Plant variety rights and patents — how it works

Content

Foreword

The Royal Swedish Academy of Agriculture and Forestry (KSLA) is an independent meeting place where dialogues on important issues affecting the green industries are in focus. The number of questions is increasing and it can be noted that the academy's areas are more relevant than ever. Plant breeding has been key to success in developing crops for sustainable food production both in terms of increased production, but also in order to achieve the best possible adaptation to a current agricultural environment. Over time, it has become increasingly important that we have tools that in a fast, efficient and precise way result in sustainable crops for both the present and the future.

KSLA has been engaged in plant breeding and biotechnology for several years and has arranged a number of round table discussions and seminars in connection with this. In May 2019, a seminar was held on the future of new genomic techniques when the "genetic scissors" CRISPR/Cas9 were discussed. In 2018, the Court of Justice of the European Union ruled that such technologies should be assessed in accordance with the EU regulatory framework for GMOs (Genetic Modified Organisms) which, according to the participants at the seminar, would have undesirable negative consequences for plant breeding and thus on forestry, agriculture and food production in Europe.

The seminar raised the question whether KSLA in the future could start a project with the aim of providing policy-makers, authorities and organizations as well as the interested public with up-to-date information, based on science and proven experience, on issues related to modern plant biotechnology and plant breeding. KSLA saw the proposal as important and started the project *Växtnoden**, which, in addition to providing up-to-date information, also aims to encourage open dialogues to increase the acceptance of new technologies with the aim of promoting the development of sustainable agriculture and forestry.

Eva Pettersson
Secretary General, KSLA

*) *https://www.ksla.se/om-ksla/projekt/vaxtnoden/*

Introduction

The present report *Intellectual Property Rights for Plants — Analysis of Intellectual Property Rights regarding plant-related innovation* has been prepared by Martin Ekvad on behalf of Växtnoden, which is a project at KSLA.
Martin Ekvad was President of the Community Plant Variety Office (CPVO) for 10 years (2011-2021), an EU agency responsible for the EU system for providing plant variety rights for new plant varieties. Prior to that, he was the head of the Legal Service of the CPVO.

He has worked as a lawyer at the law firm Linklaters in Brussels and Magnusson Wahlin Law Firm in Stockholm. Martin Ekvad is the founder of Ekvad Consulting.

Over the years, the Royal Swedish Academy of Forestry and Agriculture (KSLA) has repeatedly engaged in biotechnology issues and conducted dialogue projects and seminars. At a seminar organized by the KSLA in May 2019, the future of new genomic technologies — such as the so-called "genetic scissors" CRISPR/Cas9 — was discussed in the EU. The background was that in 2018 the Court of Justice of the European Union had taken a decision to assess such technologies under the EU regulatory framework for GMOs (genetically modified organisms). The participants at the seminar agreed that this decision would have major and undesirable consequences for plant breeding and thus on forestry, agriculture and food production in Europe, whose competitiveness and development opportunities would be negatively affected. Thus, over time, our ability to meet climate challenges and environmental problems would also deteriorate. The seminar therefore gave rise to the idea that KSLA should continue to work on these issues in a structural manner.

The discussions led to the creation of the Plant Node project, *Växtnoden*. The possibility of using new genomic technologies in the EU is determined by EU policy. Politics, in turn, must be responsive to public debate, a broad and open debate is of the utmost importance. The project's defined purpose is therefore to provide policy makers, authorities and organizations as well as the interested public with up-to-date information, based on science and proven experience, on issues related to modern plant biotechnology and plant breeding. By presenting facts, we want to contribute to an open discussion that promotes the development of sustainable food production and sustainable forestry and agriculture.

Växtnoden is a dialogue project. We have also conducted several seminars/webinars with the participation of researchers, politicians and representatives of business and other social interests. We publish a free newsletter and collaborate with other stakeholders on activities and publications. These include SLU Future Food and Members of the European Parliament.

At EU level, the above-mentioned decision of the Court of Justice of the European Union led to the start of an extensive process. The European Commission, commissioned by the Council of Ministers, has analysed what the court ruling means and is expected to come back with a legislative proposal in 2023. Växtnoden has taken the opportunity to participate in the process and has during stakeholder consultations proposed a more permissive regulation that would enable the use of new genomic technologies in the EU.

During the project, we have repeatedly noted that the discussion about new genomic techniques is increasingly focused on matters other than the methods of plant breeding. One such area, which is often addressed in the discussion and is often used as an argument against the use of the new technologies, is intellectual properties related to plants. Here, two complex areas meet — intellectual properties and gene editing — and the challenge of making that meeting understandable is great. With this report, we want to address this challenge.

The report deals mainly with what can be protected by patents and plant variety rights and how extensive these protections are in the area of plant breeding. This provides a factual basis for the discussion.

In an independent section from the report, Anders Nilsson goes into more detail on issues related to intellectual properties, which most often meet us in the public debate on new genomic techniques. Anders Nilsson has been Research Director at Svalöf Weibull/SW Seed and was also involved in the establishment of BASF Plant Science.

This report has been funded by grants to Växtnoden from Mistra and SSF. The activities of Växtnoden are financed by KSLA, SLU, Mistra and SSF.

We wish the reader an interesting and rewarding reading.

Annika Åhnberg

Chairperson of the Växtnoden project, former Swedish Minister of Agriculture

Intellectual property rights for plants

Report on intellectual property rights in relation to plant-related innovation

Martin Ekvad

1. Introduction

This report has been drawn up on behalf of Växtnoden. Växtnoden is a project run by the Royal Swedish Academy of Forestry and Agriculture, KSLA. Växtnoden strives to contribute to providing decision-makers access to a relevant basis for their decisions regarding the regulation and use of new techniques in plant breeding.

The main purpose of this report is to highlight the role of intellectual property rights in plant breeding. Parts of the study explain the legal landscape, but the intention is also to present balances and choices and thereby stimulate further discussions. The report explains some horizontal aspects of patents and plant variety rights in relation to plant-related innovations in general. The report focuses on, and examines in more detail, what can be protected by patents and plant variety rights and the scope of protection. These aspects are often raised in the public debate, but it is far too often that there are misunderstandings made as regards what can actually be protected and the scope of protection. The report seeks to increase awareness of these aspects. However, the purpose of the study is not to cover patents and plant variety rights exhaustively. Some important areas, such as infringements of intellectual property rights, are not addressed for reasons of space. Rules on the cultivation and marketing of plants are dealt with briefly with some focus on genetically modified plants. Other relevant and important areas, such as biodiversity and ethical considerations, are briefly touched upon.

The report is being presented at a time when much is happening with regard to agricultural policies. The Commission's policies "The European Green Deal" and "From Farm to Fork" are being implemented. Initiatives have been taken to review the rules on propagating material and forest plants, to review aspects of the EU GMO regulation and to implement the Commission's Intellectual Property Right Action Plan. The objective of the latter is to help Europe's creative and innovative industry remain a leader and accelerate green and digital transitions. In addition, it is foreseen that the legislation on EU Plant Variety Rights will be revised in 2023/24.

It is important that intellectual property rights are taken into account when these policies are drawn up and implemented. Hopefully, the report can help to increase the understanding of this area among the general public and policy makers. It has been my ambition to make most of the report rather general and thereby accessible to a large audience. However, the two subjects *Intellectual property rights* and *Biotechnology* are by nature rather complex and a couple of chapters therefore go into more technical details.

This English version of the Report is a translation from a Swedish version published earlier. Except for a few clarifications made in the English version the content of the two versions should be the same. Developments after October 2022 are not contained in this report.

Finally, it should be noted that ornamental plant varieties play a very important part in the EU. The horticultural market represents around 50 % of Plant Variety Right applications to the CPVO. However, the report focuses on other crops which are more relevant for the work of Växtnoden.

2. Summary

The chapter below contains text from the following chapters and thereby forms a standard summary rather than an executive summary.

2.1 Challenges and the importance of plant breeding

There are significant challenges in the agricultural sector, not only in Sweden and the EU, but also globally. We have a growing population while the agricultural area is declining. It is estimated that the world population will have risen from 7.9 billion in 2022 to around 10 billion by 2050.[1] Most of all food comes from agricultural products.

Meeting these challenges requires a series of measures that affect the overall political agendas of the EU and its Member States at macro level. Innovation and investment in technology are often mentioned as crucial when it comes to finding sustainable solutions. Plant breeding plays an important role in contributing to sustainable solutions.

Plant breeding is one of many important pieces of the puzzle in the EU agricultural policy. For farmers to be able to produce food and energy, seed and propagating material must be of the highest quality. Seeds and propagating material must also be aligned with the overall policy objectives of a healthy environment and climate change.

Plant breeding is an activity that has contributed to the efficiency of EU agriculture. A study published in 2021[2] (the HFFA study) shows, among other things, that for all major arable crops grown in the EU, about 67 % of yield growth can be attributed to innovation. This is equal to an increase in returns of 1.16 percent per year. Furthermore, it is clear that without a functioning plant breeding over the last 20 years, the EU would have become a net importer of all major arable crops. Plant breeding helps to save land resources around the world by generating higher yields per unit of area.

Innovation is also seen in general as one of the key elements for contributing to a climate-neutral society. Development and innovation projects are therefore financed in a number of areas by public resources. However, investments in plant breeding are now mainly financed by private companies. Plant breeding requires a lot of time and access to financial resources. Developing a new variety can take 15 years.

2.2 Intellectual property protection for plant-related innovation

Intellectual property rights give the holder an exclusive right to commercialize an innovation for a limited period of time. The exclusivity provides better conditions for innovators in markets that are competitive and therefore provides better opportunities for return on investments that can be used in new research projects. By protecting a plant-related innovation, the innovator is given an opportunity to decide on the production and marketing of their innovation and thereby obtain various incomes, such as royalties. This income can be invested in new innovation.

When designing an intellectual property right, the legislator considers the scope of the right so that the innovator is given a sufficiently strong right to obtain reasonable remuneration. At the same time, public interests are respected so that competition in an area is not limited to one or too few operators. As regards intellectual property rights relating to genetic material of humans, animals and to some extent plants, ethical considerations have been taken into account in connection with the legislative work in both the EU and Sweden. This has led to a prohibition on obtaining intellectual property protection for certain inventions in the relevant legal text.

The intellectual property rights available for plant-related innovations are mainly patents and plant breeders' rights. In the public debate, there are misunderstandings about what these rights mean and it is sometimes alleged that they unduly restrict access to genetic information for plants. In Europe, it has been considered of paramount importance

that plant breeders have access to the widest possible genetic material in order to produce new varieties. Under EU plant variety right legislation, the so-called breeder's exemption therefore allows everyone to use even a protected plant variety to breed a new variety.

A patent provides more extensive protection than plant variety rights. Patent protection means that the patented plant material cannot be used to the same extent as plant varieties protected by plant variety rights to produce new plant-related inventions. However, the trend in Europe is to introduce a type of breeders' exemption also in patent law. Such a derogation applies to the production of new plant varieties but not to the commercialization of the new variety. There is no equivalent provision in Sweden, but it will be introduced when the unitary patent system project enters into force in Europe.[3] Similar provisions already exist in national patent laws in France, Germany, the Netherlands and Switzerland. This trend differs from the situation in some other countries, such as the United States, where virtually all inventions that meet the relevant patent criteria can be protected.

Plant variety rights and patents may thus be considered to be well balanced and they do not unduly hinder the use of genetic resources.

2.3 Authorities handling applications for patents and plant variety rights

In order to obtain a plant variety right in Sweden, an application must be submitted to the Swedish Board of Agriculture, which handles the application and then decides whether a plant variety right shall be granted in Sweden. Applications for plant variety rights and the conditions for granting plant variety rights are set out in the Plant Variety Rights Act.[4]

Plant variety rights can also be granted in all EU Member States by the Community Plant Variety Office (CPVO).[5] CPVO processes the application and then decides on a plant variety right in all EU Member States. EU plant variety rights have the same effect throughout the territory of the EU and may only be granted, transferred or terminated for the whole of that territory. The CPVO cannot therefore grant rights in individual Member States but only for the entire territory of the EU.

A unique advantage of using the EU system is that only one application needs to be submitted, a technical test is carried out and an examination of all the conditions is carried out in order for CPVO to subsequently take a decision to grant (or refuse) plant variety rights in the territory of all EU Member States. Prior to the introduction of the EU system, it was necessary to apply for a plant variety right in each individual Member State where the breeder sought protection, with all the administrative and linguistic inconveniences resulting from this.

The Swedish Patent and Registration Office (PRV) processes applications for patents in Sweden and takes decisions to grant or reject applications. Applications for patents and the conditions for granting a patent in Sweden are set out in the Patents Act.[6]

The European Patent Office (EPO) grants European patents in the 38 Contracting States to the EPC (European Patent Convention) and several other States that have concluded cooperation agreements with the EPO. However, a European patent granted by the EPO must be validated and maintained in each country individually. In a patent application to the EPO, the applicant must indicate one or more Contracting States for which the applicant wishes the EPO to grant the patent. Thus, the EPO does not decide on a unitary patent in all the Contracting States, but a package of national patents. The centrality of the application process and the examination provides a very effective system for those in need of patent protection in all or a number of European countries. Patents granted by the EPO can be challenged centrally before the EPO through opposition proceedings. The system does not fall within the framework of the EU acquis and cooperation, although all EU Member States have acceded to the EPC.

For decades, work on the creation of an EU patent has been ongoing. When it became clear that EU Member States could not agree, another solution, with the EPO as a partner, has been created, namely the unitary patent system. Only EU Member States can participate in this scheme. The system has not yet entered into force, but when the unitary patent protection is introduced, an application may lead to a unitary patent with effect in all the EU Member States participating in the cooperation. The EPO will grant these patents.

2.4 Access to new technologies

Over the past few decades, various genetic technologies have been developed that make it possible to achieve breeding results significantly faster and with better precision. The focus now is on editing existing genes in a plant genome without introducing foreign genes, so-called targeted mutagenesis (through editing). This is done with a technical tool that is often referred to as a gene scissor. The most well-known gene scissor method is the Nobel Prize-winning CRISPR/Cas9 method.

In July 2018, the Court of Justice of the European Union ruled that plants produced from those techniques should be regarded as genetically modified organisms within the meaning of EU legislation (the GMO Directive).[7] This means that plants produced with gene editing must be authorized following an assessment of the risks that they may pose to human health and the environment and that they are also subject to traceability, labelling and monitoring obligations. The traceability requirement is impossible to meet because in a gene-edited variety, it cannot be established that the variety has been altered by genetic engineering in the manner possible when, for example, transgenic methods have been used. The administrative processes to acquire market authorizations for GMOs are expensive and time-consuming and effectively exclude many SMEs from using the technology. In the light of the cumbersome decision-making mechanism in the EU for deciding on the authorization to cultivate and market plant material covered by the GMO Directive, the ruling will in practice put an end to the use of gene editing in the EU unless new more flexible legislation is adopted.

It is therefore important that future regulation is based on documented risks with the product rather than focusing on the technology used to create the product. The HFFA study[8], which focuses on European conditions, recommends legislators and authorities to adopt a regulatory framework based on proportionate and non-discriminatory safety considerations and for rules to be adapted and possibly tailored to different technologies and products. It can be mentioned that in a number of non-EU countries, gene edited varieties are approved either by separate regulation or by deciding not to regulate this area of technology in another way than for traditional breeding. Diversified regulation in different countries is problematic for companies operating internationally, but also for states that may be accused of overly strict regulation, violating rules and agreements on free trade.

The Commission is reviewing the existing legislation for certain targeted mutagenic methods (such as gene editing methods) and intends to present a legislative proposal. This proposal must be approved by the European Parliament and the Council (composed by Sweden and the other EU Member States at ministerial level). In my view it is important to adopt rules adapted to all plant breeders, including small and medium-sized enterprises. The Commission proposal can be expected in 2023, which could coincide with the Swedish Presidency in the first half of 2023.

2.5 Access to genetic material and biodiversity

Access to genetic material is crucial for successful breeding. Companies and research organizations are looking for biological resources around the world. This approach has been criticized and is sometimes referred to as “biopiracy”.

International instruments such as CBD[9], the International Treaty[10] and the Nagoya Protocol[11] have therefore been adopted to address the problem. The instruments aim at fair compensation for the use of genetic resources. In addition, discussions are currently underway on whether or not digital sequence information should be covered by the international instruments. However, the implementation of these instruments is rather slow and the mechanisms put in place by countries often appear to be administratively complex. This applies, for example, to authorization procedures for the use of genetic resources and the determination of compensation. This does not benefit those who wish to use the relevant genetic resources or those eligible for compensation. It is important that countries continue to seek solutions that also work in practice.

2.6 Administrative challenges for plant breeders

While breeders are looking forward to deregulation that allows gene editing methods to be used in breeding projects, this may mean that more time and resources need to be invested in intellectual property strategies and adaptation to future regulation. Companies that focus on gene editing can obtain patents for breeding methods and certain plant-related products but often need to use varieties protected by plant variety rights. This may have the effect that cross-licensing of variety rights and patents becomes more frequent. In addition, any infringement into protected varieties used for gene editing and method patents may increase. It is therefore important that companies operating in this field have both the technical and legal competence necessary to assess what is covered by patent and plant variety rights in order to make the best use of the rights constructively and not to end up in tricky infringement disputes. It is important that EU and Swedish plant breeding companies prepare for this development.

For the larger multinational processors with legal and administrative capacity and experience to deal with intellectual property issues and various regional and national regulations, the above-mentioned processing may not be prohibitive. For small and medium-sized plant breeding companies and public breeding institutes, increased administration can pose significant challenges. Future regulation must therefore ensure that the new technologies can be used by all types of companies and institutions. It is therefore important that this problem is brought to the attention of the public debate.

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1. FAO, 2017. The Future of Food and Agriculture — Trends and Challenges. Rome.
2. The socio-economic and environmental values of plant breeding in the EU and for selected EU countries, HFFA Research Paper 2021, Steffen Noleppa, Matti Cartsburg.
3. The unitary patent system project is described in Chapter 5.
4. The Plant Variety Rights Act (1997:306).
5. Council Regulation 2100/94 on Community plant variety rights.
6. Patent Act 1967:837.
7. The relevant part of the Directive is elaborated in chapter 7 below.
8. The socio-economic and environmental values of plant breeding in the EU and for selected EU countries, HFFA Research Paper 2021, Steffen Noleppa, Matti Cartsburg.
9. Convention on Biological Diversity, 1993.
10. The International Treaty on Plant Genetic Resources for Food and Agriculture.
11. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Sharing from Their Utilisation to the Convention on Biological Diversity.

3. Background

3.1 Purpose of the report

The main purpose of this report is to highlight the role of intellectual property rights in plant breeding in general and with some focus on new genomic technologies. Parts of the report explains the legal landscape, mainly what can be protected by intellectual property rights and the scope of protection, but the intention is also to present balances and options, thereby stimulating further discussions.

The importance of plant breeding for efficient and sustainable agriculture cannot be overestimated. A study (EUIPO/CPVO study) shows that plant breeding contributes not only to the economy of the EU and its Member States, but also to the implementation of the EU's climate objectives and the UN Sustainable Development Goals.[12]

At a time when we need to reduce dependence on chemical pesticides, reduce the overuse of fertilizers and at the same time produce more per unit area, the quality of seeds and other plant reproductive material becomes more important than ever.

A study by the European Union Intellectual Property Office (EUIPO) and the European Patent Office (EPO), the EPO/EUIPO study, shows that intellectual property rights (IPR) are important and that companies that protect their rights contribute more to the EU economy than others.[13] The EPO/EUIPO study shows that IPR-intensive industries generated 29.2 % of all jobs in the EU over the period 2014–2016. On average, they employed almost 63 million people in the EU during this period. In addition, 21 million additional jobs were created in industries supplying goods and services to IPR-intensive industries. Over the same period, IPR-intensive industries generated nearly 45 % of total economic activity (GDP) in the EU, worth EUR 6.6 trillion. IPR-intensive industries also pay significantly higher wages than other industries. A similar study from the US shows that IPR-intensive industries in the U.S. accounted for 41 percent of domestic economic activity in 2019. In the same year, IPR-intensive industries accounted for more than 47 million U.S. jobs.[14]

Investments in plant breeding require a lot of time and access to financial resources. One way to get a return on investment is to protect innovations with intellectual property rights. Intellectual property rights give the holder of the right an exclusive right to market its innovation for a limited period of time. The exclusivity provides better conditions for innovators in competitive markets and therefore provides better opportunities for return on investment. This increases the possibility of investing in new research projects.

Patents are intellectual property rights that can be used to protect inventions in all kinds of technical genres. One of these areas is biotechnological inventions. The plant variety right is tailor-made and covers only new plant varieties. What can be protected, and the scope of protection, differs between the two types of rights. It is important to understand the differences and chapters 4 and 5 address these issues. The language of **Chapters 4 and 5** may, in some respects, be rather technical, but it has been considered necessary in order to describe what can be protected by the respective intellectual property rights.

The sale and use of seeds (plant varieties) is regulated at EU level and Sweden and the other EU Member States have therefore adapted their legislation accordingly. A brief overview of this regulation is therefore set out in **Chapter 6**.

The regulation of the new genetic technologies is currently being reviewed in the EU and a study has been drafted by the Commission with options for the regulation of such new technologies. Important work on this initiative will take place during the Swedish Presidency in spring 2023. Swedish politicians are involved in the upcoming decision-

making process in the Council, the European Parliament and the Swedish Parliament. The relevant authorities and the public will take part in the public debate. These aspects are described in **Chapter 7**.

Chapter 8 gives a brief description of patents and plant variety rights and issues related to biodiversity conservation, **Chapter 9** provides an overview of possible developments in the future and contains a concluding comment.

3.2 Challenges

It probably has not escaped anyone that there are significant challenges in the agricultural sector, not only in Sweden and the EU, but also globally. We have a growing population while the agricultural area is declining. It is estimated that the world population will have risen from 7.9 billion in 2022 to around 10 billion by 2050.[15] Most of all food comes from agricultural products. Changing consumer demand and new eating habits, mainly in countries with growing economies, are affecting the development. Climate change makes it difficult to predict the outcome of agriculture and we are increasingly seeing serious problems such as drought, even in regions that have hitherto been spared from such problems.

