité des plantes et des procédés essentiellement biologiques pour les obtenir, de nombreux pays en développement accordent des brevets sur les plantes et les composants végétaux, tels que les graines, les cellules et les gènes. Ces brevets peuvent limiter l'accès au matériel végétal pour la recherche et les sélections ultérieures, et empêcher les agriculteurs de conserver et de réutiliser les semences qui contiennent du matériel breveté. Cette étude montre comment la législation européenne a cherché à trouver un équilibre entre la protection des inventions liées aux plantes, et les droits des obtenteurs et des agriculteurs par l'introduction des exceptions spécifiques aux droits de brevet et discute des leçons qui pourraient en être tirées pour les pays en développement.

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EXECUTIVE SUMMARY

Biotechnology has increased the use of patent law to protect the outcomes of plant breeding. While the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) allows countries to exclude the patentability of plants and essentially biological processes to obtain them, many developing countries are granting patents on plants and plant components, such as seeds, cells, and genes. These patents can limit access to plant materials for further research and breeding and prevent farmers from saving and re-using seeds that incorporate patented materials. The best policy option for developing countries is to exclude plants and plant materials from patent protection. If, however, plants or their parts and components were patentable, the applicable laws would need to incorporate exceptions to the exclusive rights that take the specific features of such materials (namely their biological origin and reproducibility) into account.

The policies implemented by European countries provide some useful examples of normative approaches to address these issues in developing countries. European legislation has sought to strike a balance between the protection of plant-related inventions and the rights of breeders and farmers through the introduction of specific limitations to patent rights.

The use of genetic technologies opened up the possibility of acquiring patent rights over plants and plant materials, a possibility that is not available under plant variety protection (PVP), which only applies to plant varieties, that is, a grouping of plants characterized by a number of identifiable features. Plant materials may be protected under European law, depending on the claimed subject matter, by patents or by a *sui generis* PVP. Inventors seeking protection in Europe have the possibility to choose the national patent, the European patent granted by the European Patent Office (EPO) or the Unitary Patent (after entry into force of the Agreement of the Unified Patent Court (UPCA). Similarly, plant breeders can opt for the national protection or the Community plant breeder's rights. However, cumulative protection is prohibited.

Under European law, biological material, such as genes, may meet the technical effect requirement, even if merely isolated from nature, if a function thereof has been determined. In addition, the biological nature of a process does not exclude per se its patentability. While "discoveries" are distinguished from "inventions" and are not patentable under European law, that concept has been narrowly interpreted. Accordingly, plant parts or components may be deemed patentable.

While isolated genes may be patented under EU law, some national laws of the EU members have limited the scope of protection of genes by narrowing down the scope of claims thereof. Under EU law and the national patent regimes of France, Germany and Switzerland, patents on gene plants, to be valid, need to be limited to the specific function claimed in the application (use-bound claims), while in Austria and the Netherlands the description of the gene function is related to the fulfilment of the industrial applicability requirement.

European law excludes plant varieties from patent protection. A basic policy objective of the distinction between plants and plant varieties is to ensure the continuous development and improvement of the latter, including through the possibility—allowed under PVP—of using a protected variety to develop and commercialize a new variety, with a limitation only (with regard to commercialization), under UPOV 91 rules in situations where an essential derivation exists.

Plants, however, can be patent protected as long as the technical feasibility is not confined to a particular variety. This would be the case of a particular trait which can be transferred from one variety or plant to other varieties or plants. Hence, an individual plant (e.g., a genetically

modified plant) as such may be patented (including its cells) as well as plant groupings that do not meet the definition of a plant variety. Despite the duality between plants and plant varieties however, patents on the latter or plant materials may indirectly lead to the control of a plant variety, even if the latter is not patented. Patents can, hence, reduce the variability of starting material potentially leading in the long term to fewer and less diverse varieties, and make it difficult to benefit from research that could increase productivity, address world hunger, and alleviate poverty.

The extent to which essentially biological processes for the breeding of plants are excluded in EU law has been much debated, with various interpretations of the exclusion in the EPC rules. An interpretive problem was raised regarding whether the **product** of an essentially biological process is patentable. The response by EPO has been negative notably in the decision by the Enlarged Board of Appeal in the case G 3/19 "Pepper" of 14 May 2020, which confirmed that the exclusion from patentability as contained in Article 53(b) of EPC extends to plant and animal products that are exclusively obtained by means of an essentially biological process.

Two important limitations to patent rights introduced in EU patent legislation are the breeder's exemption and the farmer's privilege. Under article 27 of the UPCA the rights of the patent holder are limited when the biological material is used for the purpose of breeding or discovering and developing other plant varieties. In accordance with this provision, however, the breeder is not authorized to commercialize the new variety that they may have developed without the consent of the patent owner.

Provisions relating to saving and use of seeds by farmers (generally known as the "farmers' privilege") have also been introduced in EU law. Such use is permissible against the payment of royalties depending on the types of crops and the size of the exploitation. Conversely, the farmer is not allowed to sell the seeds or exchange them with other farmers. The farmers' privilege has also been incorporated into UPCA. Article 27.The establishment of the farmer's privilege under the European patent regime is also an example that developing countries should consider in their own legal systems. Developing countries could extend this exemption to all farmers. As exemplified by the Swiss law, they may stipulate as well that the farmers' privilege cannot be derogated by private agreements.

European law also provides for compulsory cross-licenses to address the cumulative protection by patents and plant variety protection, although under very restrictive conditions. Developing countries can consider the incorporation of disciplines to address, through compulsory cross-licensing situations of cumulative protection by patents and breeders' rights whenever such cumulative protection exists with the caveat that the right to obtain a compulsory license by a patent holder should only arise when the patented invention leads to a significant increase in the value for cultivation of the plant variety.

Importantly, while the above referred provisions in European law limit the exclusive rights granted to patent owners, none of them has been challenged as being incompatible with the TRIPS Agreement.

In summary, while the European law and practice on plant patents should not be deemed as transplantable to developing countries, they provide interesting elements for consideration to tackle some of the specific problems raised by the extension of patents to plants and plant materials in these countries.

I. INTRODUCTION

Advances in biotechnology have increased the use of the patent law to protect the outcomes of plant breeding based on both biotechnological tools (genetic modification, genetic editing, etc.) and conventional breeding.¹

While the TRIPS Agreement set out minimum standards for intellectual property (IP) protection, it left some policy space for WTO members to design their national regimes. Such space is particularly important in relation to plants, as the TRIPS Agreement allows countries to exclude them as well as essentially biological processes to obtain them from patentability. The Agreement requires WTO member countries to "provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof" (article 27.3b) thereby leaving significant flexibility to determine the modality and scope of protection.² The use of such flexibility, however, has been uneven in both developed and developing countries.

Recent research shows, in particular, that a large number of developing countries are not fully using the TRIPS flexibilities with regard to the grant of patents on plants or their parts and components.³ As a result, some developing countries' patent laws allow for the protection of plants, including in some cases, plant varieties, cells, genes and other components of plants. Furthermore, such laws have not introduced provisions to deal with the specific problems that the patenting of plant-related materials bring about, such as the fact that seeds may be self-reproduced, that a single plant may incorporate several protected gene constructs or components, and that plant variety protection (PVP) and patent protection, eventually conferring rights to different right-holders, may coexist. Importantly, patents on plants and plant materials may, in the absence of specific exceptions, limit access to plant materials for further research and breeding or prevent farmers from saving and re-using seeds that incorporate patented materials (or, alternatively, subject them to the payment of royalties). ⁴ In contrast to the situation in developing countries, some exceptions to the patent rights have been introduced in Europe in relation to plants and plant materials.

As further discussed below, under the European Patent Convention (EPC)⁵ and the European Union (EU) law,⁶ plants are patentable as long as the technical feasibility of the invention is not limited to a single plant variety. Whereas the European patent system explicitly excludes from patentability plant varieties, it allows patent protection on inventions which may be used in several plant varieties. A trait or a chemical characteristic can also be patentable as well as microbiological processes and the products thereof. However, this approach is limited by a second exception contained in article 53 (b) of EPC, which excludes "essentially biological processes for the production of plants or animals" from patentability and, as discussed below, the plants obtained by said processes.

¹ See Christoph Then and Ruth Tippe, "Patent applications on plants derived from conventional breeding 2016" (2017). Available from <u>https://www.no-patents-on-seeds.org/sites/default/files/2018-05/Report Patent%20applications%20on%20plants 2016.pdf.</u>

² Mark D. Janis, "Patenting Plants: A Comparative Synthesis", in *Patent Law in Global Perspective*, Ruth Okediji and Margo A. Bagley, eds. (New York, Oxford University Press, 2014).

³ See Oxfam, *The Status of Patenting Plants in the Global South* (The Hague, Oxfam Novib & Geneva, South Centre, 2018).

⁴ See e.g., Innovation and Access to Knowledge Programme Team, "Towards a More Coherent International Legal System on Farmers' rights: The Relationship of the FAO ITPGRFA, UPOV and WIPO", Policy Brief, No. 17, South Centre (March 2015).

 ⁵ Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.
 ⁶ Article 4(2) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions and Rule 27(b) of the EPC.

While the scope of patentability of plants and plant materials is relatively broad under European patent law, the EU and some European national laws have limited the scope of protection of genes and introduced specific exceptions to the conferred patent rights. Thus, Austria,⁷ France,⁸ Germany,⁹ the Netherlands¹⁰ and Switzerland¹¹ have introduced a breeder's exception to patent rights, according to which, breeders may use and improve patented material, even for commercial purposes.¹² Provisions relating to saving and use of seeds by farmers (generally known as the "farmers' privilege") have also been introduced, as well as provisions to address the interphase between patents and plant variety protection. Importantly, while these provisions limit the exclusive rights granted to patent owners, none of them has been challenged as being incompatible with article 30 (exceptions to rights conferred) or article 31 (uses without the authorization of the patent holder) of the TRIPS Agreement.¹³

While the best policy option for developing countries is to exclude plants and plant materials, such as genes, from patent protection (as allowed by the TRIPS Agreement), if plants or their parts and components are patentable, the applicable laws would need to incorporate exceptions to the exclusive rights that take the specific features of such materials (biological origin, reproducibility, etc.) into account.¹⁴ The policies implemented by European countries provide some useful examples of normative approaches to address these issues in developing countries. These countries can, however, develop their own legislative models in the context of the flexibilities allowed by the TRIPS Agreement.

This study will briefly discuss in Section 1 the main differences between conventional breeding and genetic engineering, with the aim of offering a background for the consideration of the scope of plant patent protection. Section 2 examines the subject matter eligible for patent protection under European law, while Section 3 addresses the exclusions for plant varieties and essentially biological processes. Section 4 analyzes the scope of patent protection under EU law. Section 5 examines the exceptions to patents rights relating to plants allowed under EU law, while Section 6 considers cross-compulsory licenses in cases of cumulative patent protection and PVP. Section 7 addresses the farmer's privilege, the breeder's exception (including questions regarding the commercialization of a new variety developed by a third party) and compulsory licenses as provided for at the national level by the German Patent Act (Patentgesetz, PatG), the Intellectual Property Code of France, the Patent Act and the Parliamentary Papers in the Netherlands, the Swiss Patent Act and the associated Patent Ordinance (PatV) and the Austrian Patent Act. Finally, the paper summarizes in section 7 some lessons that may be learned and their applicability in the context of developing countries.

⁷ § 2 Para. 2 and § 22c. of the Austrian Patent Act 1970, as amended.