The European Commission has adopted the "European Green Deal", a package of policy initiatives to pave the way for a green transition in the EU and whose ultimate goal is climate neutrality by 2050.[16] The Commission's Farm to Fork Strategy states that there is an urgent need to reduce dependence on chemical pesticides and antimicrobials, reduce the overuse of fertilizers, increase organic farming, improve animal welfare and reverse biodiversity loss.[17]

Meeting these challenges requires a series of measures that affect the overall political agendas of Member States at macro level. Innovation and investment in technology are often mentioned as crucial when it comes to finding sustainable solutions. The operation of agriculture is regulated in detail and the basis for decisions on what may be cultivated are the results of several control operations in a verifying chain. The most important elements are field inspection of seed production, seed control, seed sampling and laboratory analysis of the samples. These and many other issues are interrelated, and this report deals with one of these areas, namely plant breeding, and the role of intellectual property in contributing to sustainable solutions.

3.3 Plant breeding

Plant breeding is one of many important pieces of the puzzle in EU and Swedish agriculture. For farmers to be able to produce food and energy, seed and propagating material must be of the highest quality. Seeds and propagating material must also be aligned with the overall policy objectives of a healthy environment and climate change.

Plant breeding requires a lot of *time* and access to *financial resources*. How can the time be shortened from the start of a plant breeding project until a new variety is available on the market? How can plant breeding be financed?

Humanity has been breeding plants since ancient times. By choosing part of the harvest with the best properties as seed for next year's cultivation, better harvests could be obtained over time.

It was only when Mendel's[18] findings began to be applied at the end of the 19th century that modern plant breeding developed. Discoveries concerning the laws of genetic heritage were further developed in the early 20th century and a more scientific approach could be used to improve plants. As technology improved, demand for new varieties also grew. In many countries, there were also government interests in being able to support the population in the most efficient way possible. The fact that each individual farmer carried out his own local seed production was not very effective. In Europe, the majority of plant breeding took place in state institutes, while private seed companies and agricultural cooperatives took care of the propagation and marketing of new varieties.

Breeders want to provide farmers with optimally adapted varieties. In this case, it is important to combine many positive qualities in one variety. The desired properties include, among other things, a very good yield, disease resistance, high starch content, high protein or sugar content and/or good straw strength. In order to combine all these characteristics in a new variety, parental lines that carry on these desired properties are crossed. This creates a differentiating offspring generation.

In the ideal scenario, some of the resulting plant individuals carry the positive properties of both parents. Only then has the crossing produced the desired result. In the next step, the breeder makes a selection to identify individual plants with desirable properties. Several selection steps later and over a number of generations a new line has been created, combining the desired properties, and after several tests it can be registered as a new variety. This process is time- and work-intensive and can take up to 15 years. This new line can then be used in new crossings or as a component of a hybrid variety.

Over the years, plant breeding techniques have evolved. Crossing and selection have become more effective. Due to the introduction of hybrid breeding in maize in the 1920s, yields were higher and of better quality. Hybrid breeding systems are now available in many crops that are cross-fertilizers, including rye, sugar beet, rapeseed and a number of vegetable crops. Mutation breeding began in the 1930s, meaning that a plant is radiated or exposed to chemical substances that induce random mutations. Most of these are not desirable but some may be, and sometimes lead to a plant with a desired new trait being identified and used in continued plant breeding with crossing(s) and selection.

At the end of the 20th century, biotechnology took off and began to be used to a much greater extent in plant breeding. Biotechnology led to the possibility of producing transgenic plants and animals. Transgenic plants basically mean that a gene is introduced into a plant of another species, which could not happen naturally. If the new gene comes from another plant of the same species, the term *cisgen* is used. In the 21st century, techniques have been developed where the focus is on editing existing genetic information in a plant, so-called *genome editing* or gene editing. This is done with a technical tool that is often referred to as a gene scissor. A gene scissor enables gene editing, that is, a change in the genome of plants without introducing any new DNA into the plant. Gene scissors are used to change the genome in a precise way, unlike when a plant is radiated or exposed to chemical substances that induce random mutations (traditional mutation breeding). The most well-known gene scissor method is the CRISPR/Cas9 method.

Classical genetic modification has been used in plant breeding since the 1980s and in the 1990s the first products were approved for sale. The first plant to be commercialized was a tomato with delayed ripening, approved in the United States in 1994. Of the Earth's total cultivation area, genetically modified plants are now cultivated at about 12 percent[19], soybean is one of the larger crops in this regard.

Plant breeding has been an essential tool for the development of EU agriculture. The HFFA study published in 2021[20] shows, among other things, that for all major arable crops cultivated in the EU, about 67 % of yield growth can be attributed to innovation/plant breeding since the millennium shift. This means that the increase in yields attributable to plant breeding has increased yields by 1.16 per cent per year over the last 20 years. Furthermore, it is clear that without a functioning plant breeding over the last 20 years, the EU would have become a net importer of all major arable crops. Plant breeding helps to save land resources around the world by generating higher yields per unit of area. In the absence of plant breeding for larger arable crops in the EU over the last 20 years, the agricultural area in 2020 would need to be increased by more than 21.5 million hectares. The study also shows that results of plant breeding contribute to limiting CO_2 emissions and that unwelcome effects on biodiversity are mitigated. It is also apparent from the study that the use of new genetic techniques can speed up positive results for the environment.

Another recent study on the economic and environmental impact of EU plant variety rights shows similar results (CPVO/EUIPO study[21]). Examples of higher yields per unit area are given and that farmers using protected varieties

increase their income. The study shows that 90 % of holders of an EU plant variety right are small and medium-sized enterprises and individual persons, holding 60 % of the total number of protected varieties. Plant variety rights not only contribute financially to the EU economy but also to meeting the EU's environmental objectives. Annual greenhouse gas emissions from agriculture and horticulture are reduced by 62 million tonnes per year due to the fact that high-performance plant varieties require inferior agricultural area. This corresponds to the total carbon footprint of Hungary, Ireland or Portugal. In addition, water use in agriculture and horticulture is reduced by more than 14 billion m^3, a quantity of water equivalent to 1/3 of the volume of Lake Constance. By reducing environmental impact and resource use in agriculture and horticulture, by increasing farm incomes and by keeping prices lower for consumers, the system also contributes to the UN Sustainable Development Goals.

Innovation and new technologies thus contribute to solving the above-mentioned policy challenges.

Investments in plant breeding require a lot of time and access to financial resources. During the twentieth century, state-funded plant breeding was more common, but the scale has decreased. Private funding for plant breeding to produce new plant varieties has therefore increased in importance. Intellectual property rights give the holder of the right an exclusive right to market the protected innovation for a limited period of time. The exclusivity provides better conditions for innovators in competitive markets and therefore provides better opportunities for return on investment. Thus, by protecting the innovation, the innovator is given the opportunity to decide on the production and marketing of the innovation and thereby obtain various incomes, such as royalties. Intellectual property is therefore important as regards the possibility of financing plant breeding and other innovative or creative activities.

3.4 Intellectual property rights

Article 27(2). UN Charter of Human Rights:

'Everyone has the right to the protection of the moral and material interests arising from scientific, literary and artistic works of which he or she is the author.'

As mentioned above, intellectual property rights are covered by the UN Charter of Human Rights. The protection of intellectual property is also enshrined in Article 17(2) of the EU Charter of Fundamental Rights[22] and thus falls within the jurisdiction of the Court of Justice of the European Union. This is important because the judgments of the Court of Justice of the European Union have binding force in the Member States of the European Union.

In short, intellectual property means that a creator of, for example, a work, subject-matter, book, music or invention can obtain an exclusive right to use the innovation. Intellectual property is a collective term for a number of different types of rights such as copyright, patent law, design, trademark and plant variety rights.

One might ask why there are a variety of rights and why not all inventions and results of creative efforts can be protected under one law. In short, the objects of what can be protected by an intellectual property are too different in order to provide identical protection. The object of protection and the scope of protection have, for example, been considered different for an author of a book and for an inventor of a method of producing a medical product. Legislation on various intellectual property rights has been adopted as there has been a need for creators and a public interest to protect certain subject matter. What is protected by one type of intellectual property is thus, in many cases, essentially different from what is protected by another type of intellectual property.

In other cases, the difference is considerably smaller and delimitation problems may arise, for example between patents and plant variety rights, which will be highlighted below. It can also be noted that in some areas, mainly in the

digital industry, there is a trend that more than one intellectual property protection can be granted to the same object of protection. However, this is not addressed in this report.

There are many reasons for the emergence of intellectual property rights, but one of these can probably be as simple as the fact that for most people there is a sense of injustice in cases where created works are copied without the creator being recognized or compensated in any way.

In today's rapid technological development, intellectual property rights therefore play an important role in the part of the civil law that regulates economic rights and obligations between parties and businesses. Digitalization, pharmaceuticals, dissemination of information are protected by intellectual property rights, which contributes to the creation of successful and strong companies, which in turn leads to jobs and welfare.

Intellectual property rights give the holder of the right an exclusive right to promote its innovation for a limited period of time.

Intellectual property also contributes to public interests by making technology development available on the market so that more people can benefit from progress and develop further. In a well-functioning market, competition is needed and at the same time it is important that technology development is not slowed down or completely stopped by the use of intellectual property rights, which are in place to stimulate innovation.

As in so many other areas of our society, there is a need for a balance of interests, including in intellectual property. Exclusive rights are therefore limited by exceptions in intellectual property laws, such as the Patents Act, the Copyright Act. Competition law also serves as an overarching tool to curb the abuse of unwelcome anti-competitive activities, including in the field of intellectual property.[23]

An intellectual property right entitles the holder of the right to prohibit those who have not obtained the holder's authorization to exploit the protected object for industrial and commercial purposes. The right is not intended to replace or render superfluous legislation imposing any restrictions or prohibitions or regulating the monitoring of research and the use or commercial exploitation of its results, in particular in relation to public health, safety, environment and animal welfare requirements, as well as in relation to the preservation of genetic diversity and to certain ethical standards.

For example, patents can be obtained for inventions used in military contexts; this does not mean, however, that other legislation cannot prohibit the use of these inventions to the public. A plant variety produced by the use of a genetically modified organism may be protected by a plant variety right, but without the appropriate authorization the variety cannot be grown and marketed.

It took more than a decade for EU Member States to agree on the Biotechnology Directive on the legal protection of biotechnological inventions. One of the main reasons was various ethical issues. The solution finally opted for was that biotechnological inventions in principle can be patented but that their use may be prohibited by other legislation, as explained above. However, in the case of certain biotechnological inventions, *they were considered to be contrary to public order and good customs and ethical and moral principles 'due to the potentially far-reaching consequences of inventions in this field and their intrinsic connection with living materials'*.[25] Therefore, Article 6 of the Biotechnology Directive introduced a non-exhaustive list of inventions which cannot be patented, such as procedures for cloning human beings, procedures for changing the genetic identity of human germ cells, the use of human embryos for industrial or commercial purposes, and procedures for changing the genetic identity of animals which may cause them suffering, without bringing any tangible medical benefit to humans or animals. Similar provisions have been introduced in the Patents Act. Patenting of plants in general was not considered unethical per se. For other reasons, however, plant varieties cannot be patented, as discussed below in Chapter 4.

When the UPOV Convention entered into force in the 1960s, there were provisions on compulsory licences and the breeders' exemption[26] in order to balance between public and private interests.

The Commission has adopted an IPR Action Plan[27], which highlights that IPR is an important driver for economic growth as they help companies increase the value of their intangible assets. The objective of the Action Plan is to help the EU's creative and innovative industry remain the world leader and accelerate the EU's green and digital transitions. The Action Plan includes specific measures to facilitate the use of intellectual property rights by SMEs. It also underlines that the Community plant variety right regime plays a crucial role in the EU economy and that a robust system of plant variety rights provides incentives for breeders to develop new varieties and thus contribute to the achievement of the objectives of the Green Deal and the UN Sustainable Development Goals.

It has been shown that intellectual property rights for plant-related innovations are widely used, mainly patents and plant variety rights. At the end of 2021, the CPVO had received approximately 76,500 applications since 1995, of which approximately 59,420 were registered. In 2022, just over 30,000 plant variety rights are still registered.[28] EPO had received about 8 500 applications, since 1995, for genetically modified plants (method and product patents) by the end of August 2021. Of these, about 4,600 have been withdrawn or not granted, about 3,100 were granted and 900 are still under review. For plant-implemented inventions developed using traditional plant breeding (including technical tools for plant production), the EPO had received 1 137 applications by the end of August 2021, since 1995.[29]

The report below focuses on the intellectual property rights of patents and plant variety rights. The presentation is far from exhaustive but aims to explain what can be protected and the extent of protection for plant-related innovation.

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12. EUIPO and CPVO Study, Impact of the Community Plant Variety Rights System on the EU Economy and the Environment, April 2022.
13. IPR-intensive industries and economic performance in the European Union, Industry-Level Analysis Report, September 2019, Third edition, A joint project between the European Patent Office and the European Union Intellectual Property Office.
14. Intellectual property and the U.S. economy: Third Edition, USPTO.
15. FAO. 2017. The Future of Food and Agriculture — Trends and Challenges. Rome.
16. *https://www.consilium.europa.eu/sv/policies/green-deal/*
17. *https://www.consilium.europa.eu/sv/policies/from-farm-to-fork/*
18. Gregor Johann Mendel, 1822-1884, was an Austrian-Czech Catholic monk, Corinthian and hereditary scholar. Through his experiments with crossing pea varieties, he presented the first theory of how traits are inherited by randomly combining predispositions in the offspring. Many of his terms are still used today, including dominant and recessive predispositions. He published his findings in 1865, but his ideas were only noticed after his death, in the early 20th century. Mendel is now recognized as the father of genetics.
19. See report from the Swedish Gene Technology Advisory Board; Impact of the Environmental Code on Research and Development 2021.
20. The socio-economic and environmental values of plant breeding in the EU and for selected EU countries, HFFA Research Paper 2021, Steffen Noleppa, Matti Cartsburg.
21. EUIPO and CPVO Study, Impact of the Community Plant Variety Rights System on the EU Economy and the Environment, April 2022.
22. Official Journal of the European Union, 26.10.201, 2012/C 326/02.
23. OECD Report, Concentration in seed markets, Potential Effects and Policy Responses, 4 December 2018.
24. See Article 13(7) Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, OJ L 227, 1.9.1994, p. 1, see further introduction to the Biotechnology Directive, Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions.
25. Paragraph 39 of the introduction of the Biotechnology Directive.
26. See further explanation of compulsory licences in Chapters 4.6 and 5.6 and breeder's exemptions in Chapter 4.5.3.
27. An IPR Action Plan to support the EU's recovery and resilience, Brussels, 25.11.2020, COM (2020) 760 final.
28. *https://cpvo.europa.eu/en/statistics*
29. EPO documents; CA/PL 3/21, 5.11.2021.

4. Plant variety rights

4.1 Introduction

As already mentioned in Chapter 2, mankind has been breeding plants since ancient times. By choosing part of the harvest each year with the best properties as seed for next year's cultivation, better harvests could be obtained. As new scientific discoveries were made, methods improved and plant breeders focused on developing new varieties and farmers found more effective ways of farming. The problem for plant breeders was to get a return on their investments because seeds and other propagating material could be saved, reused and copied. Following pressure from interest groups representing private plant breeding companies, the French government took the initiative and called for an international conference in 1957. After a few years of negotiation, the acceding parties agreed in 1961 on special intellectual property protection for plant varieties governed by the UPOV Convention[30], which was updated in 1972, 1978 and 1991. Gradually, public plant breeding in arable crops in many countries was now taken over by private plant breeding companies.

Sweden acceded to the UPOV Convention on 17 December 1971 and on 24 April 1998 Sweden upgraded its membership to the UPOV Convention 1991. The EU was the first intergovernmental organization to join the UPOV on 29 July 2005. OAPI has also acceded to membership and has legislation consistent with the UPOV in 1991, and a protection covering the 17 territories of the Member States.[31] 76 States and 2 intergovernmental organizations are UPOV members, covering the territory of 97 countries.[32]

The Agreement on Trade-Related Aspects of Intellectual Property Rights is one of the most important international agreements on intellectual property rights, and was ratified by Sweden in December 1994. As a member of the World Trade Organization (WTO), it is obliged to comply with the obligations of the TRIPS Agreement. Without detailing these commitments, it can be mentioned that the TRIPS Agreement does not have a specific section on plant variety rights. However, Article 27, which deals with patents, concerns the issue of protection of plant varieties. As an exception to the rule that inventions of all kinds of technology may be patented, Article 27 (3) (b) provides that plants and animals which are not micro-organisms may be excluded from patentability. It follows, however, that WTO Members must provide protection for plant varieties either by means of patents or by an effective sui generis system or by a combination thereof. National legislation based on the text of the UPOV Convention may be presumed to comply with the requirements of Article 27(3) of the TRIPS Agreement.

Thus, it was the economic need of breeders to be able to protect their investments in innovation and the technological development of plant breeding that drove legislation forward. It was also essentially technical reasons that led to the creation of a special system of plant variety rights in parallel with patent law. The technical protection criteria for patents were considered less suitable for plant varieties in many countries.

The holder of a new plant variety may be granted a plant variety right, which essentially confers an exclusive right to exploit the variety on a professional basis.

The UPOV secretariat does not process and decide on applications for plant variety rights. In order to obtain a plant variety right, an application must be filed with the country or intergovernmental organization in which the applicant wishes to obtain a plant variety right. However, UPOV has developed a digital platform (UPOV PRISMA) that can be used to forward an electronic application to a competent authority in the country or intergovernmental organization where the applicant wishes to obtain a plant variety right and which accepts applications through UPOV PRISMA.[33]

In order to obtain a plant variety right in Sweden, an application must be submitted to the Swedish Board of Agriculture (Jordbruksverket) which handles the application and then decides whether a plant variety right should be granted (or refused) in Sweden. Applications for plant variety rights and the conditions for granting plant variety rights are set out in the Plant Variety Rights Act.[34]

Plant variety rights may also be granted in all EU Member States on application to the Community Plant Variety Office (CPVO) under Council Regulation (EC) No 2100/94 of 27 July 1994 on Community Plant Variety Office (hereinafter 'the Basic Regulation').[35] As the Community no longer exists, the report will mostly refer to the Union.

In order to obtain a plant variety right in the EU, an application must be filed with the CPVO, which processes the application and then decides whether to grant a plant variety right in all EU Member States. EU plant variety rights have the same effect throughout the territory of the EU and may only be granted, transferred or terminated by the CPVO for the whole of that territory.[36] CPVO is therefore not able to grant rights in individual Member States but only for the entire territory of the EU. A unique advantage of using the EU system is that only one application needs to be submitted, one technical test is carried out and one examination of all the conditions is carried out in order for CPVO to subsequently take a decision to grant (or refuse) plant variety rights in all EU Member States. Prior to the introduction of the EU system, it was necessary to apply for a plant variety right in each individual Member State where the breeder sought protection, with all the administrative and linguistic inconveniences resulting from this.

Where an EU plant variety right has been granted by the CPVO for a plant variety, the same plant variety cannot subsequently be granted national protection in a Member State. However, if a national right for a plant variety has already been granted when an application is submitted to the CPVO, that plant variety may be protected by an EU plant variety right. In these cases, the holder of the plant variety right under the national law in question cannot refer to national law in order to enforce his/her national rights as long as the EU plant variety right for the variety is in force.[37]

Thus, it is clear from the Plant Variety Rights Act that a plant variety may not be registered in Sweden if it is already registered under the EU plant variety right.[38] It is not entirely clear why this provision was introduced in the Basic Regulation, which differs from, for example, the EU Trade Marks Regulation where a national and EU trade mark rights for the same trade mark may coexist. One reason may have been that the plant variety right had not been harmonized in the EU and was thus regulated by the laws of the Member States which were not uniform.[39] EU Member States were still members of different versions of the UPOV Convention, and four EU Member States were and are not members of the UPOV.[40] It could be confusing for farmers and other users if the same variety was regulated by two different types of plant variety rights whose scope is to some extent different from each other.

The Commission intends to launch a review of the EU system in 2023 and update the Basic Regulation thereafter. Formal changes to bring the text in line with the Lisbon Agreement and the administration of the Agency itself is foreseen to be introduced. There are also expectations from breeders that, for example, the rules on provisional protection from the date of application until the date on which the right is granted will be strengthened and that the rules on the agricultural derogation are amended as regards farmers' obligation to provide processors with information on the use of farm saved seed (see below, Chapter 4.4).

Both Swedish and EU plant variety rights are based on the UPOV Convention.[41] The presentation below on plant variety rights and patent law provides a general overview of the areas of law with the main objective of describing what can be protected and the extent of the protection afforded by the registered right. Some focus is given to explaining the adjacent parts of plant variety rights and patent rights, and then analysing what protection is relevant to a plant-related innovation. Procedural issues relating to invalidity declarations, revocations, fees, appeals, questions of infringement, etc. are therefore not dealt with in this report.

4.2 What can be protected by plant variety rights?

The subject-matter that can be protected by a plant variety right is narrowly limited to product protection for plant varieties. When the idea of intellectual property protection for plant varieties began to emerge in Europe, it was considered whether patents could fulfil this function. Since patents had mainly been developed for inventions relating to non-living matter, this form of protection was not considered to be optimal.[42]

As early as 1966, the Swedish legislator considered that patents do not constitute an appropriate form of protection for plant varieties.[43] It is therefore not possible to patent a plant variety under the Swedish Patent Act. The same position has been taken in the European Patent Convention and Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (the Biotechnology Directive). In Europe, therefore, the idea is that what is covered by the definition of 'plant variety' is protected by plant variety rights and not by patents, whereas patents may be granted for inventions not covered by the definition of a plant variety.

In some countries, such as the United States, patents may be granted for plant varieties provided that the patent claims are met. In the United States, there are three different types of protection (protection of plant varieties, plant patents and utility patents) managed by two agencies (PVPO and USPTO).

The Plant Variety Protection Office (PVPO) of the U.S. Department of Agriculture (USDA) provides plant variety rights under the Plant Variety Protection Act (PVPA), based on the 1991 UPOV Convention, for new varieties of seeds, potatoes and asexually propagated plants. The varieties are protected for 20 years (25 years for vines and trees).

The United States Patent and Trademark Office (USPTO) issues plant patents under the Plant Patent Act 1930 for new and distinguishable, vegetatively propagated plant varieties. It can be noted that this law was adopted just over 30 years before the adoption of the UPOV Convention 1961. In addition, patents can be obtained for plants that meet the general patent claims under the Patent Act of 1952 (so-called utility patent) for inventions including genes, properties, methods, and parts of plants. Both plant and utility patents have a term of 20 years from the date of filing. According to jurisprudence, protection of the same plant/material may be obtained in accordance with PVPA, the utility patent Act[44] and the Plant Patent Act 1930[45], as long as the protection criteria under the respective legislation are met. It is up to the person who has developed a new plant/plant variety/gene, etc., to decide whether to protect the invention under one or more system taking into account what appears to be best suited in the case at hand.

Under the 1991 UPOV Convention, the Contracting Parties are required to grant plant variety rights for all varieties irrespective of the plant species or plant genus to which it belongs. CPVO has registered varieties for more than 2,300 species.

It can be mentioned that both CPVO and Japan have granted plant variety rights for mushroom varieties. According to EPO's practice, mushroom varieties fall outside the definition of what is covered by the plant kingdom and patents for fungi varieties have been granted. It cannot be ruled out that the issue of plant variety protection for fungi varieties may come up in discussions and/or practices before those authorities.

Practice shows that authorities granting plant variety rights (CPVO within the EU, the Swedish Board of Agriculture) have no major problems in determining whether an application concerns a plant variety or not. The reasons for this are in essence that the definition of a variety is relatively clear and that practical field tests are carried out to verify whether the technical criteria are met. Unlike patents, which can be granted in virtually all technical fields and cover both products and processes, the plant variety right is narrowly limited to only product protection for plant varieties. The term plant variety is defined as[46]

"a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:
- defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
- considered as a unit with regard to its suitability for being propagated unchanged."

In order to obtain protection for a variety falling within the above definition, three technical criteria must be met.[47] The variety must be *distinct* from all other varieties whose existence is generally known on the date of filing.[48] A plant variety is deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of application. The variety must be *uniform* with regard to its essential characteristics. A variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description.[49]

A variety must also be *stable*. A variety shall be deemed to be stable if the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.[50]

In order to verify that these technical requirements are met, the new variety is tested at an examination office in accordance with technical protocols adopted by the CPVO and in most cases based on UPOV Guidelines. When no CPVO protocols have been adopted, UPOV Guidelines or national guidelines are used. The protocol used depends on the species of the new plant variety. In essence, the protocols contain methods for testing the variety and a list of the characteristics to be observed. The characteristics are phenotypic such as height, colour, leaf shape, etc. DNA is not used as a basis for decision-making to determine whether a variety is distinct or not. However, DNA technology can be used, for instance to exclude certain reference varieties and thus limit the varieties with which the new variety has to be compared.

The technique used to produce the variety is irrelevant for assessing whether the technical conditions for plant variety rights are fulfilled. In other words, the variety can be produced using, for example, traditional mutation methods, genome editing, cisgenic/transgenic methods or traditional methods such as crossing and selection. However, the technique used must be indicated in the application as it may be decisive for the conduct of the technical tests. If a variety is subject to the rules on GMOs, an authorization for cultivation must be presented by the applicant issued by a competent body. In this respect, it can be said that the plant variety right is technology neutral. Since 1995, the CPVO has received 107 applications for GMO varieties, of which 29 varieties are still protected.

The creation of a method whereby a plant is resistant to a particular disease is not in itself sufficient to grant a plant variety right. The method used must result in a plant variety that meets the technical requirements. Subsequently, protection for the specific variety, but not the method, may be granted a plant variety right, provided that the conditions for protection are met.

The variety must also be *new*.[51] A plant variety shall be considered new, unless propagating material or harvesting material of the variety with the consent of the breeder have been sold or otherwise disposed of to others for the purpose of exploiting the variety in Sweden earlier than one year before the date of application, or abroad earlier than six years before the date of application for trees or wine, or earlier than four years before the date of application for other plant species. Similar provisions, adapted to the EU regional system, are laid down in Article 10 of the Basic Regulation.

A plant variety shall also have a *variety denomination*[52] which allows the variety to be distinguished from other varieties. The applicant proposes a denomination and the Swedish Board of Agriculture decides upon its suitability for Swedish applications and the CPVO for EU applications. Anyone offering propagating material of a protected plant variety for sale or otherwise commercializing such material is obliged to use the registered variety denomination. This also applies when the term of protection has expired or the plant variety right is no longer in force for some other reason such as if it has been withdrawn, cancelled or declared null and void. Therefore, a variety denomination that is protected becomes, in practice, generic. CPVO manages a database of over one million variety denominations from 70 countries called VarietyFinder. The CPVO collects relevant data on variety denominations from many databases, mainly but not exclusively in the EU. CPVO cooperates with UPOV, which provides CPVO with designations from systems of UPOV members outside the EU. The CPVO also receives data from EUIPO containing trademarks in Class 31. Ensuring that all protected variety denominations comply with the requirements laid down in the legislation is a rather voluminous and complex work, and the CPVO cooperates with the EU Member States in order to ensure uniform application.[53]

4.2.1 Plant variety

The plant variety right covers the plant variety registered.[54] It also includes collections of plants which are not distinct from the protected variety. When assessing whether the condition "clearly distinct" from that of another plant variety is fulfilled, the same technical criteria are used as when assessing if a variety is *distinguishable* for the purpose of granting a plant variety right.[55]

Plant varieties which can be produced only through the repeated use of the registered variety are also protected. The most common example of this is when two parent lines are used to produce a hybrid variety, a so-called F1 variety. The fact that the lines are protected has the effect that even the offspring/hybrid is protected, if the two parental lines are necessary for the production of the offspring/hybrid. Some breeders consequently only protect the parent lines in order to avoid the time and costs of protecting this type of hybrid varieties. However, the trend in recent years at the CPVO is to protect hybrid varieties too, as with some technologies it may be possible to produce hybrids without using parent lines.

The protection also covers plant varieties which are *essentially derived* from the registered variety. What is meant by a variety being essentially derived is the subject of discussions amongst stakeholders, which is why this type deserves a more detailed description.

4.2.2 Essentially derived varieties (EDV)

4.2.2.1 Background

The introduction of protection for essentially derived plant varieties in the 1991 UPOV Convention reinforced plant variety rights in comparison with the 1978 text of the Convention, which did not provide protection for such plant varieties.

As detailed below (4.5.3), one of the exceptions in the plant variety right allows a protected plant variety to be freely used as a source for further breeding *(the breeder's exemption)*. The variety resulting from such further breeding may itself be the subject of protection and may be exploited without any obligation to the breeder of the original variety.[56] In the course of reviewing the UPOV 1991 Act it was perceived as particularly unfair that the use of modern biotechnology, such as the introduction of a gene in a protected plant variety, could modify the variety which it may

have taken many years to breed, thereby creating a new variety that could be protected by a new plant variety right without any compensation to the holder of the original variety.

It was also considered unfair that a person who finds a mutation of a protected plant variety or other single variant within a protected plant variety could be granted a plant variety right to such a mutation or variant without the holder of the right of the original variety having any say. At the 1991 Diplomatic Conference, it was therefore considered important to extend the scope of plant variety rights in order to provide incentives for traditional as well as modern plant breeding in the future.[57]

4.2.2.1 Definition of essentially derived varieties

The definition of *essentially derived* varieties is set out in the Plant Variety Rights Act.[58] A plant variety shall be deemed to be essentially derived if it

1. is predominantly derived from the initial variety, or from a variety that in itself is predominantly derived from the initial variety, if it has retained the expression of the essential characteristics that result from the genotype, or combination of genotypes, of the initial variety,
2. is clearly distinguishable from the initial variety, and
3. except for the differences which result from the act of derivation, conforms with the initial variety in the expression of the essential characteristics that result from the genotype, or combination of genotypes, of the initial variety.

Article 14(5)(c) of the 1991 UPOV Convention provides certain examples of biotechnological methods by which essentially derived varieties can be produced. These methods include varieties obtained by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

These methods are not mentioned in the Swedish Plant Variety Rights Act, but the preparatory works state that the examples in the Convention, as well as the guidelines drawn up by the UPOV Secretariat, may provide guidance on the interpretation of the term "essentially derived variety".[59]

The preparatory works further states that the testing institutions in their reports on whether the technical conditions for protection are met (distinctive, uniform and stable) should indicate whether a tested variety is essentially derived. In order to facilitate this, the application must indicate the origin of the variety.[60] However, in practice the examination offices in Sweden and the EU do not report on whether a variety is essentially derived or not during the technical examination. There are no official technical protocols to determine whether a plant variety is essentially derived or not. In addition, the question whether a variety is an essentially derived variety most often arises in infringement cases and it is for the courts to determine whether a variety on the market infringes a protected right.

The above-cited definition of an essentially derived variety in the Plant Variety Act is taken from the UPOV Convention. The definition is far from clear. One of the reasons for this is that the text is the result of long discussions and compromises at the Diplomatic Conference that led to the 1991 version of the UPOV Convention. It was necessary to find a text stating at the same time that the essentially derived variety must be distinct from the initial protected variety, but not be too different.

The authors of the Convention were aware of the unclarities of the text and during the Diplomatic Conference for the Review of the UPOV Convention, held in Geneva from 4 to 19 March 1991 (the Diplomatic Conference), a resolution was adopted stating that the Secretary-General of the UPOV should begin immediately after the Conference to establish draft guidelines, for adoption by the UPOV Council, on essentially derived varieties.[61]

Already in 1992, guidelines were adopted by the UPOV Secretariat,[62] and new guidelines were adopted in 2009, so-called Explanatory Notes (UPOV/EXN/EDV/1). These were updated in 2017 after long discussions and compromises (UPOV/EXN/EDV/2). UPOV organized a seminar on 30 October 2019 *"The impact of policy on essentially derived varieties (EDVs) on breeding strategy"* and then the CAJ (UPOV Administrative and Legal Council) opened up the discussion on revising the current guidelines. A dedicated working group was set up by CAJ and in October 2021 the CAJ adopted new Explanatory Notes. For these to enter into force, they must be adopted by the Consultative Committee of the UPOV and then by the UPOV Council. A new version (UPOV/EXN/EDV/3 Draft 3) was sent to the Consultative Council at the end of 2021 for adoption by written procedure. During the written procedure, written observations were submitted to UPOV by a few members and the process is now expected to resume during the UPOV meetings in October 2022 (see further below 4.2.2.6).

4.2.2.3 UPOV Guidelines on Essentially Derived Plant Varieties

The guidelines still in force are thus (UPOV/EXN/EDV/2), below the "Guidelines". Below follows a review of the most relevant parts for the explanatory notes. As the new version, which has not been adopted, reflects important considerations, some elements of this draft are presented below (UPOV/EXN/EDV/3 Draft 3), below referred to as "Draft 3".

Essentially derived varieties (Article 14(5)(b)(i) UPOVC)

A first condition is that the essentially derived variety is predominantly derived from the initial variety or from another variety which is predominantly derived from the initial variety.

According *to the Guidelines,* the term *'predominantly derived'* means the genetic origin of the essentially derived variety. Paragraph 4 of the Guidelines states that the requirement of predominant derivation from an initial variety means that a variety can only be essentially derived from one initial variety. In addition, the Guidelines states that an essentially derived variety must retain virtually the whole genome of the initial variety.

Draft 3 contains the above, but the text is partially nuanced. Paragraph 5 of Draft 3 states that "*Predominant*" derivation means that more of the genome of the initial variety is retained than would be retained by normal crossing and selection with different parents.

"Normal crossing and selection" is described as crossing two or more phenotypically and genetically different parents for the purpose of developing a segregating population for testing and selection.

Furthermore, Draft 3 explains that a high degree of genetic conformity alone does not automatically mean that a variety *has been predominantly derived* from the initial variety.

Draft 3 also states that varieties with a single parent ("mono-parental" varieties) resulting, for example, from mutations, genetic modification or genome editing, are *per se predominantly derived* from their initial variety.

Furthermore, Draft 3 explains that varieties involving the use of two or more parents ("multi-parental" varieties) may be predominantly derived from one parent (the initial variety) by selectively retaining the genome of the initial variety, for example through repeated backcrossing. Draft 3 mentions that in these cases crop-specific genetic conformity thresholds might be defined in order to determine predominant derivation, i.e. beyond a level that would be obtained by normal crossing and selection with the initial variety. Draft 3 does not state who should draft such thresholds, but one could imagine that breeders' organizations would have an interest in doing so, at least for major crops and/or crops for which infringements are more likely to occur. Within the International Seed Federation such initiatives already have taken place.

Clearly distinguishable from the original variety (Article 14(5)(b)(ii) UPOVC)

This condition simply means that an essentially derived variety must be clearly distinguishable from other varieties in the same way as for varieties for which an application for a plant variety right is examined.[63]

Conformity in the expression of the essential characteristics of an essentially derived variety with its original variety (Article 14(5)(b)(iii) UPOV)

This is the part in which the main differences between the Guidelines and Draft 3 are found. Both documents state that that an essential characteristic is a characteristic that results from the expression of the genotype. In Draft 3 point 7 it is added that such characteristics are, but not limited to, morphological, physiological, agronomic, industrial (e.g. oil characteristics) and/or biochemical characteristics. I point 8 it is specified that an "essential characteristic" is a characteristic that is fundamental for the variety as a whole. It should contribute to the principal features, performance or value for use of the variety and be relevant for one of the following: the producer, seller, supplier, buyer, recipient, user of the propagating material and/or of the harvested material and/or of the directly obtained products and/or the value chain.

Point 10 of the Guidelines states that the differences which results from the derivation should only be *one or very few*.

This limitation may be said to be the root of the discussions within the UPOV on what is to be covered by the definition of an essentially derived variety. UPOV observer organizations consider, among other things, that the mentioned restriction does not reflect the functioning of the industry and how new varieties are bred.

Draft 3 point 13 states that Article 14(5)(b)(iii) of the UPOV Convention does not set an upper limit on the number of differences that may exist where a variety is still considered to be essentially derived. The number of differences between an essentially derived variety and the initial variety is therefore not limited to one or very few differences but may vary taking into account different methods of derivation. The differences may also include essential characteristics.

Furthermore, reference is made to the wording of the Convention, namely that differences arising from the derivation must be disregarded when determining whether a variety is essentially derived. In this respect, the following clarification is made under Point 14 of Draft 3:

"(a) In the case of mono-parental varieties, all differences necessarily result from one or more act(s) of derivation, meaning that all differences are excluded from consideration of the EDV status.

(b) In the case of a multi-parental variety, the differences between that variety and any of its parent varieties may result from normal crossing and selection or from one or more of the methods of derivation described in paragraphs 15 and 16. Therefore, when determining the EDV status of such a multi-parental variety in relation to one of its parent varieties, it is important to establish whether there have been one or more acts of derivation.

In paragraph 15 the examples of methods by which an essentially derived variety may be obtained and mentioned in the Convention are provided, namely

- selection of a natural or induced mutant, or of a somaclonal variant,
- selection of a variant individual from plants of the initial variety,
- backcrossing,
- transformation by genetic engineering.

In the case of "backcrossing", it is understood that this means repeated backcrossing to the initial variety.

Paragraph 16 of Draft 3 clarifies that the list of methods is not exhaustive. It also states that the examples of methods correspond to the methods known in 1991 and since then, breeding methods have evolved and techniques, such as genome editing, have emerged. Other breeding methods that could lead to the development of essentially derived varieties may also be developed in the future.

Paragraph 17 of Draft 3 states that the exclusive use of one or more of the mentioned methods would *typically* result in essentially derived varieties. Some may argue that the use of one or more of the mentioned methods would always lead to an EDV, whilst other would say that this would go too far. The insertion of the word typically appears to have been a compromise.

In the Guidelines and Draft 3 it is explained that a variety can be either directly or indirectly derived from the initial variety, but this will not be elaborated on further in this Report.

In the Guidelines and Draft 3, the flowchart below shows the steps to be taken when assessing whether a variety falls within the definition of an essentially derived variety.

The Guidelines do not mention variety denominations, but according to Draft 3, an essentially derived variety must have its own denomination, different from the original variety, regardless of whether or not the *essentially derived variety* is protected in itself.

4.2.2.4 The EDV concept under the EU system

The definition of an essentially derived variety under the EU Regulation 2100/94 (the Basic Regulation) differs from the wording of the UPOV Convention. In the "EU definition", part of the text in 14(5)(b)(i) of the UPOV Convention has been removed, see below over-crossed text (Article 13.6. (a) The basic Regulation)

'it is essentially derived from the original variety, or from a variety which is in itself predominantly diverted from the original variety, ~~retaining the essential characteristics resulting from the genotype or combination of genotypes of the original variety;~~'

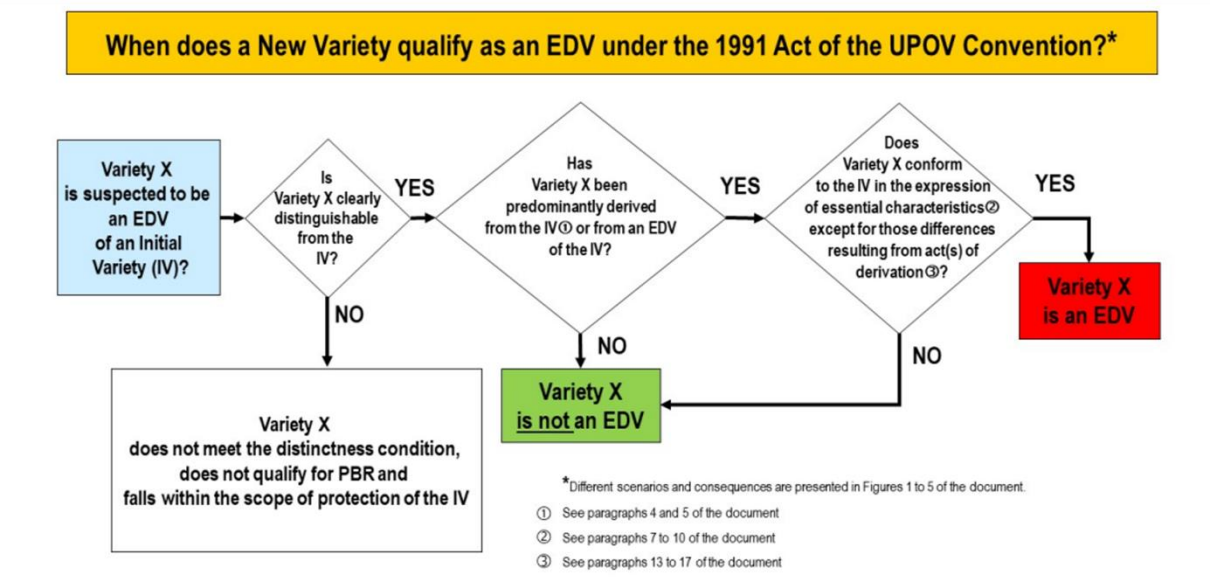
The UPOV Convention is sometimes criticized because there appears to be a contradiction between paragraph (i) and (iii) of Article 14(5)(b). It is likely that the reason for not including the over-crossed text was to reduce what often is referred to the ambiguities between paragraph (i) and (iii) of the Convention, rather than explicitly deviating from the Convention.

Article 13.7 of the Basic Regulation provides that implementing rules may be adopted in which possible acts of derivation are specified. However, no such rules have been adopted.

In addition, the Basic Regulation provides for the registration of essentially derived varieties under certain conditions. The holder of an initial variety and the breeder of a variety which is essentially derived from the initial variety shall have the right to have the identification of the varieties in question determined as initial and essentially derived. However, it is not the CPVO that determines this, but a national court. Such a court decision may be registered in the CPVO register.[64] At the time of writing, no such registrations have been made.

However, there is another way to register an essentially derived variety in the CPVO register if the holder of an original variety and the breeder of a variety which is essentially derived from the original variety *both* so wishes. A request by *one* of the parties is sufficient, provided that the party has obtained either an undisputed recognition of the other party or a final decision or a final judgment identifying the varieties concerned as original or diverted. The CPVO does not carry out technical tests as to whether the variety is an essentially diverted variety or not. The decision to register is based on a declaration by the applicant(s) for registration. Applications of this type of registration have been

submitted to the CPVO, although the number is relatively low. Most registered EDVs are ornamental varieties. The below chart is found in the UPOV Guidelines.



4.2.2.5 Dispute resolution

In Sweden and within the EU, it is considered that it is up to the right holder to ensure that his or her right is respected. This can be done through negotiations between parties, mediation, arbitration or through a dispute before a court. None of the UPOV Convention, the Basic Regulation and the Plant Variety Rights Act prescribe or specify any role for the relevant authorities to mediate and/or settle disputes related to essentially derived varieties.

There is limited case law from national courts on essentially derived varieties, and clarification by the Court of Justice of the European Union on the above-mentioned borderline problems would be desirable.

The International Seed Federation[65] has created mediation and dispute resolution tools. Protocols have been drawn up which can be used when parties cannot agree on whether a variety is an essentially derived variety. These protocols set limit values for genetic similarity. If the fixed value is higher than the limit value, it is assumed that the variety is an essentially diverted variety and the burden of proof passes to the person who created the alleged essentially derived variety. Protocols have been agreed upon for perennial ryegrass, maize, rapeseed, cotton and lettuce.

4.2.2.6 Reflections on the development of essentially derived varieties

Although in many cases it is clear what is covered by the concept of essentially derived varieties, there are delimitation problems currently under discussion in the various UPOV committees. Among the participants in these discussions are those who argue that all mutations that come from one plant individual (mono-parental varieties) should be considered an essentially derived variety, no matter how different they are in terms of phenotypic characteristics. Others argue that only the mutations leading to limited phenotypic differences between the initial protected variety and an essentially derived variety can constitute an essentially derived variety within the meaning of the UPOV Convention. Depending on the conclusion, the consequences are different, not least for new varieties produced using a gene scissor, such as CRISPR/Cas9.

If all mutations that come from a plant individual (of a protected variety) are to be seen as an essentially derived variety, this means that the breeder of the essentially derived variety who has used a gene scissor *per se* cannot market his variety without the consent of the holder of the right of the initial variety. One advantage of such an approach would be that it would contribute to greater predictability of what is an essential derived variety for mutated varieties.