⁸ Article L. 613-5-3 of the Code de la Propriété intellectuele, adopted in 2004.

⁹ Section 11.2.b of the Patent Act adopted in 2005.

¹⁰ Article 53.2.b of the Dutch Patent Act.

¹¹ Article 9 (e) of the Federal Act on Patents for Inventions, adopted in 2008.

¹² See also the Unified Patent Court Agreement (UPCA), article 27(c).

¹³ There is scarce literature on the exceptions that, consistently with the TRIPS Agreement, may be introduced in patent laws to allow breeders to use patented materials for further research and breeding (the "breeder's exception"), and farmers to save and reuse seeds (the "farmers' privilege"). For instance, Viola Prifti, *The Breeder's Exceptions to Patent Rights, Analysis of Compliance with Article 30 of the TRIPS Agreement* (Springer, 2015); Carlos Correa, *Patent Protection for Plants: Legal Options for Developing Countries*, Research Paper No. 55 (Geneva, South Centre, October 2014). Available from https://www.southcentre.int/wp-

content/uploads/2014/11/RP55 Patent-Protection-for-Plants EN.pdf; Carlos Correa, Sangeeta Shashikant, and François Meienberg, "Plant Variety Protection System: An Alternative to UPOV 1991", APBREBES Working Paper (2015); Campi Mercedes, "The Co-Evolution of Science and Law in Plant Breeding: Incentives to Innovative and Access to Biological Resources", *Journal of Intellectual Property Rights*, vol. 23 (July-September 2018), pp. 198–210; N. Louwaars et al., "Breeding Business. The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeder's Rights" (Netherlands Ministry of Agriculture, Nature, and Food Quality, 2009); F.J. Zimmer and M. Grammel, "Plant Patents in Europe", *Biotechnology Law Report*, vol. 34 (2015) pp.121–131.

¹⁴ Carlos Correa, *Patent Protection for Plants: Legal Options for Developing Countries*, Research Paper, No. 55 (Geneva, South Centre, October 2014) p. 7.

II. PLANTS OBTAINED THROUGH CONVENTIONAL BREEDING AND GENETIC ENGINEERING/GENE EDITING

Understanding the differences between conventional breeding and genetic engineering/gene editing¹⁵ is important from the patent law perspective, as the process used for the production of plants may determine the nature of the rights that can be claimed. While plant variety protection (PVP) regimes allow for the protection of varieties developed through conventional breeding, patent laws generally exclude this possibility. The essentially biological nature of the process and the degree of human intervention are key elements under the law of many countries (including in Europe), as discussed below, to determine whether a plant-related development is eligible for patent protection.

The improvement of plant varieties to obtain plants with increased agronomic value was originally driven by selection.¹⁶ Over thousands of years, farmers have selected the most suitable individual plants from the varieties they cultivate. Through this selection, the plants were slowly but steadily adapted to the human needs and over time lost the typical wild plant characteristics of their ancestors.¹⁷ With this classical breeding method, farmers could achieve great success even without knowledge of the underlying biological processes. Farmers, hence, should not be seen as only producers of food and other agricultural products but as breeders as well.¹⁸

Scientifically based plant breeding did not come into being until the middle of the 19th century, when the monk Gregor Mendel discovered the basics of heredity. From then on, selected plants were deliberately crossed with each other in order to select the best from the offspring, to cross again or to propagate them in a targeted manner (crossbreeding). Crossbreeding or combination breeding is the crossing of individuals of one species with different characteristics. The resulting generation with combined traits is then improved by selection and further crossbreeding in accordance with the breeding objective. Most of the current crop plants are the result of crossing experiments by combining desired traits from different breeds.

In conventional breeding, the number of genes that control the trait of interest is important. Breeders use methods and techniques based on the mode of reproduction of the species (self-pollinating, cross-pollinating, or clonally propagated.) They mainly breed a cultivar whose

¹⁵ Genetic engineering or modification of plants involves adding a specific stretch of DNA into the plant's genome, giving it new or different characteristics (see e.g., <u>https://royalsociety.org/topics-policy/projects/gm-plants/what-is-gm-and-how-is-it-</u>

done/#:~:text=Genetic%20modification%20of%20plants%20involves,it%20new%20or%20different%20characteri stics.&text=The%20gene%20of%20interest%20is,genome%20of%20the%20plant%20cells); gene (or genome) editing "is a group of technologies that give scientists the ability to change an organism's DNA. These technologies allow genetic material to be added, removed, or altered at particular locations in the genome" (see https://medlineplus.gov/genetics/understanding/genomicresearch/genomeediting/). It allows highly specific changes in the DNA sequence of a living organism, essentially customizing its genetic makeup. See Encyclopedia Britannica. Available from https://www.britannica.com/science/gene-editing. One of the approaches to genome editing is known as CRISPR-Cas9. For example, Chinese scientists have used this technology to delete genes in wheat strains to make them more resistant to certain pests (see Robin Feldman, The CRISPR Revolution: What Editing Human DNA Reveals About the Patent System's DNA, 64 UCLA L. REV. 392, 399, 2016).

¹⁶ Natural changes (mutations) also occur in the genetic material of all living organisms – including plants. Over time, these mutations can lead to plants acquiring new properties or losing old ones. The natural modification of the genetic material through conventional breeding is a very slow process. In order to accelerate it, plant seeds may be treated with chemicals or radioactivity, which increase the frequency of mutations and thus the probability that the plants acquire new, desirable characteristics.

¹⁷ On the evolution of the plant breeding techniques, see Mercedes Campi, "The Co-Evolution of Science and Law in Plant Breeding: Incentives to Innovate and Access to Biological Resources", *Journal of Intellectual Property Rights*, vol. 23 (July-September 2018) pp. 198–210.

¹⁸ This fact underpins the recognition of "Farmers' Rights". See e.g., Carlos Correa, *Implementing Farmers' Rights Relating to Seeds*, Research Paper No. 75 (Geneva, South Centre, March 2017).

genetic purity and productivity can be sustained by its natural mating system. Sometimes, the desired trait is found in wild relatives of the species and may be introgressed into cultivated species through pre-breeding.¹⁹

Breeding methods have evolved over time with advances in science. Basic molecular biological research began in the 1970s and has allowed to develop methods for interventions in the genome and introducing changes in DNA. In 1972 it was possible to produce what is known as recombinant DNA (rDNA). Only a few years later, researchers started using rDNA to produce human insulin (1979). As early as 1982, this was already being done on a large industrial scale. Since 1977, human proteins were produced genetically, and methods were developed to determine DNA sequences more efficiently. The application of genetic engineering was soon extended to plants: in 1980, *Agrobacterium tumefaciens* was used for the first time to insert foreign genes into plant cells.²⁰

The main difference between plants obtained through traditional and conventional breeding and those obtained through genetic engineering or biotechnology lies on the control breeders have of the breeding process.²¹ Most of the time, the results of conventional breeding are unpredictable²² and a long time is required to obtain them, ²³ while genetic engineering allows for the shortening of the development period and for specifically targeting and obtaining the desired new traits through the introduction of genetic information absent in the original material. The modern techniques simplify the breeding process: targeting of the desired gene, tracking it, and inserting it into a crop's DNA thereby excluding the potential for unwanted traits, which are often a by-product of conventional breeding.²⁴ Genetic engineering thus allows for targeted transfer (for example, to make plants resistant to pests, drought, and herbicides)²⁵ of desirable crop traits – the transgene²⁶ – and the breeding of new transgenic plants in a fast manner.²⁷

The differences between the conventional breeding method and genetic engineering lead to substantial differences in the conditions imposed by marketing approval regulations, as genetically modified plants need to be scrutinized for the human and animal health and

¹⁹ See G. Acquaah, "Conventional Plant Breeding Principles and Techniques", in *Advances in Plant Breeding Strategies: Breeding, Biotechnology and Molecular Tools*, J. Al-Khayri, S. Jain and D. Johnson, eds. (Springer, 2015) p. 1.

²⁰ H. Becker, Pflanzenzüchtung, 2. Auflage (Stuttgart, 2011) p. 223.

²¹ Breeding must go through five general steps: objectives, creation/assembly of variability, selection, evaluation and cultivar release. See G. Acquaah, Ibidem at 22. According to Acquaah, there are six basic types of cultivars: pure line, open-pollinated, hybrid, clonal, apomictic and multilines. The common methods for breeding selfpollinated species include mass selection, pure line selection, pedigree, bulk population, single seed descent, backcrossing, multiline and composite. Methods for breeding cross-pollinated species include mass selection, recurrent selection, family selection and synthetics.

²² Breeders choose the parents with the desired traits to cross but the progeny may not carry the genotype or display them in the phenotype. See also FAO, *The State of Food and Agriculture 2003-2004. Agricultural Biotechnology: Meeting the Needs of the Poor?* (Rome, FAO, 2004). Available from: http://www.fao.org/3/Y5160E/y5160e00.htm#topOfPage.

²³ It may take up to12 to 15 years from the first crossing to the approval of a plant variety. V. Prifti, *The Breeder's Exception to Patent Rights, Analysis of Compliance with Article 30 of the TRIPS Agreement* (Springer, 2015) p. 23.

²⁴ WIPO, *World Intellectual Property Report 2019, Plant biotechnology – connecting urban innovation and rural application. 2019*, p. 91. Research on transgenic plants focuses primarily on improving the quality of a wide variety of crops. Other goals include increasing yields, developing pest and disease resistance (e.g., to corn borer) and resistance to certain herbicides (e.g., Monsanto's herbicide Roundup).

²⁵ See e.g., A. Desalegn, "Application of Genetic Engineering in Plant Breeding for Biotic Stress Resistance", International Journal of Research Studies in Biosciences (IJRSB), vol. 5, Issue 9 (2017) pp. 28–35. Available from <u>https://www.arcjournals.org/pdfs/ijrsb/v5-i9/6.pdf</u>.

²⁶ The transferred gene does not necessarily have to be a gene from another plant; it can also come from a bacterium, fungus, virus or animal.

²⁷ The transgenic crops are generally referred to as "genetically modified organisms" (GMOs).

environmental risks they may create; genetic engineering has also raised ethical concerns.²⁸ Due to such risks, in many countries the use of genetically modified plants is restricted.²⁹

Those differences, as noted, also have a significant impact in relation to the type of intellectual property protection that can be obtained. Notably, the use of genetic technologies opened up the possibility of acquiring patent rights over plants and plant materials, a possibility that is not available under PVP, which only applies to plant varieties, that is, a grouping of plants characterized by a number of identifiable features.³⁰

 ²⁸See e.g., National Academies of Sciences, Engineering, and Medicine; Division on Earth and Life Studies;
 Board on Agriculture and Natural Resources; Committee on Genetically Engineered Crops: Past Experience and Future Prospects, *Genetically Engineered Crops: Experiences and Prospects*, ch. 5 (Washington, D.C., National Academies Press, 2016). Available from https://www.nap.edu/read/23395/chapter/8.
 ²⁹ See e.g., Theresa Papademetriou, "Restrictions on Genetically Modified Organisms: European Union", March

^{2014.} Available from https://www.loc.gov/law/help/restrictions-on-gmos/eu.php.

³⁰ See Article 5 of Council Regulation (EC) No 2100/94 on Community plant variety rights.