If, on the contrary, only the mutations leading to limited phenotypic differences between the initial protected variety and an essentially derived variety can constitute an essentially derived variety, it is important that criteria are established to determine what is meant by *limited differences*. However, setting general criteria is problematic from a technical point of view, as species are described under different protocols. To agree on universal and fair rules for all species (thousands) would be almost impossible in practice. In addition, opinions differ regarding establishing such quantitative differences. Some argue that it is up to the competent body (in most UPOV members a court and in some members an authority) to decide whether or not a variety is essentially derived on a case-by-case assessment. However, a case-by-case assessment without criteria introduces a certain degree of arbitrariness which does not contribute to the predictability that is so important for the undertakings operating in this field.

When comparing a protected variety (the initial variety) with a variety that is a mutation of the initial variety (the new variety), there may be significant differences in phenotypic characteristics without significantly changing the genetic setup. If only very restrictive changes in phenotypic characteristics are accepted in order to include the new variety within the concept of an essentially derived variety, a large number of varieties produced by genome editing, such as CRISP/Cas9, would fall outside the definition of an essentially derived variety. This means that the breeder of the new variety does not need to acquire authorization from the holder of the initial variety in order to commercialize the new variety.

Genome editors have an interest in using the best varieties, which are usually protected by plant variety rights, to change or add valuable characteristics that are in demand on the market. If such use can be carried out without the authorization of the holder of the initial variety, this may be unfair for the same reasons as the introduction of the concept of essentially derived varieties into the 1991 UPOV Convention (see above 4.2.2.1). It is expensive and takes a long time to breed new varieties through traditional methods, while mutation methods are often faster and (often) require lower investment.

However, there are those who argue that a broad interpretation of the concept of essentially derived varieties is not reasonable because there is a risk that those who wish to use new methods, such as gene editing, will be hindered by holders of the rights of initial varieties, either by refusing to grant an authorization or by claiming a remuneration so high that the commercialization of the new variety is not profitable, for example for start-ups with excellence in genome editing.

The question is whether this risk is imminent. Holders of the rights of initial varieties often have an interest in allowing the creator of an essentially derived plant variety to market the new variety for a reasonable remuneration. In most industries where intellectual property rights are used, it is common for market players to find solutions, often with technology transfer through licensing agreements, which provide mutual benefits to the parties involved. There seems to be few arguments in support of why such collaborations could not take place also in the plant breeding industry. In this context, it can be mentioned that genome editing of plants can lead to patents, which in turn means that plant breeders who wish to use patented plant material need authorization (see chapter 5.2 below).

In the light of the aforementioned ruling of the Court of Justice of the European Union, where gene editing was considered to be within the framework of the GMO acquis, the European Commission is currently reviewing the legislation on the use of gene editing for plant breeding (see further Chapter 7 below). If the legislator comes to a solution whereby companies will be able to use these practices in the EU, it is important that intellectual property rights

continue to provide an incentive for all plant breeders, regardless of the technology they use, to produce new plant varieties. The work within UPOV to adopt guidelines on what is to be regarded as an essentially derived variety is therefore very important.

4.3 Discoveries

One issue that often arises when intellectual property protection of plant varieties is discussed is whether plants detected in nature can be protected. In other words, should it be possible to acquire a plant variety right for a variety that is found in nature and thus not created by human efforts? This question was also raised by the Swedish Environmental Protection Agency in the proceedings for the Plant Variety Rights Act.[66] The Agency also called for an ethical discussion on the issue 'whether it is correct to provide an exclusive right to any anthropogenic form, any laboratory-created plant variety, which according to genetic expertise is deemed to arise spontaneously in nature with reasonable probability'.

These issues were also discussed at the Diplomatic Conference leading to the 1991 UPOV Convention. The 1991 text provides that a breeder who discovered a variety must also have developed it. The requirement for further development after discovery was introduced in order to clarify that anyone who only discovered a wild-growing plant variety cannot be considered a breeder. Since the text of the Convention requires a variety to be either bred or discovered and developed, it prevents anyone from obtaining exclusive rights to a variety that has only been discovered.

What is meant by "developed" can be discussed and some guidance may be found in UPOV documents. A document from 2002 states that development means propagation and selection.[67] The document distinguishes between an invention which may lead to a patent and a new variety. The discovery of a mutation is specifically indicated as an example of what can lead to protection.

Further, a document from 2013 states that the development of plant material into a variety is necessary in order for a breeder to be granted a plant variety right to a new variety. A person would not be entitled to protect an existing variety which was discovered and propagated *unchanged* by that person.[68]

To require that the characteristics of a discovered variety must be changed in order to be protected can, in my view, be problematic. If the discovered variety is propagated by an asexual method, which in principle results in the variety being propagated without changing, the variety would be excluded from the possibility of protection. Requiring that the characteristics of a discovered variety must be changed would also mean that many/all mutants could not be protected, which was not the intention of the legislator.

Another approach that can be taken from literature[69] is to look at the goal of further development, which is to produce a group of plants that meet the definition of a plant variety. From discovering a mutation in a greenhouse or in nature to having a plant variety that is distinct, uniform and stable can be quite demanding. There is therefore reason to argue that, in order to protect a discovered variety, it is sufficient that further development involves propagation and selection leading to a plant variety. For example, an identification of a colour mutant of an apple variety on a branch can give a new protected variety that is derived from the initial variety.

As regards the other issues raised by the Swedish Environmental Protection Agency, the bill states that it is clear in the text of the Convention that a person who has only discovered a wild-growing variety cannot be regarded as a breeder and that the 1991 text does not contain any exception for varieties that have been bred but which could have arisen naturally.[70]

4.4 Scope of plant variety rights

'Plant variety right' means that the holder is given the opportunity to prevent others from exploiting on a professional basis a plant variety or a collection of plants.

No one may, without the consent of the holder of the plant variety right, exploit a variety or other collection of plants covered by the plant variety right by:

1. produce or reproduce propagating material;
2. process propagating material for propagating purposes;
3. offer propagating material for sale;
4. sell or otherwise supply propagating material;
5. export propagating material from Sweden;
6. import propagating material into Sweden; or
7. stock propagating material for any of the purposes specified under 1 to 6.

Where the holder of the plant variety right has not had a reasonable opportunity to exercise his right in respect of certain propagating material, no person may, without his or her consent, use the variety by taking the measures referred to in paragraph 1 to 7 of the first subparagraph with *harvested material* obtained from that propagating material.

It is important to note that neither propagating material nor harvested material is defined in the Plant Variety Rights Act or the UPOV Convention. Article 5(3) of the Basic Regulation states that *variety constituents* (which correspond to the concept of propagating material) is a plant grouping that consists of entire plants or parts of plants as far as such parts are capable of producing entire plants. This means, in principle, that what is often considered as harvested material, such as a cut rose or a harvested potato, falls, in principle, within the definition of variety constituents, since a cut rose or a harvested potato is capable of creating new identical variety constituents. The same material can be used as seed or for consumption. The definition of propagating material and harvested material is regulated differently in different countries that have acceded to the UPOV Convention. The guidelines adopted by UPOV on propagating material[71] provide a non-exhaustive list of factors that UPOV members can take into account when defining what is meant by propagating material:

1. plant or part of plants used for the variety reproduction;
2. whether the material has been or may be used to propagate the variety;
3. whether the material is capable of producing entire plants of the variety;
4. whether there has been a custom/practice of using the material for propagating purposes or, as a result of new developments, there is a new custom/practice of using the material for that purpose;
5. the intention on the part of those concerned (producer, seller, supplier, buyer, recipient, user);
6. if, based on the nature and condition of the material and/or the form of its use, it can be determined that the material is "propagating material"; or
7. variety material where conditions and mode of its production meet the purpose of reproduction of new plants of the variety but not of final consumption.

The list is relatively straggling, which does not contribute to harmonizing the definition internationally. UPOV's guidelines on harvested material[72] also do not provide any guidance in this regard. A revision of the two guidelines is

ongoing and one of the crack points in the ongoing discussions is to highlight how to define material that from a technical perspective can be used either as propagating material or as harvested material.

Some breeders consider that the protection afforded is too weak and that both propagating material and harvested material must be protected directly.[73] In this context, breeders of perennial crops, such as fruit trees, consider it unreasonable that they can receive compensation only when the tree is sold for planting. The buyer of the tree may in many cases, throughout the life of the tree, harvest fruits without any obligation to pay compensation to the right holder. In the case of arable crops or vegetable seed, the problem is less because new seed needs to be obtained more regularly and the holder of the right can receive a more regular remuneration.

A first condition for the exploitation of harvested material to be covered by the exclusive right is that the material has been obtained by using propagating material of the protected variety *without authorization*. Furthermore, the breeder must not have had a *reasonable opportunity* to exercise his or her right in respect of propagating material used. The idea is that the right should cover harvested material only when it was not possible to invoke the right in relation to the propagating material. Accordingly, the breeder's right should be invoked at an early stage and remuneration be paid at the earliest possible stage in the production chain. The UPOV Guidelines on propagating material set out examples of what is meant by *'authorization'* and *'reasonable opportunity to exercise'*, but revision of the Guidelines is ongoing and changes and clarifications should not be excluded.

Under Article 14(3) of the UPOV Convention, Members may also extend protection to final products. "Final products" means products derived from harvested material (e.g. strawberry jam, apple juice, potato chips). Here too, it is a prerequisite that the breeder has not been able to assert his rights earlier in the production chain. The exclusive right may only apply to finished products if the breeder has not had a reasonable opportunity to exercise his right in respect of the harvested material. However, the protection of these products is optional for UPOV members to introduce. Sweden chose not to introduce such protection and refers mainly to the fact that the protection has already been extended to harvested material and to the importance of designing the national system in conformity with the EU plant variety right, which has not introduced protection for final products.[74] Article 14(4) of the Basic Regulation states that implementing rules may be adopted to ensure that the protection in specific cases applies to products obtained directly from material of the protected variety. However, such implementing rules have not been adopted. Few UPOV members have chosen to extend protection to end products.

4.5 Exemptions

The Plant Variety Right Act provides for exemptions from the exclusive rights, such as (1) acts done privately and for non-commercial purposes, (2) acts done for experimental purposes and (3) acts done for the purpose of breeding, or discovering and developing other varieties.[75] In addition, farmers are authorized to use for propagating purposes on their own holding, the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety, the so called Agricultural Exemption or the Farm Saved Seed exemption. Under the UPOV 1991 Convention, the first three exemptions mentioned above are mandatory whilst the agricultural exemption is optional. The agricultural exemption has been introduced in both Swedish and EU plant variety rights as well as in most countries that have acceded to the 1991 text of the Convention. The exemptions are dealt with below.

4.5.1 Exemptions for private and non-commercial uses

A plant variety may be used freely privately, if it is for non-commercial purposes, i.e. if the purposes are other than economic gain.

The Swedish bill states the example that if a person sells seed potatoes which he has grown in his home garden, the purpose should be considered commercial even if the activity itself does not constitute an economic activity. The act is therefore not covered by the exception, but the exclusive right applies.

The UPOV Guidelines[76] give the example that a variety propagated exclusively for use in a private garden (i.e. no material of the variety is supplied to others), is covered by the exception because the use is both private and for non-commercial purposes.

UPOV's FAQ[77] states that, "within the scope of the breeder's right exceptions provided under the UPOV Conventions, UPOV Contracting Parties have the flexibility to consider, where the legitimate interests of the breeders are not significantly affected, in the occasional case of propagating material of protected varieties allowing subsistence farmers to exchange this against other vital goods within the local community."

However, there are those who argue that intellectual property rights threaten human rights[78] and that the UPOV Convention is not compatible with the rights of farmers under the International Treaty of Plant Genetic Resources for Food and Agriculture (ITPGRFA).

UPOV's FAQ indicates that both the ITPGRFA and the UPOV Convention aim to support plant breeding activities and to encourage the development of new plant varieties. ITPGRFA does this by providing a system for facilitating access to plant genetic resources, while the UPOV Convention does so by establishing a system of plant variety rights. Where UPOV Members implement the two treaties, the relevant legislation dealing with these issues should be compatible and mutually supportive.

The organizations Oxfam, Euroseeds and Plantum took the initiative to carry out a study published in 2019 on how the mentioned exemption could be implemented in practice without defining the exact legal meaning of what was covered by the exemption.[79] This study has been presented to UPOV and a Working Party has been appointed within UPOV in order to examine whether it is appropriate to update UPOV's guidelines and/or FAQ.[80]

However, the scope of the exemption has not posed any problems in practice. From the meeting notes of the first meeting of the Working Party on 17 March 2022, it appears that there are no concrete examples of legal action against subsistence farmers, in developing countries that are members of UPOV, who have exchanged or sold small quantities of protected varieties.[81]

It is important that agriculture in developing countries is developed so that they become independent as far as possible from aid. This requires investments in a variety of areas, and plant breeding is one of them. Plant varieties must be created that are adapted to local conditions and climatic conditions. In many countries, public finances are not enough to finance the necessary investments. Intellectual property is one of many ways to finance sustainable breeding programs. When countries accede to the UPOV Convention, it is important to formulate the exceptions so that they take into account national circumstances while respecting the text of the Convention.

4.5.2 Exemptions for experiments

The use of a protected plant variety for experimental purposes is permitted without any restrictions.

4.5.3 Breeder's exemption

Of significant importance is the exemption whereby a protected plant variety may be used for the production of new plant varieties without the consent of the breeder (hereinafter referred to as the breeder's exemption). The varieties bred by using the protected variety may also be freely commercialized, unless they are considered to be essentially derived. Accordingly, a plant variety right does not exclude others from using the genetics of a protected plant variety. The exception is important and is sometimes referred to as a cornerstone of the UPOV Convention. It may seem strange that an exception to an intellectual property right is given such a prominent place. Without this exception, however, it is likely that the UPOV Convention would never been adopted, as many believe that access to genetic material, which originates from nature, should not be restricted. However, there are those who claim that the exemption is too extensive because a new variety that has taken time to produce and which is protected by plant variety rights can be used by competitors in their breeding programmes.

4.5.4 The Agricultural Exemption

The agricultural exception is a clear example of when an intellectual property right is restricted after a balance between the innovator's and other interests has taken place. Over time, farmers throughout the world have saved grain from a harvest and then used it as seed in the next season. There was, and still exists, in some countries a tradition of selling or exchanging part of the harvest with neighbouring farms, so-called neighbouring trade. The actual processing of the seed is sometimes carried out by the farmer and in other cases the farmer buys the service from others to carry out the processing.

As plant breeding developed and with that plant variety rights, holders of the rights argued that if farmers can reuse seeds and also freely sell it to others, the incentives for innovation disappear. It was argued that farmers who want access to the latest technology and the best varieties should pay a compensation, if they used farm saved seed of protected varieties. The breeders argued that if farmers were not prepared to pay for farm saved seed of protected varieties, they should not be entitled to use it. In such cases, farmers could use non-protected varieties. In Europe, there were, and still exists, a large number of varieties on the market that are not protected. Although the situation has changed since 1991, of the more than 23,800 agricultural varieties on the European common catalogue of varieties, which contain varieties that can be marketed in the EU, "only" about 9,300 were protected by the EU plant variety right at the beginning of 2022. There are therefore alternatives on the market, as was also the case when the 1991 UPOV Convention was adopted.

These were some arguments in favour of introducing a derogation in Article 14 of the 1991 UPOV Convention to the effect that, within reasonable limits and subject to the *legitimate interests of the breeder*, the Contracting Parties may restrict plant variety rights in order to allow farmers to use their harvest products for propagation purposes. The text of the Convention *"within reasonable limits"* and *"provided that the legitimate interests of the breeder are met"* allows some room for implementation in the legislation of UPOV Members. Guidelines on exemptions in the UPOV Convention provide examples of how the agricultural exemption can be implemented.[82]

However, as a condition, the material must have been harvested after sowing or planting on the farmer's land and the use for further propagation should also take place there. The exemption in the Convention is voluntary. During the Diplomatic Conference, a recommendation was adopted that the agricultural derogation should not be used for crops where there was not already a tradition of saving seeds.[83]

In the EU, the agricultural exemption was introduced in the Basic Regulation[84] and the Commission also adopted a special regulation (Regulation 1768/95).[85] The conditions for this exception, which, under Article 14(3) of the Basic Regulation, were intended to protect the *legitimate interests of breeders and* farmers, essentially confer on farmers the right to produce or reproduce on their own land propagating material and to process (self or commissioned to other) propagating material without the authorization of the holder of the right. However, it does not include the right to offer propagating material for sale, sell or otherwise provide propagating material of the protected variety. The farmer must pay the holder of the right a reasonable remuneration which shall be significantly lower than the amount required for a licence for the production of propagating material of the same variety in the same area. Small farmers do not have to pay compensation to the holder. Small farmers include those who do not use an area greater than the area required to produce 92 tonnes of cereals per year or 185 tonnes of potatoes per year.[86] The exemption applies to a fixed number of arable crops[87] but not hybrid varieties and synthetic varieties. Commission Regulation 1768/95 essentially regulates (1) the fair remuneration of the holder of the holder of the right from farmers for the use of farm saved seed, (2) the provision of information to ensure the identification of the product of the harvest left for processing and obtained after processing, and (3) verification of compliance with the derogation provisions.

The rules on farm saved seeds at EU level apply only to plant varieties protected by EU plant variety rights. However, most EU Member States have introduced legislation to ensure that the same or similar rules also apply to varieties protected by national plant variety rights.

Prior to the 1997 Plant Variety Rights Act, Sweden allowed a certain neighbouring trade between farmers.[88] Although the new rules introduced in the Plant Variety Rights Act in 1997 provided for an exception, the result was that the use/sales of farm saved seeds was restricted compared to the previous rules. The agricultural exemption introduced in 1997 cannot be regarded as covering neighbouring trade since the provision concerns only the right of a farmer to use on his own land the seed produced there.

The Swedish legislature stated in the bill that the Basic Regulation, with a distribution of rights and obligations between right holders and farmers, in many respects provides a complex, bureaucratic and difficult system.[89] Using terms such as "reasonable remuneration" and "significantly lower" does not make the text clear and exempting small farmers does not simplify the implementation of the exemption. On the other hand, creating a special Swedish system would possibly be even more problematic. The legislator therefore chose to regulate the agricultural exemption in such a way that the system introduced in the EU would also apply for national plant variety rights protected under Swedish law. Thus, it follows from Chapter 2, Section 5 of the Plant Variety Rights Act that the derogations from the exclusive right provided for in Article 14 of the Basic Regulation and in the Commission implementing rules shall also apply to a plant variety protected by a Swedish plant variety right. Unfortunately, the legislator's concerns have been realized and the provisions on the exemption have been difficult to implement in many Member States and a number of legal disputes have been brought before the EU Court on access to relevant information and the applicable fees.[90]

As regards the collection of compensation for the use of farm saved seeds, it is up to the holder of the plant variety right to choose how to do so. In several EU Member States, plant breeders have come together in an association or company form, mandated to represent the interests of breeders for various tasks, such as collecting royalties for the use of farm saved seeds in that Member State. Some parallels may be drawn to STIM which, on behalf of copyright holders, collects royalties for copyright-protected music in Sweden.

"To pay a plant variety right fee is to invest in the future. New varieties are key to the development of Swedish agriculture."

The above quote is found on the Swedish Seed Trade Association's (SVUF) website. SVUF is a trade association for Swedish plant breeding and seed companies, which was established in 1997, the same year as the Plant Variety Rights Act (1997:306) and a couple of years after the entry into force of the Basic Regulation. SVUF represents the common interests of its members in dialogues with other stakeholders at both national and international level. SVUF is a member of Euroseeds and the International Seed Federation.

One of SVUF's main tasks is to collect compensation for farm saved seed of protected varieties which is then distributed to the respective variety owner or variety representative. In this respect, SVUF collaborates with representatives of farmers and negotiates and signs agreements with the Federation of Swedish Farmers (LRF), the Swedish Grain Growers, the Swedish Seed and Oilseed Growers and the Potato Growers regarding the level of fees when using farm saved seed of protected varieties.

As mentioned above, "small" farmers are exempt from the obligation to report their use of farm saved seeds. After discussions with the LRF and the Ministry when the collection of remuneration was set up, an agreement was reached to "translate" the EU's limits of a total harvest of 92 tonnes of cereals (185 tonnes for potatoes) to be considered as a small farmer into a field area. The aim was to simplify the reporting of data from growers and the follow-up. Accordingly, in Sweden, a total area for cereals, grain legumes and oilseeds of 23.7 ha is the limit to be considered as a small agricultural unit. For potato growers, a reporting obligation applies if the cultivated potato area is equal to or greater than 4.2 ha. This applies even if the total cultivated area of the property is less than 23.7 ha. If the total area of cultivation of the crops covered by the collection of levies on a farm is below this threshold, the farmer is exempt from reporting his seed use. Sweden still has a fairly large proportion of holdings below this threshold, especially in the northern part of the country, but the farms that are required to report include, after all, almost 80 % of the arable area in Sweden and more than 90 % of the cultivated area of the crops concerned.

Every year SVUF receives information from the Swedish Board of Agriculture on which holdings that are subject to the duty of filing a declaration. All farms that are above the mentioned limits are contacted annually by SVUF with an invitation to declare their use, preferably through the association's website.

According to the applicable legislation, the licence fee levied on farm saved seed shall be lower than the fee for certified seed. According to the agreements in force between SVUF and the above-mentioned organizations, the fee is currently set at 70 % of what is paid for certified seed. Information on applicable fees per variety can be found on SVUF's website. The fees help funding breeding projects with the aim of meeting the Swedish quality requirements and with optimal productivity under Swedish cultivation and environmental conditions.

In the Nordic countries, the growing conditions are specific with many hours of daylight during the growing period. New varieties must therefore be adapted to these conditions and climate in order for agriculture to remain competitive. Major investments in research and plant breeding are required to develop new varieties. These are in essence private investments financed by licences from seed producers on sales of certified cereal seed and payments for the use of farm saved seed. Accordingly, anyone who buys certified seed or pays for the use of farm saved seed contributes to financing plant breeding. According to SVUF, this is important in order to strengthen Swedish plant breeding, which increases the competitiveness of the individual farmer and in Swedish crop production.[91] For hybrid crops (maize, rapeseed, rye and sugar beet) as well as forages, continued investments are financed by the commercial profits that the breeder can make when selling seeds either directly to individual farmers or to a distributor.