III. PATENTABILITY OF PLANTS AND PLANT MATERIALS UNDER EUROPEAN LAW

In Europe, the basic elements of patent law are governed by the European Patent Convention (EPC), which was concluded in 1973 and came into force in 1977.³¹ EPC does not create an European Community Patent Law as such, but contains a set of rules that need to be complied with by the Parties.³² It also provides an institutional mechanism, the European Patent Office (EPO), through which a single patent can be granted which translates itself into a bundle of national patents enforceable in the various national jurisdictions,³³ thereby obviating the need to go through separate proceedings in each of the States. Although EPC is independent from the European Union (EU), since the EU members form the core of EPC, European Union legislation and practice have a lasting impact on the rules and practices of the European Patent Office (EPO).

The Implementing Regulations to EPC serve as a means to put in practice the provisions of the Convention. In particular, Rules 26 to 34 of the Implementing Regulations, which relate to biotechnological inventions, were designed to bring the EPC regime into conformity with the EU legislation on biotechnological inventions.³⁴

Under European law, plant materials may be protected, depending on the claimed subject matter, by patents or by a sui generis PVP. In the context of EU, the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions³⁵ has harmonized the applicable rules related to patentability of biotechnological inventions, including plant materials, Rule 26(1) EPC explicitly refers to the Directive 98/44/EC as a supplementary means of interpreting EPC. The Council Regulation (EC) N° 2100/94 on Community plant variety rights was established as an independent scheme of protection for new plants varieties. It is based on the UPOV Act of 1991 and implemented by the Community Plant Variety Office. Inventors seeking protection in Europe have the possibility to choose the national patent, the European patent granted by EPO or the Unitary Patent (after entry into force of UPCA). Similarly, plant breeders can opt for national protection or the Community plant breeder's rights as contained in the Council Regulation 2100/94 of 27 July 1994 on Community plant variety rights, which coexists with the national systems.³⁶ However, cumulative protection is prohibited. Any variety which is the subject matter of a Community plant variety right cannot be the subject of a national plant variety right or any patent for that variety; where a national plant variety protection has been granted prior

³¹ The Convention on the Grant of European Patents of 5 October 1973 as amended by the act revising Article 63 EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996, 10 December 1998 and 27 October 2005.

 ³² P. Craig and G. De Búrca, *EU Law, Text, Cases and Materials*, 2nd Edition (Oxford, 1998) p. 1058.
 ³³ In 2012, EU countries and the European Parliament agreed on a regulation creating a European patent with unitary effect ('unitary patent') that, when finally introduced, will remove the need for national validations and provide a uniform protection. See https://www.epo.org/law-practice/unitary/unitary-patent.html.

 ³⁴ Franz-Josef Zimmer and Dr. Markus Grammer, "Plant Patents in Europe", Grünecker (16 July 2015).
 ³⁵ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. OJ L 213, 30.7.1998. Available from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044.
 ³⁶ See Regulation EC 2100/94 of 27 July 1994 on Community Plant Variety Rights, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044.

³⁶ See Regulation EC 2100/94 of 27 July 1994 on Community Plant Variety Rights, available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31994R2100</u>. See also, Niels Louwaars, Hans Dons, Geertrui van Overvalle, Hans Raven, Anthony Arundel, Derek Eaton, Annemiek Nelis, Breeding Business, *The Future of Plant breeding in the light of developments in patent rights and plant breeder's rights*, Netherlands Ministry of Agriculture, Nature and Food Quality (LNV), Wageningen, Centre for Genetic Resources (CGN) – Wageningen University and Research Centre, December 2009, p. 13.

to the grant of a Community right, the holder of the national right shall be unable to invoke it for as long as the Community rights remain effective.³⁷

Article 52 of EPC specifies that European patents shall be granted for new inventions involving an inventive step and susceptible of industrial application. "Invention" is a central concept of patent law. Scientific theories and discoveries are excluded from patent protection. Scientific theories are expressions of human ingenuity, and as such, important inputs to technological progress and follow-on innovation. However, the patent system has traditionally been built so as to exclude these building blocks of knowledge from IP protection.³⁸ By excluding scientific theories and discoveries, EPC implies that the invention needs to present a technical character. The German Federal Constitutional Court (BGH) in its 1969 decision on "Rote Taube", described the invention as a doctrine for planned action using controllable natural forces for the immediate achievement of a causally overseeable success.³⁹ The definition contained in Rote Taube has set a standard that is still valid in Europe today and is in line with the concept of invention of article 52 EPC.⁴⁰

Under European law, biological material, such as genes, may meet the technical effect requirement, even if merely isolated from nature, if a function therefor has been determined. In accordance with Directive 98/44/EC, biological material which is isolated from its natural environment or produced by means of a technical process can be the subject of a patent even if it previously occurred in nature.⁴¹ In addition, the biological nature of a process does not exclude per se its patentability. The German Federal Court (BGH) addressed the question of patentability of biological material in the above-mentioned case (BGHZ 52, 74 – Rote Taube), in which BGH considered a process of breeding animals as patentable. It asserted that the concept of "technology" is not limited to inanimate matter, concluding that the field of biology is also fundamentally open to patent protection. It asserted that the concept of "technology" was not static but can change with technological development. The court consequently ruled that biological processes can be controlled by man and predictable, therefore, the planned use of biological forces and process was considered patentable.⁴²

Genetic Information

Rule 26 of EPC defines biotechnological inventions in a comprehensive way as "inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used". The definition includes natural substances that have been extracted from their natural environment. The act of isolating (and purifying) may be regarded as a technical contribution to the art.

 ³⁷ See article 92 of the Council Regulation (EC) N° 2100/94 on Community plant variety rights.
 ³⁸ See UNCTAD, Using intellectual property rights to stimulate pharmaceutical production in developing countries: A reference guide (United Nations, New York and Geneva, 2011) p. 47.

³⁹ Own translation. See Germany, BGHZ, 52,74 GRUR 1969, 672 (673) – Rote Taube. The original text: «Technish ist eine Lehre zum planmässigen Handeln unter Einsatz beherrschbarer Naturkräfte zur unmittelbaren Erreichung eines kausal übersehbaren Erfolges, der ohne Zwischenschaltung menschlicher Verstandestätigkeit die unmittelbare Folge des Einsatzes beherrschbarer Natürkräfte ist».

⁴⁰ See e.g., Enlarged Board of Appeal, 9 December 2010, G 2/07. The requirement that inventions have a technical character was considered by the Enlarged Board of Appeal in the cases Broccoli and Tomato discussed below. The Swiss Patent Act, make references to the beneficial technical effect of an invention. Federal Act on Patents for Inventions (PatG) Article 1a and 1b.

⁴¹The German Patent Act, (PatG) in line with EU law adopts this legal principle as follows: patents can be granted for inventions even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used (Section 1.2.). In addition to art. 2(1) NPA 1995, art. 2a NPA 1995 contains, like the German Patent Act, a specific provision for inventions relating to biological material.
⁴² Germany, BGHZ, 52,74 GRUR 1969, 672 (673) – Rote Taube, para 67,22 and 26. Available from https://www.prinz.law/urteile/bgh/X_ZB_15-67-ok.

While "discoveries" are distinguished from "inventions" and are not patentable under European law, that concept is narrowly interpreted. Thus, in accordance with the EPO Guidelines for Examination:

To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as one aspect of the invention. Similarly, a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g., its use in making a certain polypeptide or in gene therapy.⁴³

Accordingly, plant parts or components may be deemed patentable. Thus, an isolated gene for which a function has been identified may be eligible for protection. Interestingly, the current approach on the matter in Europe is broader than in the USA after the Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics Inc.* in which the court invalidated claims on isolated DNA on the grounds that it was not "markedly different" from what exists in nature.⁴⁴ The court however made a distinction between DNA and cDNA, that is, a form of synthesized DNA used in genetic engineering to produce gene clones.⁴⁵ Genes, even if isolated, are not patentable in other jurisdictions as well. For example, the Brazilian Industrial Property Code (No. 9.279, 14 May 1996) excludes from patentability living beings or "biological materials found in nature", even if isolated, including the "genome or germplasm" of any living being (article 10.IX).⁴⁶

Even in cases where genes and other plant materials are eligible for patent protection—as it is the case under EU law—it may be difficult to meet the inventive step standard based on the characteristics of the isolation/synthesis process, as "it is now possible to isolate a specific region of a genome, to produce a virtually unlimited number of copies of it, and to determine the sequence of its nucleotides overnight... By related techniques, an isolated gene can be altered (engineered) at will and transferred back into the germ line of an animal or plant, so as to become a functional and heritable part of the organism's genome".⁴⁷ Since the identification of the genetic blueprint is now easily possible by automated sequencing technology and is carried out mechanically, it cannot usually constitute an inventive step.

Moreover, while isolated genes may be patented under EU law, some national laws of EU members have limited the scope of protection that can be claimed. This is in response to the fact that a gene may perform various functions, and a patent on a gene may be enforced against uses of the gene not even discovered or disclosed by the patent owner and prevent third parties from implementing such uses. In the case of plants, for instance, a single gene can contribute to multiple phenotypic traits such as the seed coat colour and the flower and

⁴³ See https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g ii 3 1.htm.

⁴⁴ In an earlier decision (*Mayo Collaborative Services v. Prometheus Laboratories Inc*) the Court had held that the mere application of natural phenomena using conventional techniques was not patentable. See e.g., Johnathon Liddicoat, Kathleen Liddell, Arlie H. McCarthy *et al.*, "Continental drift? Do European clinical genetic testing laboratories have a patent problem?", *European Journal of Human Genetics*, vol. 27 (2019), pp. 997–1007. Available from <u>https://www.nature.com/articles/s41431-019-0368-7</u>.

⁴⁵ Lawrence O. Gostin, "Who Owns Human Genes? Is DNA Patentable?", *JAMA*, vol. 310 (2013) p. 791.
⁴⁶In accordance with the Swiss Patent law, as revised in 2007, "a naturally occurring sequence or partial sequence of a gene is not patentable as such" (Art. 1*b*.*III*.1). "Sequences deriving from a naturally occurring sequence or partial sequence of a gene are patentable as inventions, if they are produced by means of a technical process, if their function is concretely disclosed and if the other criteria of article 1 (novelty, inventive step, industrial applicability) are fulfilled" (Article 1*b*(2) of Swiss Patent Law).

 ⁴⁷ "Isolating, Cloning, and Sequencing DNA", in *Molecular Biology of the Cell*, 4th edition, B. Alberts, A. Johnson, J. Lewis *et al.* (New York, Garland Science, 2002). Available from https://www.ncbi.nlm.nih.gov/books/NBK26837/.

axil pigmentation.⁴⁸ Moreover, researchers generally refrain from investigating alternative uses of a gene that has already been patented.⁴⁹

Thus, article L613-2-1of the French Industrial Property Code, as amended in 2004, clarified that the scope of a claim on a gene sequence is limited to that part of the sequence directly linked to the function specifically disclosed in the specifications, and that such a claim cannot be enforced against a subsequent claim on the same sequence that discloses another specific application thereof.

In Germany, a similar limitation on gene patents was introduced in connection with human genes by the Patent Act of 16 December 1980, as amended by the Law of 28 February 2005:

Section 1a... (3) The industrial application of a sequence or a partial sequence of a gene shall have to be specifically disclosed in the application by indicating the function fulfilled by the sequence or partial sequence. (4) Where the subject matter of an invention is a sequence or a partial sequence of a gene, the structure of which is identical to the structure of a natural sequence or partial sequence of a human gene, the use thereof, for which industrial application is specifically described in subsection (3), shall have to be included in the patent claim.