According to SVUF's website, the development of Swedish cereal production has been very positive. Since the 1950s, yields have doubled per cultivated hectare. Half of the increase can be attributed to new varieties with good adaptability, varying earliness, good resistance and good straw strength. The second half of the increase is due to better fertilizers, plant protection, more modern cultivation methods and discontinued use of less productive land. In figures, breeding has contributed to an average increase of 1,500 kilograms per hectare. The cost of processing, via the fee, is approximately SEK 80-100 (approx. EURO 9) per hectare for those who choose to use farm saved seed. The collection is effective and SVUF raises just over SEK 16 million each year (approx. EURO 1,5 million).

In general terms, there is a large gap in the functioning of collection systems in the EU. In practice, the collection works relatively well in the Nordic countries, the Netherlands and the former Member State UK, while no collection takes place at all in some EU Member States.

One of the main reasons why the system in Sweden works well is the cooperation between SVUF, LRF and various growers' organizations. Cooperation is very important for understanding and support from national growers' organizations and for a reporting structure to work optimally. The organizations understand that without the income from farm saved seed —the use of farm saved seed in certain crops amounts to 30 percent — companies' motivation to invest in new plant breeding projects would be significantly reduced. The organizations disseminate this message in their own information channels and also highlight the fairness aspect — that is, if a grower cheats on reporting, it means freeriding on other growers.

Similar collaborations are found in the UK and the Netherlands, while in some other European countries such as Poland and Germany, it is significantly more difficult for breeders' associations and farmers' associations to find common solutions on reporting systems. In Finland, information on the use of farm saved seed is part of the growers' reporting obligation when applying for agricultural subsidies. This information is shared with breeders which has proven to be particularly effective.

The CPVO/EUIPO study[92] concludes that the collection of fees for the use of farm saved seed is not so effective following decisions of the Court of Justice of the European Union on farmers' obligations to report. Another finding in the mentioned study is that there is still a lack of data and studies on the effect of the agricultural exemption since it was implemented. A study on how the agricultural exemption has been implemented in the EU would therefore be very useful and could help the Commission in its work to find the right instruments to ensure that the rules are applied equally within the EU.

There are some common denominators in the countries where the collection works well. Firstly, and most importantly, there is an active and regular dialogue between representatives of farmers, breeders and authorities. It is important that those who pay know why they pay and that those who collect can show that new varieties are to the benefit of those who pay, the farmers/growers. It is also important that the system is fair in the sense that everyone participates and that fraud is prosecuted. Access to relevant information on farm saved seed is important and cooperation with authorities has in many cases proved crucial. A simple declaration system with reasonable fee levels also contributes to good results.

4.5.5 Exhaustion of exclusive rights

Exhaustion of exclusive rights is a general principle applicable to intellectual property rights, although its application may vary. Exhaustion means that after a product covered by an intellectual property right has been sold by the holder of the right or by another party with the holder's consent, the right is said to be exhausted/consumed. For example, if an inventor obtains a patent for a new type of padlock, the holder of the right may prohibit other companies from

manufacturing and selling this type of padlock, but not prohibiting customers who have purchased this padlock from the holder of the right, or with his permission, from selling the padlock on to third parties.

Exhaustion therefore means that the exclusive right does not extend to the exploitation of protected plant material put on the market by the holder or with his consent.[93]

For the purposes of the Swedish legislation, the market refers to the European Economic Area. EU rules on exhaustion are drafted in accordance with the text of the UPOV Convention. In principle, exhaustion only applies to the material sold. If the plant material is then propagated, the exclusive right is considered to re-enter.[94] The provisions on consumption may be tricky to apply in practice, especially in international trade. However, this report does not elaborate on these issues.

4.6 Compulsory licenses

In a situation where the marketing of a protected variety is in the public interest and the holder of the right does not authorize the use of the variety, a compulsory licence may be granted under certain conditions. The general interest underlying this provision is primarily the public's need for food and other products derived from plant varieties.

The Plant Variety Rights Act specifies that if propagating material of a protected variety is not offered to the market on reasonable terms despite a public interest that the variety is put on the market, and if the holder of the plant variety right cannot provide a valid reason, any person who wishes to use the protected plant variety may obtain a compulsory licence to do so. A compulsory licence also includes the right to receive from the holder of the plant variety right propagating material of the variety under reasonable terms. The provision can only be applied in cases where public interests are at stake and is not intended to resolve disputes in order to satisfy individual interests. In the Bill to the Plant Variety Rights Act it is explained that the rules on compulsory licenses shall be regarded as supplementing competition law and contract law on unfair contracts.[95]

The Basic Regulation contains similar rules.[96] The CPVO has not granted a compulsory licence but has taken one decision rejecting an application for a compulsory licence for a variety of blackcurrants ('Ben Starav').[97] In the decision it is explained that it is important that intellectual property rights provide an incentive for innovation and that a right can only be set aside if it is in the public interest. The Decision draws a parallel with competition law and states that if there are inter-changeable products on the market, there is less need for competition authorities to intervene. The same reasoning can be considered to apply to the assessment of the public interest under the Basic Regulation. The more exchangeable varieties available on the market, the less public interest in granting a compulsory licence. In the 'Ben Starav' case, a competitor requested a compulsory licence, and it was not contested that it was in the competitor's individual interest that a licence be granted. However, the CPVO did not find it established that it was also in the public interest to grant the compulsory licence and therefore refused the request.

Looking at the present market for plant varieties in the EU, it does not appear that the instrument of compulsory licenses will be used frequently, as for most species there are a number of inter-changeable varieties available on the market. At the same time, we see that health crises and wars affect the availability of propagating material in our neighbourhood and, if access is limited or stopped, the situation can change rapidly.

The possibility of obtaining a compulsory cross-licence has been introduced in the Patents Act and the Plant Variety Rights Act as a result of the introduction of the Biotechnology Directive. The condition of such a licence is that the invention constitutes a significant technical progress of considerable economic interest compared with the protected plant variety.

Thus, it is apparent from the Plant Variety Rights Act that a compulsory licence may be obtained for holders of a patent for a biotechnological invention who cannot exploit the patent without infringing a plant variety right. In order

to obtain a compulsory licence to use the plant variety protected by a plant variety right, the patent holder must demonstrate that the invention constitutes a significant technical progress of considerable economic interest compared with the protected plant variety vis-à-vis the protected plant variety.[98] If a compulsory license is granted to a holder of a plant variety to use a patent for a biotechnological invention, the patent holder shall be entitled to a cross-licence on reasonable terms to use the protected variety.[99] Similar provisions were introduced in the EU Basic Regulation pursuant to the Biotechnology Directive.[100] If the CPVO grants such a licence, it shall cover the same territory as the patent in question. The CPVO has received no application to grant a compulsory licence under that provision.

4.7 Protection time

The term of protection in the Plant Variety Rights Act is set at 25 years for most species and 30 years for potatoes, trees and vines. The term of protection was the same under the EU Basic Regulation when the Plant Variety Rights Act entered into force. However, in 2021, the term of protection in the EU was extended to 30 years for plant varieties of the species *Asparagus officinalis* L. (asparagus) and species groups of flower bulbs, woody berry plants and woody ornamental plants.[101]

The reason for the extension was technical difficulties in breeding, due to a complex genetic background or the slow or technically complex reproduction of the species in question, which requires specific investments in research and development activities, that is to say, the same as the reason why potatoes, trees and vines have a longer term of protection. Once the protection of plant variety rights is granted for the species in question, it takes several years to propagate the plants and to build up a stock that is large enough to provide a fair income. The period during which the holder of the plant variety right may receive income on the basis of that protection is therefore limited. These investments require more time to become profitable than for most other species, such as arable crops, which often have a shorter life cycle and a larger and wider circle of customers.[102]

The plant variety right applies from the date on which the application for protection was granted and can be maintained for 25 years and 30 years respectively from 1 January of the year following the date on which the protection decision became final. The Basic Regulation contains similar provisions. The maintenance of the plant variety right requires the holder to pay annual fees. The minimum period of protection laid down in the 1991 UPOV Convention is 20 years, but for trees and vines a minimum term of protection of 25 years is provided for. The protection in Sweden and the EU is therefore longer.

Under the Basic Regulation (Article 95), the holder may require reasonable compensation from any person who has, in the time between publication of the application for an EU plant variety right and grant thereof, effected an act that he would be prohibited from performing subsequent thereto. This provision derives from Article 13 of the 1991 UPOV Convention and similar provisions are included in the Plant Variety Rights Act (Chapter 9, 9).

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30. Union Internationale pour la Protection des obtentions Végétales, *https://www.upov.int/portal/index.html.en*
31. L'Organisation Africaine de la Propriété Intellectuelle, *http://oapi.int/index.php/fr/*
32. The membership number is shown in a list dated 3 November 2021, *https://www.upov.int/edocs/pubdocs/fr/upov_pub_423.pdf*
33. *https://www.upov.int/upovprisma/en/index.html*
34. The Plant Variety Rights Act (1997:306).
35. Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, OJ L 227, 1.9.1994, p. 1.
36. Article 2 of the Basic Regulation.
37. Article 92 of the Basic Regulation.
38. Chapter 3, Section 7 of the Plant Variety Rights Act (1997:306) and Article 92 of the Basic Regulation.
39. See the preamble to the Basic Regulation.

40. Greece, Luxembourg, Cyprus and Malta are members of the EU but not UPOV.
41. *https://upovlex.upov.int/en/convention*
42. Chapter 1.03, Wurtenberger, Paul van der Kooij, Bart Kiewiet, Martin Ekvad, *European Union Plant Variety Protection*, Third edition, 2021, Oxford University Press.
43. Bill 1966:40, page 69.
44. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
45. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, 2001.
46. Chapter 1, Section 3 of the Plant Variety Rights Act (1997:306), see also Article 5 of the Basic Regulation and Article 1 of the UPOV Convention 1991. A cross reference is made in Article 2.3 in the Biotech Directive to Article 5 of the Basic Regulation
47. Chapter 3, Section 1 of the Plant Variety Rights Act (1997:306).
48. Chapter 3, Section 3 of the Plant Variety Rights Act (1997:306), Article 6 and 7 of the Basic Regulation and, what is meant by "common knowledge" is explained in Chapter 3, Section 3 of the Plant Variety Rights Act (1997:306), see also UPOV Explanatory Notes on Common Knowledge.

49 Chapter 4, Section 4 of the Plant Variety Rights Act (1997:306), see also Article 6 and 8 of the Basic Regulation and Article 8 of the UPOV Convention 1991.

50. Chapter 4, Section 5 of the Plant Variety Rights Act (1997:306), see also Article 6 and 9 of the Basic Regulation and Article 9 of the UPOV Convention 1991.
51. Chapter 3, Section 1 and 2 of the Plant Variety Rights Act (1997:306), Article 10 of the Basic Regulation.
52. Chapter 4 of the Plant Variety Rights Act (1997:306), Article 6 and 63 of the Basic Regulation and Guidelines on variety denominations adopted by the Administrative Council of the CPVO, cpvo.europa.eu.
53. For a detailed insight into variety denominations, see article by Ángela H. Martínez López, *https://cpvo.europa.eu/, The Variety Denomination Committee of the Community (EU) Plant Variety Office and Its Role as Custodians of the Designation of Plant Varieties,* and an essay by the same author *The Interface between Trade Marks and Plant Variety Denominations: Towards Clearer Coexistence at International and EU Level.*
54. Chapter 2, Section 1 of the Plant Variety Rights Act (1997:306).
55. Chapter 3, Section 1, point 2, of the Plant Variety Rights Act (1997:306).
56. Bill/Proposition. 1996/97:128, p. 60 and Records of the Diplomatic Conference for the revision of the International Convention for the Protection of New Varieties of Plants, p. 165-166, 172-180.
57. Records of the Diplomatic Conference for the revision of the International Convention for the Protection of New Varieties of Plants, p. 165–166, 172–180.
58. Chapter 2, Section 1 of the Plant Variety Rights Act (1997:306).
59. Bill/Proposition 1996/97:128, page 113.
60. Chapter 5, Section 2 of the Plant Variety Rights Act (1997:306), Prop. 1996/97:128, page 112.
61. This Resolution was published as "Final Draft" in document DC/91/140 (see Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, UPOV Publication No. 346 (E) "Further instruments adopted by the Conference", page 63.

62 IOM/6/2, 17 August 1992.

63 Article 7 UPOV 1991 Convention, Chapter 3, Section 1(2) of the Plant Variety Rights Act, Article 7 Basic Regulation.

64. Article 99 and 87(2)(h) of the Basic Regulation and Articles 78(1)(d) and 78(2)(b) of Commission Regulation (EC) No 874/2009 of 17 September 2009 laying down detailed rules for the application of Council Regulation (EC) No 2100/94 as regards proceedings before the Community Plant Variety Office.
65. *www.worldseed.org*
66. Bill/Proposition. 1996/97:128, p. 79.
67. C (Extr.)/19/2/Rev, 9 August 2002, The Notion of Breeder and Common Knowledge.
68. Paragraph 9, Explanatory notes on the definition of breeder under the 1991 act of the UPOV Convention, UPOV/EXN/BRD/1, 24 October 2013.
69. Chapter 3.06, Gert Wurtenberger, Paul van der Kooij, Bart Kiewiet, Martin Ekvad, *European Union Plant Variety Protection*, Third edition (2021), Oxford University Press.
70. Bill/Proposition 1996/97:128, p. 79.
71. Explanatory Notes on Propagating Material under the UPOV Convention, UPOV/EXN/PPM/1, 6 April 2017.
72. Explanatory Notes on Acts in Respect of Harvested Material under the 1991 Act of the UPOV Convention, UPOV/EXN/HRV/1, 24 October 2013.

73. CIOPORA Position on The Scope of the Right as approved by its Annual General Meeting on 2 April 2014 in The Hague, NL.
74. Prop. 1996/97:128 pages 88-90, see also page 59.
75. Chapter 2 Section 3 of the Plant Variety Rights Act (1997:306).
76. UPOV Explanatory Notes on Exceptions to the Breeder's Right under the 1991 act of the UPOV Convention, October 22, 2009, UPOV/EXN/EXC/1.
77. *https://www.upov.int/about/en/faq.html*
78. United Nations, Human Rights, Report of the Special Rapporteur on the Right to Food, Michael Fakhri, paragraph 96.
79. https://euroseeds.eu/news/promoting-seed-choice-for-smallholder-farmers/
80. Working Group on Guidance Concerning Smallholder Farmers in Relationship to Private and Non-Commercial Use.
81. WG-SHF/1/4, *https://www.upov.int/meetings/en/doc_details.jsp?meeting_id=67775&doc_id=574743*
82. UPOV/EXN/EXC/1 October 22, 2009, Explanatory Notes on Exceptions to the Breeder's Right under the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV Convention).
83. Doc No DC/91/139, UPOV, Geneva, 19 March 1991, Records, p 63.
84. Article 14 of the Basic Regulation.
85. Commission Regulation (EC) No 1768/95 of 24 July 1995 laying down detailed rules for implementing the agricultural derogation provided for in Article 14(3) of Council Regulation (EC) No 2100/94 on Community plant variety rights.
86. Article 14(3) of the Basic Regulation and Article 7(3) of Commission Regulation (EC) No 1768/95 of 24 July 1995 laying down implementing measures for the agricultural derogation provided for in Article 14(3) of Council Regulation (EC) No 2100/94 on Community plant variety rights.
87. Fodder plants: *Cicer arietinum* L. – Chickpea milkvetch, *Lupinus luteus* L. – Yellow lupin, *Medicago sativa* L. – Lucerne, *Pisum sativum* L. *(partim)* – Field pea, *Trifolium alexandrinum* L. – Berseem/Egyptian clover, *Trifolium resupinatum* L. – Persian clover, *Vicia faba* L. - Field bean, *Vicia sativa* L. – Common vetch and, in the case of Portugal, *Lolium multiflorum* Lam. – Italian ryegrass. Cereals: *Avena sativa* L. – Oats, *Hordeum vulgare* L. – Barley, *Oryza sativa* L. – Rice, *Phalaris canariensis* L. – Canary grass, *Secale cereale* L. – Rye, *X Triticosecale* Wittm. – Triticale, *Triticium aestivum* L. *emend.* Fiori et Paol. – Wheat, *Triticum durum* Desf. - Durum wheat, *Triticum spelta* L. - Spelt wheat. Potatoes: *Solanum tuberosum* L. – Potatoes Oil and fibre plants: *Brassica napus* L. *(partim)* – Swede rape, *Brassica rapa* L. *(partim)* – Turnip rape, *Linum usitatissimum* L. – linseed with the exclusion of flax.
88. Prop. 1996/97:128, pp. 90-94.
89. Prop. 1996/97:128, page 92.
90. C-305/00, Schulin, EU:C:2003:218; C-336/02, Brangewitz, EU:C:2004:622; C-7/05, C-8/05, C-9/05 *Saatgut-Treuhandverwaltung v. The heirs of Dieter Deppe*, EU:C:2006:376, C-239/18, *Saatgut-Treuhandverwaltung v Freistaat Thüringen*, EU:C:2019:869.
91. See SVUF's website, *www.svuf.se*
92. Chapter 2.4.2, EUIPO and CPVO Study, Impact of the Community Plant Variety Rights System on the EU Economy and the Environment, April 2022.
93. Chapter 4, Section 2, Plant Variety Rights Act, Article 16 UPOV Convention.
94. Bill/Proposition 1996/97:128, p. 62, 69, 116.
95. Bill/Proposition 1996/97:128, page 126.
96. Article 29 Council Regulation 2100/94 and Article 41 Commission Regulation (EC) No 874/2009.
97. Community Plant Variety Office, Decision (No NCL001), 28 March 2018.
98. Chapter 7, Section 3a, first paragraph, of the Plant Variety Rights Act.
99. Chapter 7, Section 3a, second paragraph of the Plant Variety Rights Act.
100. Article 29(5a) of the Basic Regulation.
101. Regulation (EU) 2021/1873 of the European Parliament and of the Council of 20 October 2021 extending the period of validity of a Community plant variety right for plant varieties of the species *Asparagus officinalis* L. and the species groups of flower bulbs, ligneous berry plants and woody ornamental plants.
102. See the introduction to Regulation (EU) 2021/1873 of the European Parliament and of the Council.

5. Patents for plant-related inventions

5.1 Introduction

The basic idea of the patent system is to stimulate technological development. Patents grant inventors a temporary exclusive right in exchange for publication of the invention. The new technology becomes accessible to all and thus provides opportunities for further research and further development of the technology. The exclusive right allows the patent holder to prevent competitors from copying the patented method or product. In this way, the patent can help to give a head start on the market. The proprietor may also choose to sell or license the patent so that others can manufacture and sell the invention.

The historical development of patents is quite diverse, but it can be noted that more modern patent legislation took shape in Europe and America at the end of the 18th century. The first Swedish Patent Act dates from 28 April 1819. The first Convention for the International Protection of Industrial Property (patents, trademarks and designs) was concluded in Paris on 20 March 1883. Sweden-Norway joined on 26 June 1885. The intention here is not to review the history of patents, but it can be concluded that the patent law was designed much earlier than plant variety rights. The current Patent Act[103] is largely based on a Nordic legislative reform in 1967. Sweden acceded to the European Patent Convention in 1978 (EPC). The TRIPS Agreement mentioned in Chapter 4 is also important for the development of patents.

As regards intellectual property protection for biotechnological inventions, Swedish legislation was substantially updated in May 2004 when the Swedish rules were aligned with the EU Biotechnology Directive. The aim of the Directive was to create uniform rules on what is patentable in biotechnology in Europe. It may seem strange that EU Member States adopted rules on patents for biotechnological inventions, even though patent law in the EU is otherwise not regulated. However, the introduction of the Directive states that biotechnology and genetic engineering play an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development. In particular, in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable. An effective and harmonized protection in all Member States was considered essential in order to maintain and encourage investment in biotechnology.[104] The introduction of the Biotechnology Directive also states that account should be taken of the potential for biotechnology for the environment and in particular its use in order to develop agricultural methods that are less polluting and more economical in their use of land. It was considered appropriate to encourage research and the implementation of such procedures through the patent system.[105] During the discussions on the Directive, various questions on ethical aspects were raised. Therefore, the Directive included an indicative list of inventions excluded from patentability, such as practices that violate the production of hybrid creatures from germ cells or totipotent cells (undifferentiated stem cells) from humans and animals.[106] The Patent and Registration Office (PRV) processes patent applications and grants patents in Sweden. The European Patent Office (EPO) grants European patents in the 38 Contracting States to the EPC and several other States that have concluded cooperation agreements with the EPO.

Some EPO practices will be described below, which is why a brief account follows on the bodies involved. Decisions on patent applications are taken at administrator level. Decisions of the EPO can be appealed to two different appeal boards depending on whether the decision concerns essentially procedural matters (Legal Board of Appeal) or decisions rejecting a patent application or an appeal concerning opposition proceedings (Technical Board of Appeal, TBA). The

Enlarged Board of Appeal (EBA) gives its views on questions addressed to EBA by the mentioned Boards of Appeal or the President of the EPO.[107] The members of the Boards of Appeal and EBA are appointed by the EPO Administrative Council on a proposal from the EPO President.

A European patent granted by the EPO must however be validated and maintained in each country covered by the patent application. In a patent application to the EPO, the applicant must indicate one or more Contracting States for which the applicant wishes the EPO to grant the patent. Thus, the EPO does not decide on a unitary patent in all Contracting States, but on a package of national patents. With the centrality of the application process and the examination, this means a very effective system for those in need of patent protection in all or a number of European countries. Patents granted by the EPO can be challenged centrally before the EPO through opposition proceedings. The system does not fall within the framework of the EU acquis and cooperation, although all EU Member States have acceded to the EPC.

As the EPO procedure is followed by the validation and enforcement of patents in each country, there are different national translation and fee payment requirements. In addition, a dispute over a European patent can be heard by courts in different countries, with the risk of different outcomes in such courts despite the fact that the patent claims are the same. This is often perceived as expensive, complicated and legally insecure. For decades, work has been ongoing to create an EU patent. When it became clear that EU Member States could not agree, another solution, with the EPO as a partner, has been created, namely the *Unitary Patent system.* Only EU Member States can participate in this scheme.

The system has not yet entered into force, but when the unitary patent protection is introduced, as is likely to happen in spring 2023, an application may lead to a unitary patent with effect in all EU Member States that participate in the cooperation.

The EPO will grant these patents. At the same time, the Agreement of the Unitary Patent Court[108] ('the Court Agreement') establishes Courts for disputes over European patents. The Court Agreement allows the contracting Member States to choose to establish a local division or to join a regional division with one or more Member States. An agreement on a Nordic-Baltic Regional Division of the Unitary Patent Court has been negotiated to establish such a division in Stockholm by Sweden, Estonia, Latvia and Lithuania. Finland and Denmark have decided, following negotiations, not to participate in the Nordic-Baltic Division, but the wording of the agreement is such that Finland and Denmark will be able to join later, should they reconsider their decisions.

The two EU Regulations establishing the Unified Patent System[109] entered into force on 20 January 2013, but will only apply from the date of entry into force of the Court Agreement, i.e. the first day of the fourth month following the deposit of the 13rd instrument of ratification or accession (provided that the three Member States where the highest number of European patents took effect in 2012 are included in these 13 States). Due to delays in national procedures, the entry into force has been delayed but it seems likely that the system will be in place in 2023.

The Swedish government expects cost savings, less bureaucracy and increased legal certainty for users.[110] In addition, innovation, growth, jobs and competitiveness are encouraged and the development and deployment of green technologies is stimulated. However, the possibility of obtaining a European patent under the EPC with effect in each country remains.

Since 1978 it has also been possible, through international cooperation, to implement a so-called PCT (Patent Cooperation Treaty) application, which can then be converted into a national/regional patent application. WIPO (World Intellectual Property Organization) administers PCT, which is an international agreement with more than 150 member states that, through a single patent application in one language, receives an international filing date. This means that the application is considered to be submitted in all PCT member states on that date. A PCT application

itself does not lead to a patent, but to a novelty review as well as a preliminary assessment of patentability. The novelty review and preliminary assessment are carried out by the applicant's chosen PCT authority. A few patent authorities equipped with the necessary resources are designated as PCT authorities, including PRV in Sweden.

5.2 What can be protected by patents?

5.2.1 What inventions can be protected?

As regards what can and cannot be patented in respect of plant related inventions, the EPO has through the years established jurisprudence, which are also codified in the Biotechnology Directive and in the EPO implementing rules. Patent attorneys have been innovative when they have written patent claims and they have appealed decisions to test what is patentable. As shown in this report, important decisions have been taken which have contributed to increased predictability. There is a lot of research on characteristics that make plants resistant to, for example, pathogenic bacteria, fungi, viruses and insects, and patents are granted regularly for this type of invention in Europe. As new technologies develop and the appetite for patent protection increases, it can be assumed that case law will develop and further develop the boundaries of patentability.

Patents can be obtained for an invention that can be *used industrially*. The invention must be *new* and there needs to be an *inventive step*. Inventive step means that the invention should differ substantially from everything that is known. 18 months after filing, an application becomes public and is made available in the Swedish patent database. A patent application may also be withdrawn by the applicant within this time limit and then remains secret. The patent claims are not dealt with extensively in this report. Focus is on the types of plant related inventions that can be protected.

In principle, patent protection must be available in all technical fields.[111] The law is, in principle, designed in such a way that, if a technical field is not excluded, inventions in the field can be patented. The first paragraph of the Patent Act contains a number of exceptions indicating which technical areas are not patentable.

Biotechnological inventions can be patented. Biotechnology is a collective term for technical applications of biological processes in microorganisms, plants or animals. Biotechnology is mainly used in the food industry, agriculture and medicine. This report is limited to what can be patented and what cannot be patented in respect of plants, plant varieties and genetic engineering of plants.

Chapter 1, Section 1a of the Patents Act essentially states that a patent may be granted on an invention relating to a microbiological procedure or a microbiological product. 'Microbiological procedure' means a procedure carried out on microbiological material or by which such material is used or produced.

A biological material isolated from its natural environment, or produced by a technical procedure, may be the subject of an invention even if it is already present in nature. Biological material includes material that contains genetic information and which can reproduce itself or can be reproduced in a biological system.

According to EPO case-law, the possibility of patenting microbiological procedures does not mean that specific plant varieties produced by such practices are patentable.[112] In view of the fact that plant varieties cannot be granted patents, see exceptions below.

A microbiological procedure covers not only procedures exploiting micro-organisms — such as viruses, plasmids, non-differentiated plant and animal cells (e.g. cell lines), protozoa (animals) and single-cell algae — but also procedures for the production or isolation of microorganisms, such as genetic engineering procedures. The EPO guidelines equate genetic engineering procedures with microbiological procedures.[113] Accordingly, genetic procedures and their subject-matter are patentable.

5.2.2 Exemptions to what can be protected by patent

5.2.2.1 Plant Varieties

Chapter 1, Section 1a of the Patents Act expressly states that patents may not be granted on plant varieties or animal breeds.[114] However, a patent may be granted on an invention relating to plants or animals, if the feasibility of the invention is not technically limited to a particular plant variety or animal breed. The same paragraph refers to Chapter 1, Section 3 of the Plant Variety Rights Act which contains the definition of a plant variety. Accordingly, the definition of a plant variety is the same for the purpose of plant variety rights and patents. In this report, patents on animal breeds will not be dealt with.

The main reason behind the design of the exception for plant varieties is that they are instead protected under the plant variety right system. Plant variety rights and patent law cover different areas. The plant variety right protects specific varieties, whilst patent law protects technical applications that are not limited to one or more specific varieties.

The fact that a patent may be granted on an invention relating to plants, where the feasibility of the invention is not technically limited to a particular plant variety, has been the subject of decisions before the EPO. The boundaries of what is a plant and what is a plant variety were dealt with by the EPO's Enlarged Board of Appeal (EBA, the highest decision-making body of the EPO) in the Transgenicplant/Novartis decision.[115] The patent claim concerned transgenic plants and their production methods. The question was whether the result of the invention constituted a plant variety and therefore was not patentable. The EBA decided that derogations should be interpreted restrictively and ruled that the result was not a plant variety because the invention had a more general use. It follows, for example, that a gene that gives a plant a certain property and which can be introduced into several plant varieties can be patented.

If the patent relates to a technical method of producing a plant variety, but does not include the variety itself, a method patent may in principle be granted. Hybrid varieties, which are produced by crossing lines, are considered plant varieties and therefore cannot be patented.[116] A method of producing hybrid varieties in a given plant species can therefore be patented if the claims are met, whereas the hybrid variety produced by the method cannot be patented in itself. A microbiological method and products of such a method, such as plants and animals, can also be patented. However, as mentioned above, plant varieties such as these cannot be patented.

5.2.2.2 Exemptions for the production of plants by an essentially biological process

Chapter 1, Section 1a of the Patents Act states that patents are not granted on an *essentially biological process* for the production of plants or animals. An essentially biological process for the creation of plants or animals means a process consisting of natural phenomena as a whole. Natural phenomena include crossing and selection. The wording of the patent legislation comes from Article 4(1) of the Biotechnology Directive and the same provision is contained in Article 53(b) EPC. If a variety has been produced by mixing whole gene sets, it must be regarded as an essentially biological process even if genetic tools (e.g. genetic molecular markers) were used to select a specific result of that mixture.[117] However, a procedure whereby genetic molecular markers are used in the selection process may in itself be subject to patent protection. Genetic markers are short DNA sequences with known location within the genome that are inherited together with a certain trait (for example, a gene). Using molecular markers, these traits (genes) can be quickly and easily identified before appearing in the fully developed plant.

The scope of this exception has been examined before the EPO decision making bodies in several cases and over a long period of time, which has put EPO's decision-making to the test and has engaged political bodies at national and European level. Below is an overview. The main issue with regard to Article 53(b) of the EPC was long whether its

wording excludes not only essentially biological processes (that is, method claims) from patentability, but also products from essentially biological processes (i.e. product requirements linked to a procedure, *product-by-process*).

In the notable "pepper case" G 3/19[118], the EBA, following a lengthy process and by amending previous positions, took a ground-breaking decision extending the exemption for patents for plants (and animals) obtained through an essentially biological process. In this case, the question arises as to whether a pepper produced by an essentially biological process could be patented.

Prior to the case of the pepper plant, it was considered clear that patents for essentially biological processes could not be granted but that products produced using such a method could be patented. In the 'Tomatoes II' and 'Broccoli II' cases (G2/12 and G2/13), decided in 2015, EBA carried out a comprehensive analysis and considered that the correct interpretation of Article 53(b) of the EPC, including the Biotechnology Directive, was that the term 'essentially biological processes for the production of plants' could not be interpreted as covering the products obtained by such procedures.

In the pepper case, the EPO followed this practice and granted a patent. The EPO's decision was challenged before the Technical Board of Appeal (TBA).

However, the decisions to grant a patent for the pepper plant were not well received by organizations representing the more traditional part of the plant breeding industry, as well as a number of EU Member States and the European Parliament. They all considered, essentially, that patents in this area represented a risk of reduced access to genetic resources for traditional plant breeders.

The European Parliament adopted a resolution in December 2015[119] to the effect that patents should not be granted for plants produced through an essentially biological process. The Commission presented a paper in November 2016,[120] a non-binding notice stating that, when the relevant provisions of the Biotechnology Directive were adopted, the intention was to exempt products from essentially biological processes from patentability. However, the European Parliament and the Commission's initiative had no direct effect on the decision making process of the EPO, which is an independent authority.

In order to change the position of the EPO, an amendment to the EPC or its implementing rules was required. An amendment to the EPC requires, in principle, a diplomatic conference or a unanimous decision of the Administrative Council of the EPO, composed of a representative of each Contracting State.[121] An amendment to the implementing rules may be adopted by the Administrative Council of the EPO by simple majority. The implementing provisions are a secondary legislation designed to facilitate the interpretation of the EPC. A change to the EPC would from a legal perspective be the more elegant and robust solution but all involved were fully aware that opening the EPC would not only be time consuming, but also that it would be unpredictable how such a process could end. Instead, on 1 July 2017, the Administrative Council of the EPO adopted an amendment to implementing rules (Article 28(2)) to exempt plants produced by essentially biological processes from patentability.

When the appeal against the pepper case was to be decided by TBA[122], everyone was excited whether the TBA would follow previous practice or refer to the new implementing rules. The TBA decided that the previous case law on the interpretation of Article 53(b) of the Convention remained in force and that an implementing provision cannot overrule the wording of the Convention. The TBA found no reason to refer the case to EBA.

Following the TBA's decision, in September 2019, the European Parliament issued a second resolution reiterating its view.[123] The political attempts to bring about a change appeared to have failed. However, the President of the EPO has the opportunity, under certain conditions, to refer a question of law to EBA, which he did in this present case.[124] After examining a number of procedural issues, the EBA was asked whether to follow previous practice or to examine

whether there was room for interpretation to maintain the validity of the new rule of implementation Article 28(2)[125] despite previous case law on the interpretation of Article 53(b) EPC in cases G2/12 and G2/13.

The EBA found that previous decisions on the scope of Article 53(b) of the EPC, based on classical interpretation methods (i.e. grammatical, systematic, teleological and historical) were in themselves correct. However, the EBA considered that a certain interpretation of a legal provision can never be considered to be carved in stone, as the meaning of the provision may change or evolve over time. Taking into account the decision of the Administrative Council to introduce Article 28(2) of the Implementing Provisions, the preparatory work on this provision and the circumstances surrounding its adoption, and the legislative developments in the EPC Contracting States, EBA concluded that a dynamic interpretation of Article 53(b) of the EPC was appropriate.

By applying that dynamic interpretation, the EBA abandoned its previous interpretation of Article 53(b) of the EPC in Decisions G 2/12 and G 2/13. The EBA took the view that, following the introduction of the new Article 28(2) of the EPC, Article 53(b) of the EPC should be interpreted as excluding plants, plant material or animals from patentability, if that product is obtained *exclusively* by means of an essentially biological process.

In order to ensure legal certainty and to protect the legitimate interests of patent holders and patent applicants, EBA concluded that the new interpretation of Article 53(b) EPC of G 3/19 had no retroactive effect on European patents containing claims made before 1 July 2017 or on ongoing European patent applications, containing claims filed before that date.

The case shows that it is possible, through political processes, to change a situation which, in the eyes of the legislator, does not appear desirable.

5.2.2.3 Examples of plants produced by an essentially biological process

In addition to the fact that the derogation for essentially biological processes covers plants, it is clear from the EPO practice and its guidelines that parts of plants produced by an essentially biological process are also covered if the material in question can be used to produce whole plants that constitute propagating material, such as seeds. Therefore, although plant cells and cell cultures can be considered as a product of a microbiological process, plant material capable of propagating the entire plant is excluded from patentability in accordance with EBA in the pepper case (G 3/19), if the plant from which the material originates has been produced exclusively by an essentially biological process. Patents for plants produced by essentially biological process granted before 1 July 2017 continue to be in force and applications with such claims received before that date are processed in accordance with the previous case law.

5.2.2.4 Examples of plants produced by a technical procedure

As mentioned above, technical methods for the production of plants can be patented. Technical methods include, for example, genetic engineering and technically induced mutagenesis (CRISPR-Cas9) but also methods such as radiation and chemical mutagenesis, referred to above as traditional mutation methods (see Chapter 3.3). In order to ensure that a patent relating to a plant obtained by such a technical method does not cover the same plant produced exclusively by means of an essentially biological process, it follows that the claim must contain a disclaimer, stating that the patent claims do not cover plants with an equivalent characteristic produced by an essentially biological process. The omission of a disclaimer may result in the patent application being rejected. A disclaimer basically means that the applicant for the patent describes that a certain part of the invention is not to be covered by the patent claim. This means that once the patent is granted, the patent holder cannot invoke infringement against anyone who uses what is described in this disclaimer. However, in cases where it is quite clear that the invention can only be produced by a technical method, such as a transgenic plant, no disclaimer is required.[126]

The technical method used must be clearly described in the application and before a patent is granted, the granting authority PRV/EPO must be satisfied that the criteria for patents have been met.

Given that research in biotechnology leads to new findings that could not be foreseen by legislators, it is highly likely that boundaries of what should be considered essentially biological processes, or not, will be important in the future and therefore need to be clarified.

5.3 Discoveries

Chapter 1, Section 1 of the Patent Act states that a mere discovery can never be considered to be an invention, and is, thus, not patentable. While an invention is the result of constructive work, a discovery constitutes a finding of something existing. This means, for example, that the identification of a gene falls within the concept of discovery and that this discovery cannot be patented. If the same gene is isolated and a certain use of the gene can be described, this invention can be patented. If a gene contributes to a plant obtaining a certain property, such as resistance to a particular pathogen, patents can be obtained. Accordingly, DNA found in nature is not patentable as such. Only "artificial DNA molecules" or DNA isolated and used for a particular purpose can be patented.

5.4 Scope of protection

Under Section 39 of the Patents Act, the scope of patent protection is determined by the claims. In order to fully understand the claims, guidance can be taken from a description provided by the applicant. It is the inventor who in his patent application defines the patent claims, which in turn defines the scope of protection sought. Description and drawings submitted by the applicant may be used to interpret the claims.

The requirements shall consist of two parts, an introductory part and a characteristic part. The introductory part describes what the invention has in common with known technology. The characteristic part describes what is new and peculiar about the invention. A process claim defines a new method. A product requirement defines a new product. A "product by process claim" defines a new product by indicating how it has been produced.

In conclusion, the exclusive right granted by a patent means that no one may commercially use, manufacture, sell patent protected products or processes without the consent of the patent holder.

Chapter 1, Section 3 of the Patents Act provides, inter alia, that the consent of the patent holder is required to manufacture, offer, place on the market or use a proprietary subject matter or import into Sweden or possess such subject matter for any of these purposes. The scope applies not only to *products* but also to a product that has been manufactured using a patent protected *process*. Anyone who uses a patented invention without permission from the patent holder commits a patent infringement.

In the event of an infringement, it is necessary to assess whether the alleged infringement falls within the scope of the claims. In practice, this can be very complicated and patent experts are often needed to determine the facts and how the facts relate to the applicable law. It can be noted that today's patent descriptions can be extremely extensive. There are exceptional examples of descriptions of approximately 50 000 pages for DNA sequences.[127]

For microbiological processes or products, it may be difficult to specify the invention in writing with sufficient precision. In these cases, in addition to what can be described in writing, the microorganisms are to be deposited at one of the 80 international deposit authorities under the so-called Budapest Agreement to which Sweden has acceded. If a biological material has been deposited, everyone is entitled, subject to certain limitations and under certain conditions, to obtain samples from the deposited material (Section 8b of the Patent Act). Such samples may, for example, be used by parties for opposition proceedings and disputes when the validity of the patent is challenged.

A patent on an invention gives the proprietor the right to prohibit third parties from exploiting it for industrial and commercial purposes. Patent law is not intended to replace or render superfluous national, European or international law which imposes any restrictions or prohibitions or regulates the monitoring of research and the use or commercial exploitation of its results, in particular in relation to public health, safety, environmental and animal welfare requirements, as well as in relation to the preservation of genetic diversity and to certain ethical standards.[128]

As mentioned above, inventions for gene sequences and self-reproducing materials introduced into a plant to add a certain property can be protected by patents if the claim does not constitute a plant variety.

Specific provisions on the scope of protection for patented biological material are regulated in Section 3a of the Patent Act, which implements the Biotechnological Directive.[129] Under the Patent Act, 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. 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. Furthermore, the exclusive right means that the protection of a subject matter containing or consisting of genetic information covers all material in which the subject-matter is incorporated and in which the genetic information is included and performs its function.

In the Monsanto case, the Court of Justice ruled on a question whether the meaning of the term *performs its function* in Article 9 of the Biotechnology Directive. Monsanto possessed a patent in a number of countries, including in the Netherlands. The patent concerned an enzyme and the DNA sequence that, when introduced into a soybean, made the bean resistant to the herbicide Roundup. As a result, the soybeans were not affected when the product Roundup was used, while growing unwanted weeds died. The bean was called RR soybean. Some companies imported soymeal into the Netherlands, produced from RR soybean, grown in Argentina (where patents were not granted) and containing the DNA sequence protected by the Dutch patent. It was not disputed that the DNA in question was present in the soy meal and also that it could not perform its function in the flour which, in this context, was regarded as "dead material". The Court found that the function of the invention, that is to say resistance to Roundup, had ceased. The fact that the genetic information had previously exercised its function in the material in which it is incorporated, or that the genetic information could re-exercise that function in another material, did not alter the Court's conclusion.[130]

This issue has been addressed in a report by an expert group convened by the EU Commission. It is described that in a situation where a patent for an invention (for example, a DNA sequence encoding for a particular protein or property) is introduced into a plant variety, this may have certain consequences. When such plant varieties are used for further plant breeding, it may happen that after several crossings, the originally functional DNA sequences that make up the patented invention remain in the newly developed and commercialized variety without expressing any function. The question raised was whether patent protection for the originally patented DNA sequence should cover the new variety.[131] No conclusion was reached in the report but the question is not hypothetical and it is possible that it will have to be examined by judicial bodies in the future.

5.5 Exemptions/restrictions on the scope of protection

5.5.1 Introduction

The exclusive right conferred by a patent can sometimes appear as an obstacle to the business sector that is not in harmony with other public interests. A balance has therefore been made to safeguard the interests of patent holders as well as those of third parties and wider societal interests. The scope of the exclusive rights under patent law is therefore balanced with a number of important exceptions. In this report, only the exceptions for non-professional use, exceptions for experimentation, the agricultural exemption and the granting of compulsory licenses in relation to plant varieties protected by plant variety rights will be addressed.

5.5.2 Exemption for non-commercial use

Non-commercial use is excluded from the exclusive right. This means, for example, that the use in your own garden of seed that contains patent protection, this seed and its offspring can be reproduced freely as long as it is not transferred to others. It also follows from the exception that scientific research and teaching can take place without the consent of the patent holder.

5.5.3 The Experimental Exemption in Patent Law

The reasons why patent law has created an experimental exemption are several. An important reason is to facilitate research into and further development of science and technology. Such work would probably be made more difficult if a researcher wishing to further develop a patented invention would have to negotiate with the patent holder about access to the technology. Another important reason is that someone other than the patent holder should be able to verify that an invention is actually working and, if not, to gather the facts for an action for revocation of the patent.

The TRIPS Agreement provides that exemptions to the exclusive right conferred by a patent may be made under certain conditions.[132] Neither the European Patent Convention (EPC) nor the Biotechnology Directive contains rules on experimental exemptions. Whether and to what extent it is permitted to carry out experiments with patented technology is regulated by national patent laws. In Europe, therefore, regulation differs from relatively limited experimental exemptions to more generous ones. The United States, Canada and Australia have no experimental exemptions. However, in these countries, there is an experimental exemption based on case law, the demarcation of which, however, is partly unclear.

In Swedish law, the experimental exemption is provided for in Paragraph 3(3)(3) of the Patents Act, which provides that the use of an invention for experiments relating to the invention itself is excluded from the exclusive right conferred by a patent. The Experimental Exemption is aimed at both research and teaching in universities and colleges and research that takes place within a company. On the other hand, there is no equivalent to the "breeder's exemption" described above in Chapter 4.5.3.

In the future unitary patent system, Article 27(b) of the Unified Patent Court Agreement states that patent law is limited in respect of acts carried out for experimental purposes relating to the subject-matter of the protected invention.

Of interest to this report is the inclusion of a limited breeder's exemption in Article 27(c) of the above-mentioned court agreement. This provision limits the possibility for the patent holder to prevent others from using patented biological material for breeding purposes or for the detection and development of new plant varieties. In principle, the provision introduces an exception for the production of new plant varieties. The provision does not cover the commercialization of the new variety, which means that the breeder must obtain authorization from the patent holder

for commercialization. Similar provisions already exist in national patent laws in France, Germany, the Netherlands and Switzerland. There is no corresponding provision in Sweden.

The Government Bill 2013/14:89 on unitary patent protection in the EU states in Section 5a of the draft law that once the unitary patent system is in place, Articles 25–30 of the court agreement shall apply as law in Sweden with regard to which acts are covered by the exclusive rights and restrictions to the exclusive rights. This means, therefore, that the Swedish Patent Law and the unitary EU patent are harmonized in this part.