The European Parliament also called on the European Patent Office and the Member States:

to grant patents on human DNA only in connection with a concrete application and for the scope of the patent to be limited to this concrete application so that other users can use and patent the same DNA sequence for other applications (purpose-bound protection) (paragraph 5).⁵⁰

Although the German law and the European Parliament's call refers to human genes only, there is no reason not to apply the same approach to genes found in other living organisms, including plants. In fact, in *Monsanto Technology LLC v Cefetra BV, Cefetra Feed Service BV, Cefetra Futures BV, Alfred C* (Case C-428/08), both the EU Advocate General and the EU Court of Justice (ECJ) argued in favour of the limitation of the scope of patents specifically in relation to plant genes, to what the patent applicant has actually claimed. Both argued that, under the European Directive on the matter, only purpose-bound claims are admissible in the case of genes. The Advocate General also elaborated on the TRIPS-consistency of such claims. He stated that:

...to grant absolute protection to an invention consisting in a DNA sequence, thereby conferring on the patent holder exclusive rights over that sequence, extending to all its possible uses, including those unspecified or unknown at the time when the application was lodged, would be in breach of that fundamental principle, in so far as it would confer on the patent holder a disproportionate level of protection (para. 32).

Nor are there problems of compatibility with Article 30 of the TRIPS Agreement, which concerns possible exceptions to the rights conferred on a patent holder. Above all, in fact, to recognise purpose-bound protection does not mean providing for exceptions from the scope of protection of a patent: what is defined in narrow terms rather, is the extent of the right itself, which is not recognised in respect of uses other than those described in the patent application.

⁴⁸ See, e.g., Ingrid Lobo, "Pleiotropy: One gene can affect multiple traits", *Nature Education*, vol. 1, Issue 1 (2008). Available from <u>http://www.nature.com/scitable/topicpage/pleiotropy-one-gene-can-affect-multiple-traits-569</u>.

⁴⁹ Nikolaus Thumm, "Patents for genetic inventions: a tool to promote technological advance or a limitation for upstream inventions?", *Technovation*, vol. 25, Issue 12 (December 2005) p. 1410.

⁵⁰ European Parliament resolution on patents for biotechnological inventions. Available from <u>https://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2005-0407+0+DOC+XML+V0//EN</u>.

There is no obligation under the TRIPS Agreement to recognise that the protection accruing to DNA sequences is "absolute"-that is to say, protection in respect of all possible uses, including even unforeseen and future uses (para. 75).⁵¹

The European Court of Justice in its decision on this case held that:

...it should be borne in mind that recital 23 in the preamble to the Directive states that 'a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention (para. 43).

Moreover. the import of recitals 23 and 24 in the preamble to, and Article 5(3) of the Directive is that a DNA sequence does not enjoy any protection under patent law when the function performed by that sequence is not specified (para. 44).

The Swiss Patent law, as revised in 2007, similarly limits patents on genes (whether human or not) to their specific functions:

Sequences that are derived from a naturally occurring sequence or partial sequence of a gene may, however, be patented as an invention if they are produced by means of a technical process, their function is specifically indicated, and the further requirements of Article 1 are fulfilled... (Art. 1b.III.2).

Under the Austrian legislation, the functionality does not limit the scope of the patent claim but serves to demonstrate that the invention is industrially applicable.⁵² The Austrian Patent Office in its Examination Guidelines related to Biotechnological Inventions provides the following:

... This is not the case if the product is unusable or useless. It is therefore necessary to consider whether the claimed invention fulfills a useful purpose. Directive 98/44/EC (recital 22) and § 89a Patent Law stipulates that the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed. Therefore, the intended use of a sequence, i.e., its function, has to be derivable from the application as filed at the filing date. [...] The possible use of short DNA sequences or ESTs (= partially sequenced cDNA clones) as probes, is not considered to be sufficient.

Similarly, the Dutch Patent Act requires the description of the specific function of an invention related to a gene sequence, or partial sequences thereof, with the purpose of compliance with the industrial application requirement.⁵³

In summary, under EU law and the national patent regimes of France, Germany and Switzerland, patents on gene plants, to be valid, need to be limited to the specific function claimed in the application (use-bound claims), while in Austria and the Netherlands the description of the gene function is related to the fulfilment of the industrial applicability requirement.54

⁵¹ Opinion of Advocate General Mengozzi, delivered on 9 March 2010 (1), Case C-428/08. Available from http://curia.europa.eu/juris/document/document.jsf?docid=80052&doclang=EN.

⁵² See § 1 para. 1 of the Austrian Patent Law. ⁵³ See Art. 25.3 of the Dutch Patent Act.

⁵⁴ See for an overview of European countries' legislation on the matter, Bostyn, S., Iserentant, H., Sattler de Sousa e Brito, C., Taormino, J., Farquharson, A., Yeats, S., Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering, The Netherlands, 17 May 2016, p. 220. Available from https://dare.uva.nl/search?identifier=f875d3c8-517d-4e0c-8058-1c5de5c927f5.

Plants

As discussed below, European law excludes **plant varieties** from patent protection. **Plants**, however, can be patent protected as long as the technical feasibility is not confined to a particular variety (EU Directive 98/44/EC, rec. 29; Rule 27(b) EPC). This would be the case of a particular trait which can be transferred from one variety or plant to numerous other varieties or plants. The concept of "plant variety" is defined in Rule 26(4) EPC as a "plant grouping within a single botanical taxon of the lowest known rank" that meets a number of specific conditions. Hence, an individual plant (e.g. a genetically modified plant) as such may be patented (including its cells) as well as plant groupings that do not meet the definition of a plant variety set out in Rule 26(4) EPC.

EPO case law has aimed at preventing situations in which certain traits, claimed as not limited to a particular variety, are in fact confined to one or more varieties. In accordance with the EPO Guidelines for Examination "a claim cannot escape the exclusion of plant varieties under Article 53(b) by consisting of a large number of varieties, not even if there are hundreds of them".⁵⁵ Only if the subject-matter of the claim comprises at least one embodiment which does not constitute a variety is the claim allowable.⁵⁶ In T 1208/12 (Oilseed/PIONEER HI-BRED) of 7.2.2017, for instance, the Board of Appeal of the EPO found that a "hybrid seed and the plant grown therefrom as subject-matter of the claim each and every time belong to a particular plant grouping which complies with the definition of plant variety pursuant to Rule 26(4) EPC" (para. 25).⁵⁷

The duality between plants and plant varieties, however, may indirectly lead to the control of a plant variety, even if the latter is not patented. For example, if a plant incorporating a herbicide-resistant gene is patented,⁵⁸ a grouping of this plant that conforms to the definition of plant variety would be *de facto* subject to the exclusive rights of the patent owner. The same would occur if a patent is granted on any parts or components of a plant.⁵⁹ In decision G 1/98 the EPO Enlarged Board stated: "A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it may embrace plant varieties."

Granting exclusive rights on plants and/or their components may, however, inhibit follow-on innovation. In the absence of legal exemptions, and even if a plant variety is not patented as such, breeders would depend on the goodwill of the patent holder to use the patented material for further research and breeding. Significantly, "patent claims may be very broad and in most cases it is almost impossible for a breeder to know whether a particular plant variety is covered by a specific patent or not".⁶⁰ In addition, such patents are likely to infringe on other patented technology resulting in the relatively high amount of litigation seen in the seeds industry.⁶¹ As a result, breeders might be discouraged to explore or make use of plant genetic material for fear of patent infringement. If a relevant patent is identified, the breeder would need to request a license that, if denied or subject to unreasonable conditions, would in practice impede access to the biological material. Patents can, hence, reduce the variability of starting material potentially leading in the long term to fewer and less diverse varieties,⁶² and make it difficult to benefit from research that could increase productivity, address world hunger problems, and alleviate poverty.

⁵⁵ See <u>https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_4_1.htm</u>.

⁵⁶ Ibidem.

⁵⁷ https://www.epo.org/law-practice/case-law-appeals/pdf/t121208eu1.pdf.

⁵⁸ Generally, patents relating to genetically modified plants include claims on gene constructs (or parts thereof such as transit peptides), the modified cells and plants.

⁵⁹ See, e.g., Oxfam, op. cit.

⁶⁰ See Bostyn, S., Iserentant, H., Sattler de Sousa e Brito, C., Taormino, J., Farquharson, A., Yeats, S, op. cit., p. 17.
⁶¹ WIPO, World Intellectual Property Report 2019, Plant biotechnology – connecting urban innovation and rural application (2019) p. 89.

⁶² See Bostyn, S., Iserentant, H., Sattler de Sousa e Brito, C., Taormino, J., Farquharson, A., Yeats, S, op. cit., p. 18.

IV. EXCLUSIONS FROM PATENTABILITY

Plant Varieties

The European Patent Convention mentions a few inventions for which no patents are granted. One of these exclusions refers to plant and animal varieties and essentially biological processes for the breeding of plants or animals (EPC Art. 53 (b)). As noted, the term "plant varieties" (Art. 53 b EPC) does not mean "plants", but only a taxonomic unit as defined under European law, consistently with UPOV 1991.⁶³

The distinction between plants (which may be patent protected) and plant varieties (which can only be protected under PVP) is a clear-cut characteristic of European law, which has influenced many national laws around the world⁶⁴ and (albeit only partially) the TRIPS Agreement.⁶⁵ In decision G 1/98 the EPO Enlarged Board, for instance, stated that:

Article 53(b) EPC defines the borderline between patent protection and plant variety protection. The extent of the exclusion for patents is the obverse of the availability of plant variety rights. The latter are only granted for specific plant varieties and not for technical teachings which can be implemented in an indefinite number of plant varieties. This is not a question of arithmetical logic but based on the purpose of plant variety rights to protect specific products which are used in farming and gardening (para. 3.10).

A basic policy objective of the distinction between plants and plant varieties is to ensure the continuous development and improvement of the latter, including through the possibility—allowed under PVP—of using a protected variety to develop **and** commercialize a new variety, with a limitation only (with regard to commercialization), under UPOV 91 rules—in situations where an essential derivation exists.⁶⁶ This possibility—conferred under what is known as the breeder's exemption—is essential for food security and the continued progress in agricultural development. The European Court of Justice (ECJ) has emphasized the public interest involved in the regulation of plant varieties in a recent decision (Case C-176/18, *Club de Variedades Vegetales Protegidas v Adolfo Juan Martínez Sanchís*, ECLI:EU:C:2019:1131, 19 December 2019) in which it held:

...even though the scheme introduced by the European Union is intended to grant protection to breeders who develop new varieties in order to encourage, in the public interest, the breeding and development of new varieties, such protection must not go beyond what is necessary to encourage such activity, otherwise the protection of public interests such as safeguarding agricultural production and the need to supply the

https://www.natlawreview.com/article/protecting-plant-innovations-patents-united-states-australia-and-newzealand. See also Oxfam, op. cit. regarding the situation in some developing countries. ⁶⁵ Article 27.3(b) of the TRIPS Agreement does not exclude the protection of plant varieties by patents:

⁶³ Additionally, microbiological processes and the products obtained from them can be patented.

⁶⁴ Only a few countries, such as USA and Australia, allow for patents on plant varieties. See Michael Christie, and Margaux L. Nair, "Protecting Plant Innovations: Patents in United States, Australia, and New Zealand", *National Law Review*, vol. VII, no. 200 (19 July 2017). Available from

⁶⁵ Article 27.3(b) of the TRIPS Agreement does not exclude the protection of plant varieties by patents: "...Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof...".