5.5.4 Agricultural Exemption

Section 3b of the Patents Act states that if the patent holder or a person with his consent transfers plant reproductive material to a farmer for use in agriculture, the farmer may, notwithstanding Sections 3 and 3a, use the harvest for reproduction in his own farm. The scope and conditions of that exemption from the exclusive right of the patent holder are set out in Article 14 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights and from the implementing rules adopted pursuant to that article. The reference to the rules on plant variety rights means that the rules on agricultural exemptions for patents and plant variety rights are the same. A more detailed presentation of the agricultural derogation can be found in Chapter 4.5.3.

When the above provision, stemming from Article 11 of the Biotechnology Directive, was introduced into the Patent Act, some referral bodies expressed concern that pollen transfer and crossing could result in the dissemination of patented material without the consent of the patent holder, and that this could cause involuntary patent infringement. In the Bill[133] it states that compensation for the use of, for example, a protected crop is to be paid to the patent holder only if and to the extent reasonable (Section 58(2) of the Patents Act). Therefore, whether any compensation is to be paid is determined by a general assessment of fairness taking into account all the circumstances. Any liability for compensation is limited to compensation for the use. In order to be liable to pay compensation at all, special circumstances should be required, for example, that the exploitation has taken place to a more significant extent. The Government therefore considered that there was no need to introduce a specific provision in this part.

A similar provision on agricultural exemption has been introduced in the unitary patent system, Article 27 (i) the Unified Patent Court Agreement.

5.5.5 Exhaustion

The exhaustion principle described in Chapter 4.5.4 also applies in relation to patents. In the case of living organisms, such as a micro-organism, sold with the consent of the right holder, the right is exhausted. However, for a possible offspring of the micro-organism, patent protection continues to apply.

5.6 License and compulsory license

A patent means, as stated in the previous section, that the patent holder may, for a certain period of time, prevent others from exploiting the invention professionally. However, the patent holder may allow another person to use the invention or variety. Such exploitation is normally based on agreements (licence agreements). Patent licensing agreements are very important for the patent holder, who can optimize the exploitation of his right through collaborations that benefit both parties to the agreement. It is also in the public interest that technology is disseminated and may be useful in solving technical problems.

In order to promote the spread of patent-protected technologies, a so-called patent pool can also be established. An interesting example of this is *The International Licensing Platform Vegetable* (ILP).[134] In recent years, discussions have

increased on patents on plant properties for vegetable varieties. Proponents of such patents argue that they promote innovation, knowledge exchange and continued investment in R & D. Opponents argue that such patents are unnecessary because of the intellectual property protection that can be obtained through plant variety rights and that patents hinder the work of breeders because they limit access to biological material. In light of these developments, a number of breeding companies, both listed companies and family businesses, decided to set up an international patent licensing platform/pool, in order to provide plant breeders around the world faster, more efficient and more cost-effective and guaranteed access to key patented plant properties from ILP member companies. ILP provides an easy way for plant breeders to obtain a licence for the characteristics they need at a fair and reasonable cost so that they can bring new products to the market, demanded by growers and consumers. The members of ILP make all their patents, related to plant characteristics for vegetable varieties, available to the members under the terms of ILP. The objectives of ILP Vegetable are thus to guarantee access to patents, covering biological material for plant breeding, and to ensure that incentives for innovation, which depend on access to patent protection, remain intact. A similar platform is being created for agricultural crops (ACLP, Agricultural Crop Licensing Platform, www.aclp.eu).

Situations may also arise where there is reason to derogate from the premise that the right holder can freely decide whether and how the protected subject-matter is to be used. For example, strong public interests may suggest that the invention or variety can be exploited to a greater extent than the right holder does or permits. The Patent Act and, as mentioned in Chapter 4, the Plant Variety Rights Act contain rules that make it possible to decide on so-called compulsory licences. A compulsory licence means that a person other than the right holder may exploit the protected invention without the consent of the right holder. The Patents Act contains some general provisions on compulsory licences, but this report is limited to licences covering biotechnological inventions.

Technological developments in the field of biotechnology have led to situations whereby there may be an overlap of patents and plant variety rights for certain plant related innovations. Against this background, and as mentioned in Chapter 4.6, the EU legislator considered that there was a need for compulsory licences also in cases where the use of an exclusive right requires authorization from another right holder and one of the exclusive rights is a patent and the other a plant variety right (so-called cross-licence).[135] Article 12 of the Bio Directive contains provisions on cross-licences introduced in the Patents Act and the Plant Variety Rights Act.[136]

A compulsory licence to exploit an invention may be granted to a plant breeder who cannot obtain or exploit a plant variety right without infringing a patent. A corresponding compulsory licence may be granted to the holder of a patent for a biotechnological invention who cannot exploit it without infringing a plant variety right. The right holder who is forced to accept a compulsory licence shall be entitled to a licence to exploit the other's protected object, often referred to as a cross license. Such a licence is granted only if the applicant demonstrates that the plant variety constitutes an important technological advance of significant economic interest in relation to the invention.[137] In Sweden, decisions on this type of compulsory licences are taken by a court. Decisions on compulsory licences for Community plant variety rights are taken by the CPVO. A decision should cover the extent to which the invention may be used, as well as the remuneration and other relevant conditions of the licence.

5.7 Protection time

A patent granted may be maintained until 20 years have elapsed from the date of filing of the patent.[138] For certain inventions, medicinal products[139] and plant protection products[140], protection can be extended by five years. The reason for this is that before the product can be marketed, authorization must be obtained by the competent authority and that this may take several years. For genetically modified plants, permission to grow and market is needed but, so far,

very few GMO plant varieties have been granted cultivation and marketing authorizations within the EU. It remains to be seen whether in the future the complexity in getting a market authorization will trigger the legislator to allow an extended term of protection in these cases.

In order for a patent to remain valid, a fixed annual fee shall be paid. The term of protection is shorter than for plant variety rights. The longer term of protection for plant varieties can be justified for the reasons mentioned above in Chapter 4.7. It is probably not the term of protection that is crucial for companies faced with the possibility of obtaining patents and/or plant variety rights, but rather other reasons, such as the scope of protection.

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103. SFS 1967:837.
104. Paragraphs 1-3 Introduction to the Biotechnology Directive.
105. Paragraph 10 Introduction to the Biotechnology Directive.
106. Paragraph 38 Introduction to the Biotechnology Directive.
107. For a more detailed account of the Boards of Appeal, see *https://www.epo.org/law-practice/case-law-appeals/about-the-boards-of-appeal.html*
108. Official Journal of the European Union, C 175/1, 20.6.2013.
109. Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection. Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection as regards the applicable translation arrangements.
110. Bill/Proposition 2015/16:124, Increased legal certainty in the unitary patent system, page 1.
111. See also the Agreement on Trade-Related Intellectual Property Rights (TRIPS) (1), signed by the EU and its Member States, which provides for patent protection to be granted to products and practices in all technologies.
112. O.J. EPO 2000, p. 111, Art 53 b EPC.
113. EPO Guidelines, Part C, Chapter IV, 3.5.
114. The corresponding provisions of Article 53b EPC and Articles 2(3), 2(4a) and 4(2) of the Biotechnology Directive.
115. 20.12.1999, G1/1998, O.J. EPO 2000, p. 111.
116. EPO Guidelines, G-II, 5.4.1.
117. G 1/08, G2/07.
118. G 3/19, OJ EPO 2020, A119, 14 May 2020.
119. European Parliament resolution of 17 December 2015 on patents and plant breeder's rights (2015/2981) (RSP).
120. CA/D 6/17, Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.
121. Article 33(1)(b) and Article 35(3) EPC.
122. Case T 1063/18.
123. European Parliament resolution of 19 September 2019 on patentability of plants and essentially biological procedures (2019/2800) (RSP).
124. Article 112 EPC.
125. The vote on the introduction of the Rules of Procedure was passed by a significant margin and 35 of the 38 representatives were in favour, 1 for the opposition, 1 to abstain and 1 absent. According to the new Rule 28(2), '[i]n Article 53(b), European patents shall not be granted for plants or animals produced exclusively by means of an essentially biological procedure'.
126. EPO Guidelines, G-II, 5.4.
127. Marianne Levin and Åsa Hellstadius, Lärobok i immaterialrätt, twelfth edition, 2019, page 241.
128. Introduction to the Biotechnology Directive, paragraph 14.
129. Articles 8 and 9 of the Biotechnology Directive.
130. C-428/08 Monsanto Technology, 6 July 2010, Article 9 of the Bio Directive, Levin, p. 264 et seq., 312.
131. Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering, p. 203, 17 May 2016.
132. Article 30 of the TRIPS Agreement provides that exceptions to the exclusive right conferred by a patent may be made on condition that those exceptions (a) are limited, (b) are not disproportionately contrary to the normal use of a patent, (c) do not unduly prejudice the proprietor of the patent, and (d) take into account the legitimate interests of third parties.

133. Prop. 2003/04:55, Limits on gene patents, etc. — implementation of the EC Directive on the legal protection of biotechnological inventions, p. 101.
134. *https://www.ilp-vegetable.org/*
135. Paragraphs 52 and 53, introduction to the Biotechnology Directive.
136. The TRIPS Agreement also contains relatively detailed provisions on compulsory licences (Article 31).
137. Section 46a, first and second paragraph, of the Patent Act.
138. 40§ of the Patent Act, see also Marianne Levin and Åsa Hellstadius, Lärobok i immaterialrätt, twelfth edition, 2019, page 336.
139. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.
140. Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

6. Overview of the regulation of production and making plant reproductive material available on the market

In Europe, seed companies and farmers have been driving the regulation of seeds. Compulsory variety registration was developed in several countries in Europe during the first half of the 20th century and in the EU the regulation began in the 1960s. The aim of seed legislation is to maintain and promote high-quality plant production by ensuring the production and use of high quality seed suitable for the current growing conditions and providing the necessary information on the seed. This quality assurance system gives confidence to farmers in certified seeds.

Seed is the crucial input in agriculture and provides conditions for good harvests. In addition, product development in plant breeding and seed production can help reduce the need and use of pesticides in agriculture. Efficient agriculture is of great importance to households as well as to a society's economy. Many factors play a role in achieving a good result of crop production, be it cereals, potatoes, vegetables, ornamentals or other crops. A good soil, which is well drained, a suitable climate and access to a well-balanced variety of nutrients are important prerequisites.

In the EU, the marketing of seeds and other plant reproductive material, including forest plants, is currently regulated by 12 Council Directives, the oldest of which dates from 1966. These 12 directives are composed of one overarching directive on the Common Catalogue of varieties of agricultural crops and 11 directives on the marketing of seed and reproductive material of different species. The 11 Directives are based on two basic principles, namely the registration of varieties and certification/inspection. The current EU legislation on plant and forest reproductive material dates back to the 1960s. The Commission has therefore taken an initiative to revise legislation with a view to modernizing it and better aligning it with the objectives of the European Green Deal and the Farm to Fork Strategy, the Biodiversity, the new EU Forest and Climate Adaptation Strategies. The review aims to ensure that legislation is implemented in a more harmonized way across the EU, more efficient and effective, more transparent to integrate new and future developments and contribute to the United Nation's SDGs, the protection of biodiversity and climate change adaptation and mitigation.[141]

In Sweden, the sale of seeds is regulated by the Seeds Act and various regulations. In order for seed of a variety to be certified and sold, it must be registered in a catalogue of varieties managed by the Swedish Board of Agriculture. Different requirements are imposed on varieties of vegetable and agricultural plants, amateur varieties, conservation varieties and fruits and berries. Regulation concerning the marketing of ornamental plants is less intrusive. This report is not intended to describe the regulatory framework in detail. However, it may be useful to know that there are important contact points between the rules on marketing and the rules on intellectual property. It has even been described that in order to get a proper understanding of how the seed market works, one cannot ignore the interdependence of the mentioned rules.[142]

In order to market seed, the new variety must be tested, in particular with a view to verifying that the variety is distinct, uniform and stable, which are the same technical conditions as for the grant of plant variety rights. This means that the same test results for the same plant variety can be used in both systems under certain conditions. The variety of an agricultural crop must also meet certain VCU (value for cultivation and use) requirements. These values include agronomic characters with an emphasis on yield, quality and resistance to diseases. In Sweden, the evaluation of field trials is carried out by the Swedish University of Agricultural Sciences on behalf of the Swedish Board of Agriculture and in other EU Member States by equivalent authorities. Moreover, the rules on variety denominations are, in

principle, the same as for the grant of a plant variety right. There is already a well-functioning cooperation between the CPVO, the EU Member States and the Commission aimed at a uniform application of the rules and avoiding duplication of work. With the above-mentioned Commission's initiative, there is an opportunity for even further synergies.[143]

EU Member States are obliged to report on the content of their national list to the Commission who in turn compiles the national lists in the EU Common Catalogue. The Common Catalogue is therefore merely a compilation of the national lists of the Member States and the Commission does not carry out any technical tests or studies. Varieties on the Common Catalogue can be marketed in all EU Member States.

According to a Commission report, there are around 7,200 European plant breeding and seed companies.[144] Compared to other regions of the world, the European plant breeding sector can still be characterized as diverse, with companies operating very different business models: some companies focus on research and development and breeding, while others focus on seed production and marketing.

On the Common List there are about 23,800 agricultural crop varieties of which 9,260 have been granted EU plant variety rights and about 21,100 varieties of vegetables of which approximately 5,250 have been granted EU plant variety rights.

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141. A description of the Commission's initiative can be found in the Journal of the Swedish Seed Association, 2 2021, Ingrid Karlsson, see also the websites of the Swedish Board of Agriculture and the Commission.
142. Impact of the Community Plant Variety Rights System on the EU economy and the environment, p. 42.
143. See CPVO opinion, *https://ec.europa.eu/food/system/files/2022-02/prm_leg_review_iia-2021-comments_cpvo.pdf*
144. Impact of the Community Plant Variety Rights System on the EU economy and the environment.

7. Overview of regulation of GMO plants and the development of new genomic methods

7.1 Background

In the case of plants produced by traditional plant breeding, such as cross-breeding and selection, as set out in Chapter 6, an authorization to market plant reproductive material of most species, excluding ornamental plants, is required. Where a plant has been produced by gene modification, it has been considered appropriate to introduce additional regulations, determining the extent to which such plants may be grown and marketed. The main reasons for the specific regulation are identified as risks to public and animal health and ecological risks.

GMO stands for a genetically modified organism which, according to legislation, means an organism where the genetic material has been altered in a way that does not occur naturally by, for example, mating and/or cross-fertilization.

7.2 Regulation

In the EU, there is common legislation on GMOs, including Directive 2001/18/EC (the GMO Directive)[145] on the deliberate release into the environment of genetically modified organisms.

The Directive has been transposed into Swedish law by the Regulation 2002:1086 on the release of genetically modified organisms into the environment and the Environmental Code. The Directive covers all organisms except humans and lays down rules for both commercial use and experimental activities in the environment. Regulation (EC) No 1829/2003 covers food and feed containing, consisting of, or produced from genetically modified organisms and Regulation (EC) No 1830/2003 lays down rules on traceability and labelling.

The legislation sets out which methods are covered by the GMO Directive, which methods are not, and which methods are technically covered but which are then excluded.[146] Sweden has implemented the legislation and the Swedish Board of Agriculture handles matters concerning genetically modified plant varieties.

In particular, the GMO Directive provides that GMOs are to be authorized following an assessment of the risks they pose to human health and the environment and subject them to traceability, labelling and monitoring obligations. In the EU, decisions are taken on the release of plant varieties produced using a GMO method in accordance with a decision-making process involving several actors and steps.[147] The decision-making process, its majority rules and differences of opinion have led to very few GMO plants being approved due to lack of political support. On the Common Catalogue there are 116 GMO varieties. Most of these varieties contain the same GMO trait, namely resistance to European corn borer. As mentioned above in Chapter 4.2, since 1995 and until June 2022, the CPVO has received 107 applications for varieties covered by GMO legislation, of which 29 varieties are still protected by plant variety rights.

In July 2018, the Court of Justice of the European Union delivered a judgment[148] on a question on the applicability of the Directive to *mutagenesis*. Mutagenesis is a collective term for the development of mutations. Mutagenesis is listed as an exception in the Directive.

The Court held that organisms produced by mutagenesis are genetically modified organisms within the meaning of the GMO Directive, in so far as the methods of mutagenesis alter the genetic material of an organism in a way that does not occur naturally. It follows that those organisms fall, in principle, within the scope of the GMO Directive and are subject to the obligations laid down by that directive. However, when considering if the techniques in question fell

within the exemption of the GMO Directive, the Court stated that the only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of the GMO Directive.

In practice, the ruling means that plants mutated with new technologies such as CRISPR/Cas9 are subject to GMO legislation while plants developed by traditional mutation-inducing techniques (such as radiation and chemical treatment) are exempted. This means that plants produced with gene editing must be approved after an assessment of the risks they pose to human health and the environment and that they are also subject to traceability, labelling and monitoring obligations. These administrative approvals are expensive and time-consuming and effectively exclude many SMEs from using the technology. In addition, the traceability requirement is impossible to meet because in a gene-edited variety it cannot be established that the variety has been developed using a gene editing technique in the same way as when transgenic methods are used. In the light of the rather cumbersome decision-making mechanism to take decisions on plant material covered by the GMO Directive, the ruling effectively puts an end to the use of gene editing in the EU in practice, unless new more flexible legislation is adopted.

The ruling was considered by many EU Member States as well as the plant breeding industry as a confirmation that the legislation is outdated. The Council therefore instructed the Commission to carry out a study on New Genomic Techniques in the light of that judgment. This study was presented by the Commission on 29 April 2021.[149] A so-called '*Inception Impact Assessment*' was then presented by the Commission on 24 September 2021, summarizing the study with options on possible follow-ups. The Commission has conducted a *Public consultation on plants produced using certain new genomic methods* from 29 April to 22 July 2022, receiving input from all stakeholders via the Commission's website.[150] The Commission intends to present a legislative proposal in the second quarter of 2023.

The document *Initial Impact Assessment*[151] shows that the applicable legislation is not fit for purpose and not predictable for certain practices involving gene editing and products thereof, and that the legislation needs to be adapted to scientific and technological progress. The Commission's work is in principle limited to a possible regulation of mutagenesis and cisgenic methods.

It is also recognized that plants obtained from genome editing have the potential to contribute to the objectives of the European Green Deal and in particular to the Farm to Fork Strategy and Biodiversity Strategy and the UN Sustainable Development Goals for a more resilient and sustainable agri-food system. It is also noted that EFSA[152] concluded that plants produced by targeted mutagenesis and cisgenesis generally present lower risks than plants obtained by conventional genetic modification techniques (transgenesis). In addition, EFSA has concluded that, in some cases, plants produced by targeted mutagenesis and cisgenesis do not present new risks compared to plants produced using classical mutagenesis or conventional breeding techniques. Nevertheless, they are covered by GMO legislation following the above-mentioned decision of the EU Court of Justice.

The Commission report also states that GMO legislation contains requirements for authorization, traceability and labelling which, for certain plants obtained through targeted mutagenesis or cisgenesis, raise challenges for implementation and compliance, as it will be difficult or impossible to distinguish them from plants produced by conventional breeding. In the report, the Commission opens up the possibility that the genetic technologies in question will not be subject to the same rules as the current GMO legislation, and that any risk assessment and authorization procedure should be proportionate to the relevant risks. The Commission is also considering introducing a sustainability analysis to examine whether, and how, these products contribute to sustainability, taking into account the criteria developed in the policy measures for a framework for sustainable food systems. Specific regulatory mechanisms may be considered to introduce sustainability-related requirements or incentives.

It may be mentioned that half a page of the Commission's study is devoted to the advantages and disadvantages of intellectual property protection for new breeding techniques, mainly patents. The study explains that some Member States and stakeholders highlighted the importance of incentivising new research through patent protection and by licensing patents for new technologies. Others saw risks that patents could exclude access to new technologies and to genetic material needed to breed new varieties, which the plant variety right does not do in the same way. Reference was made to the EU plant variety right system in this respect. Intellectual property is not mentioned in the Commission document *Inception Impact Assessment*. It remains to be seen what the Commission will propose and to what extent the European Parliament and the Member States are willing to allow for a possible deregulation.

In addition to EFSA, other renowned scientific institutions in the world (e.g. in the US, Australia and New Zealand) have come to similar conclusions. These institutions propose that regulation be based on documented risks of the product instead of the technology used to create the product.[153] In the HFFA study[154], which focuses on European conditions, regulators and authorities are recommended to adopt a differentiated regulatory framework based on proportionate and non-discriminatory safety considerations for different technologies and resulting products.

It can be mentioned that in a number of non-EU countries, gene editing is approved either by regulation or by deciding not to regulate this area of technology in another way than for traditional breeding.

Different regulations in different countries makes it difficult for companies operating internationally. It can also be a challenge for states that may be accused of violating rules and agreements on free trade with an overly strict regulation. There are already concrete examples of Swedish companies with cutting-edge expertise in genome editing for plants that may be forced to place all or part of their research activities and the entire marketing work and sales to countries outside the EU because of the political climate in the EU. The same applies, of course, not only to Swedish companies but to all European companies operating in this field.

The FAO Strategic Framework 2022 states that innovation is important to meet the challenges of supporting an increasingly growing population and that there is a wider acceptance that innovation in biotechnology, such as CRISPR/Cas9, can contribute to solutions.[155]

In addition to the fact that it is important that Sweden and Europe are not left behind in important research areas, such as biotechnology, gene editing techniques bring promises of more efficient plant breeding that can contribute to the EU's climate goals and the UN's sustainability agenda. For example, case studies with fungal-resistant wheat and grape varieties developed through gene editing can significantly reduce the number of fungicide applications in European agriculture and thus contribute to environmental protection. Whereas rapeseed varieties less prone to pod-shattering, virus-resistant sugar beet varieties and drought tolerant maize varieties developed using modern technology, to take other examples, have the potential to significantly increase yields and thus minimize pressure on limited natural resources such as arable land.[156] For the successful and safe use of biotechnology, a modern approach based on scientific trade-offs is needed.

The HFFA study underlines that public opinion plays a crucial role in how politicians will act and that it is therefore important that factual information on the relevant technologies be communicated to the public and policy makers.