⁶⁶ See e.g., Angela Martinez Lopez, "Introduction to the Notion of Essentially Derived Varieties", *European Seed*, 25 September 2019. Available <u>from https://european-seed.com/2019/09/introduction-to-the-notion-of-essentially-derived-varieties/</u>.

market with material offering specified features, or the main aim of maintaining the incentive for continued breeding of improved varieties may be jeopardized.⁶⁷

The EPO Guidelines for Examination make it clear that "the method for the plant's production, be it by recombinant gene technology or by a classical plant breeding process, is irrelevant" for asserting the non-patentability of plant varieties. Accordingly, the Guidelines indicate that "plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability".⁶⁸

The exclusion of plant varieties, as noted above, cannot be circumvented even by claims encompassing a large number of varieties, not even if there are hundreds of them, or when hybrids are developed. For instance, a claim directed to a hybrid of a specific deposited Brassica variety with any high-yielding Brassica variety results in a Brassica hybrid variety, which is not patentable.⁶⁹ In the case of hybrids, while the productivity of seeds of the second and subsequent generations of seeds decreases sharply, controlled hybrids with inbred parents are excluded from patentability "as they define either a seed or a plant which necessarily belongs to a particular plant grouping within the meaning of plant variety pursuant to <u>Rule 26(4)</u> EPC".⁷⁰

Essentially Biological Processes

A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection, which are conventional breeding methods.⁷¹ Plant breeding is a process that has been practiced by farmers and farming communities since the beginning of agriculture, but as noted above, the processes of breeding have evolved to involve human intervention in one or more of the several steps in plant production.

In Europe much of the discussion has been focused on the degree and impact of human intervention required to consider whether a process is "essentially" biological or not. While some interventions may mean that a process is not "purely" biological, it does not mean that it is not "essentially" biological and excluded from protection.⁷² While some European laws have introduced provisions to address this issue⁷³ EPO examination guidelines and jurisprudence has attempted to clarify the contours of the exclusion of such processes. In T 0915/10 (Soybean event/MONSANTO) of 11.6.2015, ⁷⁴ for instance, the Board "considered that the claimed subject-matter was a method for the production of plants by means of genetic-engineering techniques, which involves laboratory techniques essentially different from breeding methods and which as such have been accepted in the case law to be patentable".⁷⁵

⁶⁷ Available from <u>http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-176/18</u>.

⁶⁸ See <u>https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_4_1.htm</u>.

⁶⁹ Ibidem.

⁷⁰ Ibidem.

⁷¹ See Rule 26.5 EPC.

⁷² See D. Borges Barbosa and K. Grau-Kuntz, *Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights* (WIPO, SCP/15/3, 2010) p. 61.

⁷³ For instance, the Intellectual Property Code of France states in article L611-19: "The following shall not be patentable: ... (3) essentially biological processes for obtaining plants and animals; processes which require exclusively natural phenomena such as crossing or selection shall be considered such...". Article 3(1) NPA 1995 of the Netherlands refers to processes consisting entirely of natural phenomena such as hybridisations or selections in order to produce plants or animals and the products obtained thereby.

⁷⁴ See <u>https://www.epo.org/law-practice/case-law-appeals/recent/t100915eu1.html</u>.

⁷⁵ See <u>https://www.epo.org/law-practice/legal-texts/html/caselaw/2019/e/clr_i_b_3_3_2_a.htm</u>.

In 2010. The Enlarged Board of Appeal in its Decision Tomatoes I (G1/08)⁷⁶ and Broccoli I (G2/07)⁷⁷ ruled that processes containing or consisting of the steps of crossing and selection should be excluded from patentability as being "essentially biological". It ruled that "such a process does not escape the exception to patentability merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants".⁷⁸ The selection had been made in these cases utilizing molecular assisted selection (MAS) but the Board dismissed it as a sufficient step to overcome the exclusion of essentially biological processes from patentability. It noted that "the use of molecular markers such as DNA markers is a well-known step in the selection of plants with desired characteristics. Methods to discover and produce molecular markers that segregate with a desired trait were commonly known in the art and had already been used in the context of Brassica species. This feature is therefore not able to contribute anything beyond a trivial level to the claimed invention".⁷⁹ It added that "even the most traditional forms of plant breeding consisting entirely of crossing and selection are unlikely to occur in nature as such but are characterised by some form of human intervention".⁸⁰

While this case law clarified to some extent⁸¹ when the exclusion of essentially biological processes applies, another interpretive problem required additional consideration: is the product of an essentially biological process patentable? Patents were in fact granted by the EPO on broccoli⁸² and tomato⁸³ products despite that the claimed products were obtained from essentially biological process,⁸⁴ which created further controversy regarding the scope of the exclusion of article 53.b and Rules 26. 5 and 28.2 EPC. In an Amicus Curiae letter to the EPO Enlarged Board of Appeals it was rightly noted that:

if Article 53 (b) EPC excludes a process for the breeding of plants and animals from patentability, then this encompasses product protection for products manufactured with this process. To then grant a patent on a product which was derived from the process and which is excluded from patentability according to Article 53 (b) EPC, undermines the intention of the legislator and provides protection for something that would have been already within the scope of the (excluded) patent on the process, which, according to Article 53 (b) EPC, cannot be granted.85

In 2015 the Enlarged Board of Appeal had ruled on the patentability of products from conventional breeding in its decision Tomatoes II (G2/12)⁸⁶ and Broccoli II (G2/13)⁸⁷ stating that "While processes for conventional breeding cannot be patented, plants and animals stemming from these processes are patentable". In response, the European Commission

78 https://www.epo.org/law-practice/legal-texts/html/caselaw/2019/e/clr_i_b_3_3_2_a.htm.

⁸⁰ Ibidem.

⁸² EP 1069819 consisting of a method to produce Brassica oleracea.

⁷⁶ G 0001/08 Tomatoes/State of Israel of 9.12.2010. Available from https://www.epo.org/law-Practice/case-lawappeals/recent/g080001ex1.html. ⁷⁷ G 0002/07 Broccoli/Plant Bioscience of 9.12.2010. Available from https://www.epo.org/law-Practice/case-law-

appeals/recent/g070002ex1.html.

⁷⁹ See https://www.epo.org/law-practice/case-law-appeals/recent/g070002ep1.html.

⁸¹ Duncan Matthews and Herbert Zech, eds., Research Handbook on Intellectual Property and the Life Sciences (Edward Elgar, 2017) p. 138. Available from https://www.e-elgar.com/shop/gbp/research-handbook-onintellectual-property-and-the-life-sciences-9781783479443.html.

⁸³ EP 1211926 consisting of a method for breeding tomato plants that produce tomatoes with reduced fruits water.

⁸⁴ Michael Blakeney, Patents and Plant Breeding: Implications for Food Security, Amsterdam Law Forum, vol. 3, No. 3 (2011). Available from http://ssrn.com/abstract=1927220.

⁸⁵ No-patents-on seeds, Amicus Curiae letter regarding G3/19, available at https://www.no-patents-onseeds.org/sites/default/files/2019-08/Npos_Amicus%20Curiae%20letter%20on%20G3_19.pdf.

⁸⁶ G 0002/12 Tomatoes II of 25.3.2015. Available from https://www.epo.org/law-practice/case-lawappeals/recent/g120002ex1.html.

⁸⁷ G 0002/13 Broccoli II of 25.3.2015. Available from https://www.epo.org/law-practice/case-lawappeals/recent/g130002ex1.html.

issued an explanatory notice, which concluded that plant and animal products obtained through essentially biological processes are excluded from patentability.⁸⁸ The apparent contradiction on the interpretation of the same provision by the two institutions led to the adaptation of EPO legal practice to EU rules, and in 2017 the Administrative Council of EPO added the new rule 28 (2) to the Implementing Regulations of EPC, which states that under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.⁸⁹

However, in a decision of 5 February 2019, the EPO Technical Board of Appeal found that the Rule 28.2 was in conflict with Article 53(b) of EPC as interpreted by the Enlarged Board of Appeal in the two referred to decisions "Tomatoes II" and "Broccoli II" of 25 March 2015. The EPO President subsequently referred the decision of the Technical Board to the EPO Enlarged Board of Appeal, aiming to reverse it.

The European Parliament (see Box 1) noted in this regard that "plant and animal varieties, including parts and traits, essentially biological processes as well as products emanating from such processes, shall not in any way be patentable, pursuant to the EU legislator's intention".⁹⁰ The Parliament also considered that "any attempt to patent products derived from conventional breeding, including crossing and selection, or on genetic material necessary for conventional breeding undermines the exclusion established in Article 53(b) of the EPC and in Article 4 of Directive 98/44/EC".⁹¹

Box 1: European Parliament: no patents on naturally obtained plants and seeds

Patent-free access to biological plant material is essential to boost innovation and competitiveness of the European plant-breeding and farming sectors, to develop new varieties, improve food security and tackle climate change, MEPs stressed in the resolution. Furthermore, access to genetic resources must not be restricted, as this could lead to a situation where a few multinational companies have a monopoly on plant breeding material, to the detriment of EU farmers and consumers, many MEPs said in Monday's plenary debate.

Parliament called on the European Commission to do its utmost to convince the European Patent Office (EPO) not to grant patents to products obtained from essentially biological processes. It also urged the EPO to immediately restore legal clarity on the matter, stressing that none of 38 states which signed the European Patent Convention allow conventionally bred products to be patented.

Source: News European Parliament (Press release of 19-09-2019) <u>https://www.europarl.europa.eu/news/en/press-room/20190912IPR60934/no-patents-on-naturally-obtained-plants-and-seeds</u>.

The Enlarged Board of Appeal in the case G 3/19 "Pepper" of 14 May 2020⁹² abandoned its previous approach and confirmed that the exclusion from patentability as contained in Article 53(b) of EPC extends to plant and animal products that are exclusively obtained by means of an essentially biological process.⁹³ It concluded that:

⁸⁸ European Commission, Notice 2016/C 411/03, 3 November 2016.

⁸⁹ See <u>https://www.epo.org/law-practice/legal-texts/official-journal/2017/07/a56.html</u>.

⁹⁰ European Parliament, Patentability of plants and essentially biological processes. Resolution of 19 September 2019 (2019/2800(RSP)). Available from <u>https://www.europarl.europa.eu/doceo/document/TA-9-2019-0020_EN.html</u>.

⁹¹ Ibidem.

⁹² Opinion G3/19 of the Enlarged Board of Appeal of the European Patent Office (EPO).

⁹³ See Enlarged Board of Appeal (EBA), opinion G 3/19 of 14 May 2020. Available from <u>http://documents.epo.org/projects/babylon/eponet.nsf/0/44CCAF7944B9BF42C12585680031505A/\$File/G_3-19_opinion_EBoA_20200514_en.pdf</u>.

the exception to patentability of essentially biological processes for the production of plants or animals in Article 53.b EPC has a negative effect on the allowability of product claims and product-by-process claims directed to plants, plant materials or animals, 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.

Therefore, plants that are the result of conventional crossing and selection methods are not patentable. While this decision did not affect patents granted before 1 July 2017, it will discourage future patent applications based on essentially biological processes. It also offers an interpretation of the exclusion that other countries, or eventually a panel in WTO, may apply to prevent the protection of plants produced with such essentially biological methods, including if molecular techniques for selection are used.

Nevertheless, some outstanding issues remain on this matter. For instance, the lack of retroactivity,⁹⁴ as the patents granted prior to the 1 July 2017 will continue to block the access of breeders to the genetic material for twenty years since the date of filing of the respective application. While further research on the economic impact of the lack of access due to the non-retroactive decision is advisable, the G 3/19 noticed the fact that 18 appeals against decisions based on Rule 28(2) were still pending at EPO, as well as 250 examination and 7 opposition cases in which the application in line with the current interpretation could be decisive.95

On the other hand, as a particular plant product can in principle be developed through both technical intervention and essentially biological processes, further legal clarifications are needed. For instance, a clear definition of "essentially biological processes" that include random processes such as random mutagenesis, is required. Clear definitions would facilitate the examination procedures and can help to close the loopholes that allow the use of "technical toppings", such as those describing random mutations, to claim plants and animals as "inventions".⁹⁶ Until then, legal uncertainty that facilitates companies to escape the current exclusions from patent protection will continue.97

⁹⁴ See Decision of the Administrative Council of 29 June 2017 amending Rules 27 and 28 of the Implementing Regulations to the European Patent Convention (CA/D 6/17), available at https://www.epo.org/law-practice/legaltexts/official-journal/2017/07/a56.html.

⁹⁵ On this issue see Michael A. Kock, G 3/19 "Pepper" – Patentability of plants obtained by breeding processes. Is this the end? Bio Science Law Review, vol. 17, Issue 5, 2020, p. 189.

⁹⁶ No Patents on Seeds!, European Patent Office gives green light to prohibit patents on plants and animals Enlarged Board of Appeal agrees with restrictive interpretation of patent law, 14 May 2020. Available from https://www.no-patents-on-seeds.org/index.php/en/node/638.

V. SCOPE OF PROTECTION

Article 64 (1) EPC referring to the rights conferred on the proprietor of a European patent, provides that the "rights conferred" by a patent are a matter to be solely determined by the designated Contracting States, "for example, as regards what acts of third parties constitute infringement of the patent, and as regards the remedies which are available in respect of any infringement".⁹⁸ This explains why, as discussed below, disciplines on the "farmers privilege" and on the breeder's exemption have been included in European legislation.⁹⁹

However, Directive 98/44/EC contains detailed provisions on the scope of patent rights specifically regarding biotechnological inventions, in response to the special characteristic of biological materials, such as the ability of plants to replicate indefinitely. Given this characteristic, the patent protection may cover not only the product that contains the subject-matter but also those derived from that biological material possessing those same characteristics. In accordance with the Directive, "The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics" (Article 8.1 of Directive 98/44/EC).¹⁰⁰

The scope of protection is then extended in a vertical direction to any future generation derived from the patented biological material when possessing those characteristics that made the material inventive in the first place. That scope is, on the other hand, extended in horizontal direction to embrace all biological material where patented genetic material has been incorporated and performs/ed its function.¹⁰¹ This provision was key in the ECJ dismissal of the complaint by Monsanto arguing that soya meal produced from genetically modified soya infringed patents covering the latter. The Court stated that:

the function of Monsanto's invention is being performed when the genetic information protects the soybean plant against the effect of the herbicide glyphosate. However, that function of the protected DNA sequence can no longer be performed when it is in a residual state in the soy meal, which is a dead material obtained after the soy has undergone several treatment processes. As a result, the protection conferred on European patents is not available when the genetic information has ceased to perform the function it performed in the initial material from which the material in question is derived.¹⁰²

New plant varieties that incorporate a genetic modification as a product of cross-breeding could fall within the scope of patent protection if the specific genetic information has been incorporated in the new variety, according to Art 9 of the Directive 98/44/EC. A common patenting strategy of the genetic engineering industry is to claim only parts of a plant, such as a gene incorporated by means of genetic engineering, in order to cover several potential

⁹⁹ As noted above, Article 27 of the UPCA C 175/01/2013 provides for a set of exemptions to patent rights.
¹⁰⁰ Article 8.2 of the same Directive refers to cases where the subject matter of the patent is a process: "The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics".

⁹⁸ See Enlarged Board of Appeal G 2/88 of 11 Dec 1989, Para. 3.3.

¹⁰² Court of Justice of the European Union, PRESS RELEASE No 73/10, Luxembourg, 6 July 2010, Judgment in Case C-428/08 *Monsanto Technology LLC v Cefetra BV and Others*.

varieties or crops incorporating the gene. As noted above, this may allow the patent owner to indirectly (but effectively) control the whole plant variety.

A question also arises concerning the principle of exhaustion of patent rights. According to this principle under European law, the protection of a patented product ends when it has been placed on the market by the patent holder or with his authorization.¹⁰³ Taking into consideration the self-replicating nature of biological materials and the wording of articles 8 and 9 of Directive 98/44/EC, it may be inferred that protection could be indefinitely extended when the product conserves the same protected characteristics. However, article 10 of the Directive clarifies this question by excluding from patent protection the biological material obtained from the propagation or multiplication if the biological material has been "placed on the market by the holder of the patent or with his consent" for the purpose of propagation or multiplication; in other words, if a seed containing protected elements has been sold for the purpose of planting, the plant grown from the seed is not covered by patent protection. However, the resulting plant may be sold and used but not for the purpose of subsequent propagation or multiplication.¹⁰⁴ This rule, in principle, would prevent farmers from saving and planting the seeds they have obtained with protected materials, thereby knocking down an ancestral practice that is essential for the sustainability of agriculture and food security. As discussed below, some European countries have addressed this problem.

It is worth mentioning that the German patent law, as well as the Swiss federal patent law, incorporate interesting provisions that address situations of non-intentional infringement of patents over biological materials. Section 9.c. of the German law provides that Sections 9a (1) to (3)¹⁰⁵ "shall not apply to biological material obtained during agricultural activity by chance or in such a manner as to be technically unavoidable. As a rule, a claim cannot therefore be brought on this ground against a farmer if he used the seeds or plants not subject to such patent protection". A similar provision is contained in Article 9.1 f. of the Swiss federal patent law.¹⁰⁶ These provisions would allow the courts to dismiss, *inter alia*, legal actions based on the unintended use of a protected gene in a plant, as epitomized by the Schmeiser case in Canada in relation to Roundup Ready® canola seed, where Monsanto's lead investigator admitted "there was no indication that Schmeiser had illegally obtained the patented gene".¹⁰⁷

¹⁰³ Exhaustion should also be deemed to occur when a product has been put on the market in other legitimate manner, for instance, under a compulsory license.

¹⁰⁴ The purchaser of the protected seed could also use it for private and research purposes. See Carlos Correa, *The International Dimension of the Research Exception*, Advancing Science, Serving Society (2005). Available from http://sippi.aaas.org/Pubs/Correa_International%20Exception.pdf.

¹⁰⁵ Section 9a: (1) Where the patent concerns biological material possessing specific characteristics as a result of an invention, the effects of section 9 shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. (2) Where the patent concerns a process, which enables biological material to be produced with specific characteristics as a result of an invention, the effects of section 9 shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. (3) Where the patent concerns a product, which contains or consists of genetic information as a result of an invention, the effects of section 9 shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function. Section 1a (1) shall remain unaffected. ¹⁰⁶ See Article 9.1 f. of the Swiss federal patent law, which states: "The effects of the patent do not extend to

biological material that is obtained in the field of agriculture by chance or because it is technically unavoidable". See also, FAO Secretariat, "Views, Experiences and Best Practices on the Implementation of Farmers' Rights Submitted by Contracting Parties and Relevant Organizations", 2012. Available from <u>http://www.fao.org/3/a-bb904e.pdf</u>.

¹⁰⁷ Stephanie M. Bernhardt, "High Plains Drifting: Wind-Blown Seeds and the Intellectual Property Implications of the GMO Revolution", *Northwestern Journal of Technology and Intellectual Property*, vol. 4, Issue 1 Fall (2005). Available from https://scholarlycommons.law.northwestern.edu/njtip/vol4/iss1/1.

VI. LIMITATIONS TO PLANT PATENT RIGHTS UNDER EU LAW

While, as described above, the scope of patentability of plants and plant materials is relatively broad under European law, many European countries have introduced exceptions to the conferred patent rights specifically applicable in this field.

Patent rights, as discussed above, may protect not only plants, but also its parts, such as genes, and breeding methods if not essentially biological. Furthermore, the protection is extended vertically and horizontally to plants containing the same elements as the subject matter or directly resulting from the use of the same process. Protected plants and plant-related material, therefore, are only accessible to third parties for commercial use during the lifetime of a patent if an authorization is given by the patent holder, unless a compulsory license is granted. The extent of the rights conferred by plant patents has been however limited under EU law, as explained below.

Farmers' Privilege

Article 11 of the Directive 98/44/EC provides an exemption in favour of farmers to use the patented product of "his harvest for propagation or multiplication by him on his own farm" and "the protected livestock for an agricultural purpose".¹⁰⁸

The Directive introduced for the first time what is generally known as "the farmers' privilege" in patent law subject to the conditions "determined by national laws, regulations and practices" (article 11.1). It has been specifically regulated under the patent laws of Germany, the Netherlands, Austria, and France (and was also introduced in Switzerland), as discussed below. Art. 11 allows farmers to save seeds and use the product of his harvest for propagation or multiplication by him on his own farm under the conditions set out under Article 14 of Regulation (EC) No 2100/94 which provides for Community plant variety rights. This means that such use is permissible against the payment of royalties depending on the types of crops and the size of the exploitation. Conversely, the farmer is not allowed to sell the seeds or exchange them with other farmers.

The farmers' privilege under Regulation (EC) No 2100/94 only applies to specific agricultural plant species with "no quantitative restriction of the level of the farmers" holding to the extent necessary for the requirements of the holding' (article 14.3). The product of the harvest may be processed for planting, either by the farmer himself or through services supplied to him, without prejudice to certain restrictions which Member States may establish regarding the organization of the processing of the said product of the harvest, in particular in order to ensure identity of the product entered for processing with that resulting from processing. Small farmers¹⁰⁹ shall not be required to pay any remuneration to the holder. Other farmers shall be

¹⁰⁸ This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity. ¹⁰⁹ There is no general definition of "small farmers" under EU law. The Commission Regulation (EC) No 1768/95 of 24 July 1995 implementing rules on the agricultural exemption provided for in Article 14 (3) of Council Regulation (EC) No 2100/94 on Community plant variety rights

^{(&}lt;u>https://www.wipo.int/edocs/lexdocs/laws/en/eu/eu109en.pdf</u>) established definitions based on the volume of production in respect of certain fodder plants and potatoes only (article 7). In accordance with the EU "Small

required to pay an equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area. The actual level of this equitable remuneration may be subject to variation over time, taking into account the extent to which use will be made of the derogation provided for in paragraph 1 in respect of the variety concerned.¹¹⁰

The farmers' privilege has also been incorporated into the UPCA. Article 27 (i) permits the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, provided that the plant propagating material was sold or otherwise commercialized to the farmer by or with the consent of the patent proprietor for agricultural use. This provision refers as well to the extent and the conditions for the permitted use in accordance with Article 14 of Regulation (EC) No 2100/94 (2).

The establishment of the farmers' privilege under the EU patent regime for biotechnological inventions is a positive development that developing countries should consider in their own legal systems. However, such countries can follow their own models and, in particular, may not impose a remuneration on the seeds obtained by the farmer regardless of the crop concerned or the size of the exploitation.

Breeder's Exemption

There are cases where a plant variety is protected by breeder's rights¹¹¹ while patent rights are claimed in relation to material incorporated into the plant variety where it performs its function.¹¹² This may lead, as noted above, to a de facto protection of the whole variety. This monopolization would impede the use by other breeders of a variety (as allowed by the breeders' exemption recognized under plant variety protection law)¹¹³ to create a new variety. The same would apply to varieties bred by means of a patented process.¹¹⁴ Moreover, the patent protection of plant materials incorporated into a plant variety would prevent breeders from developing new plant varieties (and farmers from saving and re-using seeds). This limitation has been partially addressed under EU law by UPCA.

farmers scheme" (SFS) "more than three quarters of farm holdings in the European Union are small – below 10 hectares – with a large number being below 5 hectares" (<u>https://ec.europa.eu/info/food-farming-fisheries/key-policies/common-agricultural-policy/income-support/additional-optional-schemes/small-farmers-scheme_en#:~:text=Related%20links-</u>

<u>EU%20support%20for%20small%20farms.of%20applying%20for%20income%20support</u>). However, "no strict definition of 'small farmer' is provided for under the SFS" (<u>https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/key_policies/documents/small-farmers-scheme_en.pdf</u>). See also recent statistical studies related to the farm structure in EU in EUROSTAT, Archive: Small and large farms in the EU – statistics from the farm structure survey. Available from <u>https://ec.europa.eu/eurostat/statistics-</u>

explained/index.php?oldid=406560#:~:text=Small%20farms%20have%20always%20been%20a%20cornerstone %20of,consumption%20and%20is%20thus%20not%20an%20economic%20unit.

¹¹⁰ Article 14 of Regulation (EC) No 2100/94.

¹¹¹ For the differences between breeders' rights and patent rights please see *supra* section 1, Box 1.

¹¹² Carlos Correa, *Patent Protection for Plants: Legal Options for Developing Countries*, Research Paper, No. 55 (Geneva, South Centre, October 2014) p. 34.

¹¹³ Article 15 (c) of Regulation 2100/94/EC on the Community plant variety rights provides for the breeder's exemption. It thus allows for the free access to protected varieties for further breeding and commercialization (unless the variety is "essentially derived"), without any obligation towards the right holder of the protected variety. By doing so, the continued creation of improved varieties and the access to genetic variation are guaranteed by the EU PVP law. See, e.g., Gert Würtenberger, "Protection of plant innovations", in *Research Handbook on Intellectual Property and the Life Sciences*, Duncan Matthews and Herbert Zech eds. (Edward Elgar Publishing, 2017), p. 7.

¹¹⁴ Viola Prifti, op. cit. p. 63.

The exclusive rights granted by patents and their limitations are contemplated in articles 25, 26 and 27 of the UPCA. Article 25 refers to the right to prevent the direct use of the invention. It prevents third parties from making, offering, placing on the market, importing, or using the subject matter of a product or a process. Furthermore, Article 25.c) prohibits the same acts as related to a product obtained directly by a process which is the subject matter of a patent.

On the other hand, Article 26.1 defines the right to prevent indirect use. This is important as the use by breeders and farmers of the genetic material could be considered as indirect exploitation of the invention. Therefore, Article 26 and 27 must be read together for a comprehensive view on the scope of the rights and exemptions granted by the UPCA. Article 27 UPCA provides for a comprehensive list of exemptions to patent rights, which include breeders in paragraph c) and farmers in paragraphs i), j), and I). Accordingly, the rights of the patent holder are limited when the biological material is used for the purpose of breeding or discovering and developing other plant varieties.¹¹⁵ This provision, however, introduces a limited breeder's exemption, as the breeder is not authorized to commercialize the new variety that he may have developed without the consent of the patent owner.

Compulsory Cross-Licenses

The EU Directive on biotechnological inventions provides for compulsory cross-licenses to address the cumulative protection by patents and PVP. In article 12 the Directive addresses the situation where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, or the patent holder concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right. In these cases, any of them can apply for a compulsory license for non-exclusive use of the third party's protected subject matter, subject to payment of an "appropriate royalty". The holder of the patent or variety right will be also entitled to a cross-license on reasonable terms. The grant of this cross-compulsory license is subject to several conditions:

Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual license.

(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.¹¹⁶

While the requirement in article 12.3(a) is equivalent to the requirement imposed under article 31(b) of the TRIPS Agreement, the conditions set out in article 12.3(b) reflect those prescribed in article 31(l) of the TRIPS Agreement with one important difference: the latter refers to cases of overlapping **patented inventions**; article 12.3, instead addresses the cumulative protection by patents and breeders' rights, two different categories of legal entitlements. Hence, the EU was not compelled to apply the same conditions as provided in the TRIPS provision and, in fact, in doing so the EU Directive may defeat the very purpose of the cross-licensing system— the Directive is requiring to assess whether there is "a significant technical progress of considerable economic interest" by comparing the subject matter of two completely different rights. It is unclear how can an improvement on a **plant variety** that is eligible for protection under PVP be compared with a patented part or component of a **plant**.

No precedent seems to exist regarding the application of article 12 of the EU Directive. As noted by Louwaars et al:

¹¹⁵ See Article 27.c UPCA.

¹¹⁶ Article 12.3 of Directive 98/44/CE.

the conditions for compulsory licensing in Article 12(3) of the Biotechnology Directive make effective use of this instrument very difficult. Proving that the invention (e.g., trait) constitutes 'significant technical progress of considerable economic interest' when it can be used in the variety of company X, cannot be demonstrated a priori. In more general terms (i.e., also in other sectors) it is difficult to demonstrate that one has in vain addressed the patent holder to obtain a license. Article 12(3) of the Directive in this respect not even refers to obtaining a license under 'reasonable conditions', a term already difficult to apply in legal practice.¹¹⁷

Notwithstanding the limitations and flaws of article 12, in any case it provides an interesting example of the policy space that developing countries can use to address situations of cumulative protection by patents and breeders' rights that may eventually arise out. Like in the case of the farmers' privilege, however, they may determine conditions for the grant of the licenses different from those stipulated under the EU law.

¹¹⁷ Niels Louwaars, Hans Dons, Geertrui van Overwalle, Hans Raven, Anthony Arundel, Derek Eaton, Annemiek Nelis, "Breeding Business. The future of plant breeding in the light of developments in patent rights and plant breeder's rights", Centre for Genetic Resources, the Netherlands, 2012. Available from https://www.researchgate.net/publication/299820637_Breeding_business.

VII. LIMITATIONS TO PLANT PATENT RIGHTS UNDER NATIONAL LAWS

As mentioned, under EU law national laws can provide for exceptions to the rights conferred under a patent. The farmers' privilege is contained in the patent laws of Germany, the Netherlands, France, Austria, and Switzerland. Importantly, the exceptions in some of those countries are not limited to the farmers' privilege but also provide for a breeder's exception comparable, but more limited, than that allowed under PVP regimes. In line with Directive 98/44/EC, the Netherlands, France, and Austria have provisions on compulsory cross-licensing.

Farmers' Privilege

The national laws examined in this paper provide for an equivalent to the farmers' privilege generally admitted under PVP (that is, the possibility for farmers to save seeds from protected varieties and use them in further plantation) consistently with the standards set out on the matter by Directive 98/44/EC.

The Austrian Patent Act, for instance, disciplines the farmer's privilege in § 22c. (2), consistently with the provisions contained in Article 14 of Decision 2100/94/CE. The German Patent Law provides for such farmers' privilege in Section 9c PatG, which establishes that the farmer may use part of the harvest for reseeding for the needs of his own farm. Nevertheless, it does not allow the sale of the seeds thus obtained. It provides that:

(1) Where plant propagating material is marketed by the proprietor of the patent or by a third party with the consent of the proprietor of the patent to a farmer for agricultural use, the latter shall, contrary to Sections 9, 9a and 9b, second sentence, be entitled to use the product of his harvest for propagation or multiplication by him on his own holding. Article 14 of Council Regulation (EC) No 2100/94, as amended, as well as the implementing rules adopted on that basis shall apply to the conditions and extent of this authorization.

Where claims arise therefrom for the proprietor of the patent, these claims are to be asserted pursuant to the implementing rules adopted based on Article 14 paragraph 3 of Council Regulation (EC) No 2100/94. (2) Where livestock or animal reproductive material are marketed to a farmer by the proprietor of the patent or by a third party with the consent of the proprietor of the patent, the farmer shall, contrary to Sections 9, 9a and 9b, second sentence, be entitled to use the livestock or the animal reproductive material for agricultural purposes. This entitlement shall also include making the livestock or other animal reproductive material available for the purposes of pursuing the farmer's agricultural activity, but not the sale for the purpose or within the framework of a commercial reproduction activity.¹¹⁸

In the Netherlands, farmers' use of patented inventions is regulated in article 53c NPA 1995. It provides that the sale of vegetable propagation material or another form of putting vegetable propagation material on the market by the patent holder or with his consent to a farmer for the purposes of agricultural exploitation implies a right for the latter to use the products of his

¹¹⁸ Sec. 9c(2) Patent Act: This provision implements Article 11 of the Directive 98/44/EC).

harvest for further propagation or multiplication by himself in his own company, also with due observance of art. 14 of Regulation (EC) no. 2100/94.¹¹⁹

Articles L613-5-1 and L613-5-2 of the French CPI similarly introduced into patent law the farmers' privilege. Article L613-5-1 allows farmers to re-use, on certain conditions, the product of the harvest from protected seeds, without infringing the right in a patent or in a plant breeder's certificate. This provision states that:

By way of exception to the provisions of Articles L613-2-2 and L613-2-3, the sale or any other act of marketing of plant reproduction material by the patent owner, or with his consent, to a farmer for agricultural working purposes implies for the farmer authorization to use the product of his harvest for reproduction or propagation by himself on his own holding. The conditions of such use shall be those which are provided for in Article 14 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.¹²⁰

The scope of the exceptions under the German, Dutch and French laws are, thus, limited by the conditions set out in art. 14 of Regulation (EC) no. 2100/94 and the implementing regulation No. 874/2009. They do not add or detract from the EU disciplines on the matter.

The Swiss exception for farmers' use of patented inventions is contained in Article 35a of the patent law:

"1. Farmers who have acquired plant propagated material placed on the market by the patentee or with his consent, may propagate the product harvested from such material on their own farms.

2. Farmers who have acquired animals or animal reproductive material placed on the market by the patentee or with his consent, may propagate the animals raised from those animals or that material on their own farms.

3. Farmers must obtain the consent of the patentee in order to transfer to a third party, for the purposes of reproduction, the product of crops, animals or the reproductive animal material concerned.

4. All agreements restricting or invalidating the farmers' privilege with regard to food and animal feed shall be void."

This exception permits farmers to continue using seeds or their own animals for livestock farming, even if the gene sequences are protected by patents. On the basis of Article 35b, the Federal Council defined the plant species to which the farmers' privilege applies (annex 1 to the Order of 25 June 2008, on the protection of plant varieties (SR 232.161)). It is worth noting

¹¹⁹ The farmer's privilege for plant material (art. 53c(1)) constitutes the implementation of Directive nr. 98/44/EC of 6 July 1998 concerning the protection of biotechnological inventions. At the same time, a kind of farmer's privilege for animal material was implemented: the sale of breeding cattle or another form of putting breeding cattle on the market by the patent holder or with his consent to a farmer implies for the latter party the right to use the cattle that is protected by a patent for agricultural purposes. This use is in any event taken to include making the animal or animal propagation material available for use in a farmer's agricultural exploitation, but not selling within the context of or with a view to commercial cattle breeding (Parliamentary Papers 26568, 1998-1999, 26568, nr. 3).

¹²⁰ Article L613-5-2 of the CPI also refers to animal breeding as follows: "By way of exception to the provisions of Articles L613-2-2 and L-613-2-3, the sale or any other act of marketing of breeding animals or animal reproduction material by the patent owner, or with his consent, to a farmer, implies for the farmer authorization to use, where appropriate for remuneration, protected livestock for an agricultural use. This authorization shall involve making the animal or animal reproduction material available for the continuation of his agricultural activity but shall exclude sale as part of a commercial reproduction activity".

that paragraph 4 of article 5a makes it clear that the farmers' privilege is of public order as it cannot be derogated by private agreements.

Breeder's Exemption¹²¹

Some European laws went beyond the farmers' privilege exception, as adopted by the EU legislation in 1994 and the laws referred to above, by providing an exception comparable to, but more limited than, the breeder's exemption under PVP, which—as noted above—is essential for food security and the continued progress in agriculture.

Thus, the French law specifically introduced in 2004 an exception regarding the use of plant varieties for further breeding. Article L613-5-3 of IPC stipulates that the exclusive rights conferred by a product or process patent on a biological material do not extend to the acts accomplished with a view to creating or discovering and developing other plant varieties.

Section 11.2.a of the German Patent Act, adopted in 2005, similarly provides that the effects of a patent shall not extend to "the use of biological material for breeding, discovery and development of a new plant variety type".

The Swiss law was also amended to specifically address this issue. It stipulated in article 9(e), amended in 2007, that the rights conferred by a patent do not extend to the "use of biological material for the purpose of the production or the discovery and development of a plant variety".

A similar breeder's exemption was incorporated into the EU legislation itself. Article 27(c) of the Agreement on a Unified Patent Court (2013) included "limitations to the effects of a patent" that comprises an exception regarding "the use of biological material for the purpose of breeding or discovering and developing other plant varieties".

An important question in relation to the described breeders' exemptions under patent laws is whether they are fully equivalent to the breeder's exemption under PVP, which (except in the case of essentially derived varieties in countries that apply UPOV 1991 or similar rules) authorizes the breeder not only to undertake **research and breeding** but also to **commercialize** the new variety he has developed. As drafted, such exceptions seem to be narrower than under PVP regimes, as the breeder of a new variety would presumably require an authorization from the patent holder at the time he intends to multiply (except for private and non-commercial purposes), offer for sale, or sell the new variety (even though such authorization was not needed to develop it).

The compatibility of those exceptions with article 30 of the TRIPS Agreement seems to be out of question,¹²² as they would comply with the three-step test even if narrowly interpreted in line with the WTO panel ruling in *Canada–Patent Protection for Pharmaceutical Products*.¹²³ This seems to be confirmed by the fact that there has been so far no complaint submitted to WTO arguing that such an exception—as adopted by the countries mentioned above and by EU—violates the TRIPS Agreement.

Further questions include whether a breeder's exemption limited to the process of development may actually attain its intended purpose of encouraging breeding of new varieties by third parties, and whether a broader exception (including commercialization of a new variety) would also be compatible with the TRIPS Agreement. A breeder is unlikely to

¹²¹ This section is partially based on Carlos Correa, 2014, op. cit.

¹²² See, e.g., V. Prifti, op. cit.

¹²³ Available from <u>https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm;</u> see also Carlos Correa, op. cit., 2020; Viola Prifti, op. cit.

undertake the development of a new variety if its commercialization is subject to the discretionary authorization of the right holder and the investment needed for such development can only be recovered (if the market conditions are still favourable) when the patent protection expires.¹²⁴ The compatibility of a broader exception is debatable¹²⁵ but it has never been tested under the WTO dispute settlement system. The legal treatment of this issue may depend on the way in which article 30 of the TRIPS Agreement is interpreted, notably whether the three steps are subject to a separate and independent assessment or to a comprehensive overall assessment under which failure to comply with one of the three conditions need not result in the exception being disallowed.¹²⁶

In summary, European law provides an interesting example of the partial transfer of an exception that is typical under PVP to the field of patent law, thereby generating some space for the development of new plant varieties incorporating patented materials.

Compulsory Cross-Licenses

In the Netherlands, compulsory licenses for plants are regulated in similar terms¹²⁷ as the EU Directive on biotechnological inventions. Thus, if a patent holder is granted a license on the grounds of art. 42(2) of the Dutch Seeds and Planting Materials Act, the holder of the plant breeder's right can get a reciprocal license or cross-license,¹²⁸ at the latter's request, to use the protected invention subject to reasonable conditions (see art. 57(6) NPA 1995).¹²⁹ In the absence of agreement, the court shall fix the fee that the licensee must pay to the patent holder.¹³⁰

In France, Article L613-15-1 of CPI states that "Where a breeder may not obtain or work a plant breeder's right without infringing an earlier patent, he may request the grant of a license for this patent to the extent that this license is required for working the plant variety to be protected and insofar as the variety constitutes, in relation to the invention claimed in this patent, significant technical progress and is of considerable economic interest. Where such a license is granted, the patent owner shall obtain, on equitable conditions, on a request submitted to the court, the grant of a reciprocal license for using the protected variety. The provisions of Articles L613-12 to L613-14 shall apply".

The Austrian Patents Act also contains provisions on compulsory licenses for breeders in §36 (2), applicable in cases, where a plant breeder cannot obtain or exploit a plant variety right without infringing a prior patented invention. The law considers the plant breeder as entitled to a nonexclusive license to the patent to the extent that the plant variety represents a significant technical advance of substantial economic interest over the patent-protected invention and to the extent that such license is necessary for the exploitation of the plant variety to be protected.

The Swiss law also provides for a cross-compulsory license with a clarification regarding the requirement of "significant technical progress of considerable economic interest" that may

¹²⁴ For this reason, the Dutch seeds association Plantum NL proposed to adopt what has been termed as a "comprehensive breeding exception" conferring third parties not only the right to do research and breeding but also the right to commercialize the new variety. Plantum NL argued that the same "balance" found under PVP between rewarding breeders and allowing for "continual improvement of varieties by other breeders" should be found under patent law. See "Plantum NL position on patents-and plant breeders' rights", 6 May 2009. ¹²⁵ See Viola Prifti, op. cit.

¹²⁶ See "Declaration on Patent Protection Regulatory Sovereignty under TRIPS". Available from <u>https://www.mpg.de/8132986/Patent-Declaration.pdf</u>.

¹²⁷ Art. 57(5) and 57(6) NPA 1995.

¹²⁸ Art. 57(4) NPA 1995 (dependent patent).

¹²⁹ See as reference the Plant Breeders: Parliamentary Papers 26568, 1998–1999, no. 3.

¹³⁰ Art. 58(6) NPA 1995.

increase the legal certainty for the effective use of such licenses. Article 36a-1 of the Swiss Patent law links that requirement "to the seed market authorisation, while leaving room for further clarification: If an agricultural plant variety demonstrates a 'value for cultivation and use' (VCU) required for the market authorisation, the requirement of a 'technical progress' could be automatically satisfied. VCU requires 'a clear improvement either for cultivation in general or for the specific uses which can be made of the crops or the products derived therefrom".¹³¹

¹³¹ Michael A. Kock, op. cit. p. 200. Emphasis in the original.

VIII. CONCLUSIONS: LESSONS FROM THE EUROPEAN LAW ON PLANT PATENTS

The European law examined above shows, at the same time, the complexities of implementing patent rights in relation to plants, and the policy space that governments have to legislate in this respect. While many developing countries have followed the European approach regarding the non-patentability of plant varieties, they can go further in their laws and exclude plants in general, including but not limited to plant varieties. While the way in which EPO and courts have delineated the distinction between protectable plants and non-protectable plant varieties may be useful for those countries that follow such an approach, they may apply their own criteria on the matter, in particular in order to prevent the indirect control over plant varieties on the basis of patents covering plants or their parts and components (such as gene constructs).

As elaborated above, while isolated genes may be patented under EU law, patents must be limited to the specific function claimed in the application (use-bound claims). This is an important approach that developing countries which allow for patents on genes should also follow in relation to plants' genes (as well as other genes). While the ideal option is not to allow for the appropriation in any manner of genetic and other natural material, if patents thereon are admissible, specific legal provisions limiting the protectable subject matter would be desirable. In interpreting national laws patent offices and the courts may apply a limitation on the scope of gene patents as the European Court of Justice did, based on general patent law principles, notably that a patent can only protect what has actually been invented and specifically claimed.

The debates and decisions in the European context regarding the elusive concept of "essentially biological processes" may also be of interest to developing countries, a large majority of which exclude such processes from patent protection. Moreover, the recent decisions on the non-patentability of the **products** obtained with such processes provide a necessary clarification in the absence of which the exclusion from protection would in practice be nullified.

Regarding the scope of protection of patents relating to genetic information, European law also provides interesting guidance, notably the limitation of protection to situations in which the patented genetic information actually performs its function in living material, and the immunity conferred (e.g., under German and Swiss law) in respect of the unintended use by farmers of patented materials.

The establishment of the farmer's privilege under the European patent regime is an example that developing countries should consider in their own legal systems. Importantly, although it has been deemed debatable¹³² whether the farmers' privilege can legitimately be provided for consistently with article 30 of the TRIPS Agreement, the compatibility of the EU exception has never been questioned in the context of the dispute settlement system of the World Trade Organization. As noted above, under the EU Directive the exception operates—for certain crops and categories of farmers—without payment of any remuneration. Developing countries could extend this treatment to all farmers and crops in implementing the farmers' privilege under their patent laws so as not to burden them with payments that may put their livelihoods and food security at risk. As exemplified by the Swiss law, they may stipulate that the farmers' privilege cannot be derogated by private agreements.

¹³² See e.g., <u>http://www.fao.org/3/y5714e/y5714e03.htm</u>; Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (The Hague, Kluwer Law International, 2000), p. 155.

Given the importance of promoting a flow of new varieties, the European law may also inspire reforms in the patent laws of developing countries aimed at introducing a breeder's exemption, which would allow for the use of patented materials in the development of new varieties. The freedom to breed clause as incorporated in such law enshrines an important principle for agricultural development and food security. While, as formulated under European law, the exemption (which does not extend to the commercialization of the new developed variety) does not seem to risk a challenge in terms of its TRIPS consistency, further exploration will be required if a more comprehensive exemption (including commercialization of such variety) were considered.

Finally, developing countries may consider the incorporation of disciplines to address, through compulsory cross-licensing situations of cumulative protection by patents and breeders' rights. In doing so, however, it will not be advisable to strictly follow the EU Directive model as the conditions for the grant of the licenses are not appropriate and it would be very difficult to prove them *ex ante*. The compulsory cross-licensing regime should apply whenever such cumulative protection exists with the caveat that the right to obtain a compulsory license by a patent holder should only arise when the patented invention leads to a significant increase in the value for cultivation of the plant variety (such as differences in productivity, biological characteristics, quality of the obtained produce, chemical and technological characteristics from the standard variety, including commercially important characteristics and suitability under agro-climatic conditions).¹³³

In summary, while the European law and practice on plant patents should not be deemed as transplantable to developing countries, it provides interesting elements for consideration to tackle some of the specific problems raised by the extension of patents to plants and plant materials.

¹³³ Requirements of this kind may prevent the request for compulsory licenses based on genetic engineering modifications that may only lead to trivial or "cosmetic" changes. See e.g., A. Allan Schmid, "Biotechnology, Plant Variety Protection, and Changing Property Institutions in Agriculture", *North Central Journal of Agricultural Economics*, vol. 7, No. 2 (July 1985). Available from https://www.jstor.org/stable/1349334?seq=1.

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