That the Court of Justice of the European Union 'branded' gene editing techniques as GMOs constitute an uphill path in explaining what distinguishes CRISPR/Cas9 from the more traditional GMO techniques. A survey in Sweden shows that the knowledge about gene scissors and their use is relatively low.[157] The survey shows, for example, that every second Swedish person have knowledge of gene scissors but that only one in ten knows gene scissors well. More than half are unsure whether a tomato contains DNA and the majority of Swedes are to some extent concerned about the impact that the use of gene scissors in plant breeding can have on health and the environment. It also appears that if the purpose of using genome editing in plant breeding is of benefit for society, a clear majority is positive. Also, this

survey shows that it is important that information on the general benefits of these technologies is passed on to the public and policy makers.

Biology and genetic engineering are complex areas and it is therefore understandable that we do not all fully understand the different technical aspects. It is also sometimes difficult to understand what distinguishes the different technical methods. As mentioned above, there are therefore those who argue that regulation should focus on results/products rather than methods/technologies. Even experts may have different perceptions of risks. However, there are areas where there is broad consensus in the scientific community that there are no or very limited risks to human health and the environment. Under the current legislation, an authorization to grow and sell varieties that are safe should be granted. Despite this, decision-makers have often chosen to follow a compass that is guided by other motives than those based on facts, science and proven experience.

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145. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
146. Article 2 and 3 of the Directive and Annex I(A) and Annex I(B).
147. How is the release of GMOs into the environment approved? Directive 2001/18/EC requires an undertaking wishing to market a GMO first to submit an application to the competent national authority of the Member State where the product is to be first placed on the market. The application must include a full environmental risk assessment. If the national authority approves the application, it shall inform the other Member States via the European Commission. If the other Member States or the European Commission have no objections, the authority that made the initial assessment approves the placing on the market of the product. The product may then be placed on the market throughout the EU under any conditions specified in the authorization. If someone raises objections that cannot be rejected, a decision must be taken at EU level. The Commission first asks for the opinion of one of its scientific panels composed of independent researchers qualified in medicine, nutrition, toxicology, biology, chemistry and other similar sciences. The expert panels are the responsibility of the European Food Safety Authority (EFSA). If the scientific experts support the application, the Commission submits a draft decision to the Competent Committee of the representatives of the Member States. If the Committee agrees with the draft, the Commission adopts the decision. If the Committee does not agree with the draft, the Commission shall forward it to the Council of Ministers, which may adopt or reject it by qualified majority. If the Council does not act within three months, the Commission shall adopt the decision. During the processing of the application, the public is kept informed. It has access to the public data on the Internet (*http://gmoinfo.jrc.it*) containing inter alia a summary of the application, the assessment of the competent authorities and the opinions of the scientific panels. For experimental release applications are examined and approved by the authorities of the Member State where the organism is to be released. See *https://ec.europa.eu/commission/presscorner/detail/sv/MEMO_04_102*, *https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-authorisation/eu-decision-making-process-explained_en*
148. Case C-528/16, ECLI:EU:C:2018:583, judgment of the Court (Grand Chamber) of 25 July 2018, Confédération paysanne and Others v. Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt.
149. Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16. European Commission Brussels, 29.4.2021 SWD (2021) 92 final.
150. *https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Lagstiftning-for-vaxter-som-produceras-med-vissa-nya-genomiska-metoder_sv*
151. Inception Impact Assessment, Ref Ares (2021) 5835503, 24 September 2021.
152. *https://www.efsa.europa.eu/en/efsajournal/pub/2561*, *https://www.efsa.europa.eu/en/efsajournal/pub/2943*, *https://www.efsa.europa.eu/en/efsajournal/pub/6299*
153. Regulatory approaches for genome edited agricultural plants in select countries and jurisdictions around the world, 10 May 2021, Genome Editing in Plants.
154. The socio-economic and environmental values of plant breeding in the EU and for selected EU countries, HFFA Research Paper 2021, Steffen Noleppa, Matti Cartsburg.
155. FAO's Strategic Framework 2022, Point 35, page 11.
156. The socio-economic and environmental values of plant breeding in the EU and for selected EU countries, HFFA Research Paper 2021, Steffen Noleppa, Matti Cartsburg.
157. Swedish citizens' perception of gene editing in the plant breeding sector, The Swedish Gene Technology Advisory Board (Gentekniknämnden), Dnr 3.1.1-2021-027.

8. Access to genetic material

Access to genetic material is crucial for successful breeding. Companies and research organizations are therefore looking for biological resources worldwide that they use for the research and manufacture of new products, including agricultural, food and pharmaceutical products. This approach has been criticized and it has been considered inappropriate to use resources commercially derived from local biodiversity, often in developing countries, without any appropriate remuneration to the local communities. International instruments such as CBD, the International Treaty[158] and the Nagoya Protocol[159] have therefore been adopted to address the challenges. The Nagoya Protocol has also been implemented in the EU through Regulation 511/2014.[160] The instruments aim at fair compensation for the use of genetic resources by plants, animals, bacteria, or other organisms, for commercial, research or other purposes. The instruments contain mechanisms on how access to genetic resources can be obtained, but also provisions on how the benefits of resources should be shared equitably (Access and Benefit Sharing, ABS). In addition, discussions are currently underway on whether or not digital sequence information should be covered by the international instruments.[161]

However, the implementation of these instruments is rather slow and the mechanisms put in place by countries often appear to be administratively complex. This applies, for example, to authorization procedures for the use of genetic resources and the determination of compensation. This neither benefits those who wish to use the relevant genetic resources, nor those eligible for compensation. It is important that countries continue to seek solutions that also work in practice.

In connection with the introduction of the Biotechnology Directive, Section 5a of the Patent Act introduced a requirement for applicants to indicate the origin of genetic material. This can be helpful for countries that wish to monitor the implementation of the instruments in force and ensure that reasonable compensation is paid.

Indent 25 of the introduction to the Biotechnology Directive states that where an invention concerns biological material of plant or animal origin, or if such material is used, the patent application should include, where appropriate, an indication of the geographical origin of the material, if known. The foregoing should apply without prejudice to the examination of patent applications and the validity of the rights conferred by the patents granted. An equivalent provision has not been introduced in the Basic Regulation governing the EU system for plant variety rights.

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158. The International Treaty on Plant Genetic Resources for Food and Agriculture.
159. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Sharing from Their Utilization to the Convention on Biological Diversity.
160. Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users in the Nagoya Protocol on Access to and Fair and Equitable Sharing of Benefits from the Utilization of Genetic Resources in the Union.
161. Digital Sequencing Information (DSI) is a term used in the context of certain international political fora, in particular the Convention on Biological Diversity, to refer to data derived from genetic resources. Most agree that the term includes nucleic acid sequence data and it can be interpreted as including other types of data derived from or linked to genetic resources, such as protein sequencing data. DSI is very important for research in a wide range of contexts, including plant breeding but also pharmaceuticals, and biodiversity.

9. Analysis

9.1 Comparison of plant variety rights and patents

Intellectual property rights for plant related inventions are increasingly important for innovators and society at large.

For technical reasons, it is appropriate that a separate intellectual property protection system for plant varieties be maintained. In addition, the scope of patent protection did not appear appropriate in many countries for plant varieties as the genetic material could not be freely used for further processing when it was patented. The reason for the generous breeder's exemption in the area of plant variety right is that in Europe it has been considered crucial that plant breeders have access to as large a genetic basis as possible in order to be able to produce new varieties.

As regards the content of protection, plant variety rights and patents are equal in so far as both systems of rights confer on the holder an exclusive right to dispose of the protected property. However, a patent provides a stronger protection as the exemption for conducting experiments and developing new inventions, based on a patented invention, is more limited than under the plant variety right.

Although patent protection is more extensive than plant variety rights in Sweden and Europe, it is interesting that of the two systems have become more similar in recent decades in terms of the extent of what is being protected. The protection of essentially derived varieties was introduced in order to strengthen the rights of plant breeders. An essentially derived variety may be produced from a protected variety without the consent of the holder of a plant variety right for the protected variety. However, authorization is required from the holder of the protected variety used to produce a new essentially derived variety in order to market the derived variety. Access to genetics for the production of new essentially derived varieties was thus ensured, while maintaining a reasonable level of protection for the holder of the plant variety right of the initial variety.

The agricultural exemption (often referred to as the Farm Saved Seeds exemption), which previously existed only within the scope of the plant variety right, is also contained in patent law and the possibility of cross-licence between the two systems has been introduced. The breeder's exemption, albeit a limited one, has entered into the system of unitary patents and will be introduced into Swedish patent law when the unitary patent system is in place. Similar provisions already exist in national patent laws in France, Germany, the Netherlands and Switzerland. That protection is therefore similar to the protection of essentially derived varieties, namely free access to genetic material to create new varieties without the consent of the right holder, whereas consent is required for commercialization. In the 'paprika case' G0003/19, the EPO adopted a decision extending the exemption for patents for plants obtained through an essentially biological procedure. The decision means that plants obtained from an essentially biological process are no longer patentable. This trend differs from the situation in some other countries, such as the United States, where virtually all inventions that meet the claims can be protected by patents.

In view of the fact that plant varieties cannot be protected by patents, the principle of free access to protected plant varieties is enshrined as a resource for the creation of new varieties. In other words, plant variety rights do not block access to plant varieties for renewed research and marketing in Sweden and Europe. However, a patent on a gene present in a plant means that that gene cannot be used in other plant varieties without the consent of the patent holder. Accordingly, if a patented gene has been introduced into a plant belonging to a plant variety, for practical reasons, most of the use of such plant material will be subject to the consent of the patent holder.

With recent technological developments, such as the increasing number of gene-related patents and rapid advances in genetic engineering, patents and plant variety rights are more interconnected. The above-mentioned trend of extending plant variety rights (essentially derived varieties) and at the same time restricting patent law (limited breeder's

exemption, agricultural exception, and extended interpretation of the exemption for essentially biological procedures) shows that the scope of the two protections is approaching.

However, patents and plant variety rights remain separate intellectual property rights with different conditions of protection, scope and exceptions. Breeders may use the plant variety right and patent, or a combination in some cases. Another important difference between the systems is that it is possible to protect methods and products with a patent, while a plant variety right only protects one product, one plant variety.

Plant variety rights and patents may be considered to be well-balanced and do not unduly hinder the use of genetic resources.

With regard to what can be protected, the practice shows that authorities granting plant variety rights (CPVO within the EU, the Swedish Board of Agriculture in Sweden) have no major problems in determining whether an application concerns a plant variety or not. The reasons for this are that the definition is rather clear and that practical field tests are carried out to examine whether the technical criteria are met. As regards what can and cannot be patented for plant related inventions, there is more practice and the European Patent Office (EPO) has set certain boundaries. Patent attorneys have been innovative when they have written patent claims and they have appealed decisions to test what can be protected with a patent. As shown in this report, important decisions have been taken by the EPO which have contributed to increased predictability. Research into properties that make plants resistant to, for example, pathogenic bacteria, fungi, viruses and insects has intensified and patents are granted regularly for these types of inventions in Europe. As new technologies are developed and the need for patent protection increases, more interesting delimitations will probably need to be made. For example, it may be interesting to follow how the condition for a patent, *the inventive step,* will be used for certain mutation techniques. The results of random mutagenesis or traditional mutation treatment by radiation or chemistry can be patented. The distinction between *"natural random mutagenesis"* (e.g. an essentially biological procedure) and *"technical methods of mutagenesis"* (technical, patentable procedure) will probably need to be clarified in practice in the future. Representatives and other parties may challenge the legal situation and a continued debate on these issues can be expected.

Looking at the future, one of the most important measures is to get the unitary patent system in place, which will likely happen in 2023. The review of EU plant variety rights is also welcome as the legislation has soon been in place for 30 years. Experience shows that although the system works well, it is important to correct and improve. There is an expectation that fundamental provisions on what is covered by the concepts of propagating material (referred to as variety constituency in the Basic Regulation) and harvested material will be clarified, that provisional protection will be strengthened and that the definition of essentially derived varieties is clarified. There is also room to improve the possibility of addressing infringements and to review the regulatory framework for the collection of information on the use of farm saved seed, which currently means that farmers in some EU Member States contribute while farmers in other countries do not.

9.2 Technology transfer

Exclusive rights rarely mean that technology stays with an inventor who prevents others from using it. The fact that patent applications and applications for plant variety rights are published and that the innovator often markets the new innovation means that the public becomes aware of what is covered by the innovation. Cooperation with the innovator is possible in which case conditions for use can be determined in agreements, licenses. Technology transfer through licensing is very common and contributes to the benefit of new technologies for private and public interests while at the same time providing the innovators with a fair remuneration for their efforts that can be used for new investments. Private initiatives on patent pools have been developed in Europe such as the International Licensing Platform for

Vegetables. All this, and more, shows that there is an interest in finding a balance where, on the one hand, innovation is rewarded but at the same time there is the possibility of using modern technologies protected by intellectual property under reasonable conditions.

9.3 Ethical aspects

When intellectual property rights for plants, biotechnology and living matter are addressed in the public discussion, questions often focus on ethical aspects. Is it fair that a person can get an exclusive right to biological phenomena which stems from nature? The legislator has taken into account ethical issues when legislation has emerged. Medicinal products and foodstuffs were for long excluded from patents, but as society developed and the risks and ethical reasons previously invoked were not long regarded as an obstacle, patents could be obtained for those products with certain limitations and exceptions. It took more than a decade for EU Member States to agree on the Biotechnology Directive. One prominent reason was various ethical issues, which eventually led to some inventions not being patentable. Questions were also raised when plant variety right systems were put in place, such as the extent to which an exclusive right can be obtained for living material. Like patent law, restrictions on plant variety rights have been introduced such as compulsory licences and breeder's exemption in order to balance social and private interests.

9.4 Biodiversity

Plant breeding contributes to maintaining biodiversity, for instance by the fact that high yields of harvests require less arable land. Creating new varieties does not in itself mean that existing varieties are lost, but measures often need to be taken to ensure that existing varieties do not disappear. It is of great importance that measures are taken to promote and conserve biodiversity. However, the solution does not lie in limiting plant breeding and using only existing varieties, nor would abolishing intellectual property rights for plant related innovations solve the preservation of biodiversity. Balanced solutions with the use of landraces to some extent and the preservation of genetic material in gene banks are pieces that can be useful when the large puzzle is laid. The granting of intellectual property rights for new plant-related innovations can help to mitigate the problems of biodiversity loss.

9.5 Regulation regarding the use of gene editing

In addition to access to genetic material, plant breeders need to develop and have access to a modern toolbox. Biotechnology is making rapid progress and so-called gene scissors, such as CRISPR/Cas9, can help make breeding much more efficient by creating predictability in the research and production of new plant varieties. In addition, the new genome editing methods can help to incorporate the EU's environmental objectives. It is therefore important that future regulation of new genome editing methods is scientifically based and that any risk assessments and authorization procedures are proportionate to the relevant risks. Cooperation with non-EU countries is important in order to achieve regulations that, as far as possible, provide similar solutions. Sweden is traditionally a country known for its excellence in technological development and it is important to create conditions that contribute to the maintenance of research and development in Sweden and the EU, whilst at the same time safeguarding human health and the environment.

9.6 Needs for competence

While breeders are looking forward to deregulation that allows gene editing methods to be used in breeding projects, this may mean that more time and resources need to be invested in intellectual property strategies and adaptation to future regulation. Companies that focus on gene editing can obtain patents for certain breeding methods and certain

plant-related products, but often need to use varieties protected by plant variety rights. This means that cross-licensing of plant variety rights and patents may be used more frequently. In addition, the technical development may lead to an increase in infringements of protected varieties, used for gene editing and method patents. It is therefore important that companies operating in this area have both the technical and legal skills necessary to assess what is covered by patent and plant variety rights in order to be able to make the best use of the rights constructively and not end up in tricky infringement disputes. This can be a challenge given that delimitation challenges still exist, for example with regard to the definition of essentially derived varieties. The question is whether Swedish plant breeding companies possess this competence.

For the larger multinational breeding and plant biotech companies with legal and administrative capacity and experience to deal with intellectual property issues and various regional and national regulations, the above-mentioned processing may not be prohibitive. For small and medium-sized plant breeding companies and public breeding institutes, increased administration can pose significant challenges. Future regulation must therefore ensure that the new technologies can be used by all types of companies and institutions. It is therefore important that this problem is brought to the attention in the public debate.

9.7 Communication

It is a challenge to explain the importance of intellectual property rights and to demonstrate that ethical balances have actually been considered, and that both private and public interests have been taken into account when the relevant intellectual property laws were enacted. Individual companies and breeders' organizations do launch communication campaigns on the benefit of plant breeding and intellectual property rights. However, a more comprehensive communication strategy from European and national administrations would be welcome in order to ensure that individuals, businesses, authorities and decision-makers have access to relevant knowledge and facts on these issues.

9.8 Summary

In conclusion, intellectual property rights play an important role in the development of modern societies. Intellectual property rights provide an exclusive right to innovative individuals, associations, universities and businesses and can help fund new research and innovation. This is particularly important in research-intensive areas such as plant breeding. Publishing applications for intellectual property rights and technology transfer means that more people can profit from innovations and build on them. The content of an intellectual property right is restricted by the legislator and appropriate exceptions have been introduced in order to safeguard certain horizontal public interests. For example, existing legislation allows the use of protected plant varieties to produce new varieties. As regards intellectual property protection for products/methods derived from plant breeding and genetic engineering, ethical trade-offs have been of particular importance when the legislation was adopted. Patents and plant variety rights have been granted for products/plant varieties that are genetically modified, but this does not mean that such innovation can be put on the market if they pose a risk to human health or the environment. Plant breeders must have access to modern technologies and regulation on the use of gene editing and other genetic techniques should be determined, based on real risks to health and the environment. There is a tendency that existing regulation is applied strictly, which makes it administratively complex to put certain varieties on the market, which in turn does not promote the efficient use of available resources. It is important to continue to communicate and promote the benefits of intellectual property rights for plant-related innovations.

Abbreviations

The Biotechnology Directive	Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions
CPVO	Community Plant Variety Office
CBD	Convention on Biological Diversity
EBA	Enlarged Board of Appeal at the EPO
EFSA	European Food Safety Authority
EU	The European Union
EPC	European Patent Convention
EPO	European Patent Office
EUIPO	European Intellectual Property Office
Basic Regulation	Council Regulation 2100/94 on Community plant variety rights
GMOs	Genetically modified organisms
The GMO Directive	Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
ITPGRFA	The International Treaty on Plant Genetic Resources for Food and Agriculture
KSLA	The Royal Swedish Academy of Agriculture and Forestry
LRF	The Federation of Swedish Farmers
OAPI	L'Organisation Africaine de la Propriété Intellectuelle
Patent Act	The Swedish Patent Act 1967:837
PRV	The Swedish Patent and Registration Office
PVPO	Plant Variety Protection Office, USA
SVUF	Swedish Seed Trade Association
TBA	Technical Board of Appeal at the EPO
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UPOV	Union internationale pour la Protection des obtentions Végétales/International Convention for the Protection of Varieties of Plants
USDA	U.S. Department of Agriculture
USPTO	U.S. Patent and Trademark Office
Plant Variety Rights Act	Swedish Plant Variety Rights Act 1997:306
WTO	World Trade Organization

Short glossary of technical terms

Cisgenesis	Introduction of foreign genetic material into a receiving organism from a donor that is sexually compatible (cross-fertilization).
CRISPR/Cas9	An example of a mutagenic technique.
Hybrid	Hybridization is a biological process that results from sexual reproduction between individuals who are genetically different. Individuals can be of, for example, different species and populations.
Hybrid variety	F1 variety. Name of a variety obtained by pollinating a male sterile mother line (without pollen production) by a father line. Only seeds on the mother line are harvested for use as seed, making seed production complicated and expensive. On the other hand, this hybrid variety can combine good properties of the parent lines for e.g. high yield (heterosis effect). Only first-generation seeds are sold as seeds because later generations are not genetically stable. The male sterility of the maternal line is usually inherited but systems for the production of the hybrid seed may also be based on the removal of male flowers on the maternal line (maize).
Phenotype	An organism's phenotype is either its entire physical shape or a specific physical characteristic, such as its size or colour. The phenotype is determined to some extent by the genotype. Many phenotypes are determined by several different genes and are also affected by environmental factors.
Genetic (molecular) markers	Genetic markers are short DNA sequences with known location within the genome that are inherited together with a certain trait (for example, a gene). Using molecular markers, these traits (genes) can be quickly and easily identified before appearing in the fully developed plant.
Genotype	The genotype is the exact genetic properties of a plant (its genome) usually in the form of DNA.
New genomic methods	An overarching term used to describe a variety of methods that may alter the genetic material of an organism and which have been developed since 2001, when the existing EU legislation on GMOs was adopted.
Mutagenesis	The creation of one or more mutations in an organism, without the introduction of foreign genetic material.
Classical (or random) mutagenesis	An overarching term used to describe mutagenesis methods that have been used since the 1930s. They include irradiation or treatment with chemicals to produce random mutations, without the introduction of foreign genetic material. Organisms produced by such methods are regarded as genetically modified organisms in the EU, but they are exempted from the EU legislation on GMOs.
Targeted mutagenesis/ gene editing	An overarching term used to describe new mutagenesis methods that induce one or more mutations at specific, selected locations in the genome, without the introduction of foreign genetic material.
Transgenesis	The introduction of foreign genetic material into a receiving organism from a donor organism that is not sexually compatible with the receiving organism.
Plant breeding	Humanity has been involved in plant breeding since ancient times by selecting plants with desired properties and multiplying them. Today, various techniques are used in plant breeding, including genetic engineering.

Intellectual property in the debate on genetic engineering

Anders Nilsson

In the debate on modern genetic engineering, such as gene scissors, it is increasingly rare that the technology itself is being debated. On the other hand, those who are hesitant about the use of these techniques, or even explicit opponents of this, often raise questions relating to the functioning of patents and plant variety rights. It often comes back to questions that relate to three different questions.

- Opportunities for growers to use farm saved seed
- If plant variety rights and patents on plant-related innovations are ethically defensible
- If intellectual property, especially patents, only benefits the really big companies.

It is therefore appropriate to address and describe how intellectual property rights work and apply in these three areas in practice, not only in the EU but also in a number of other countries of interest in this context. My aim is to answer these three questions in a more complete way than it is usually possible in connection with seminars and other discussions.

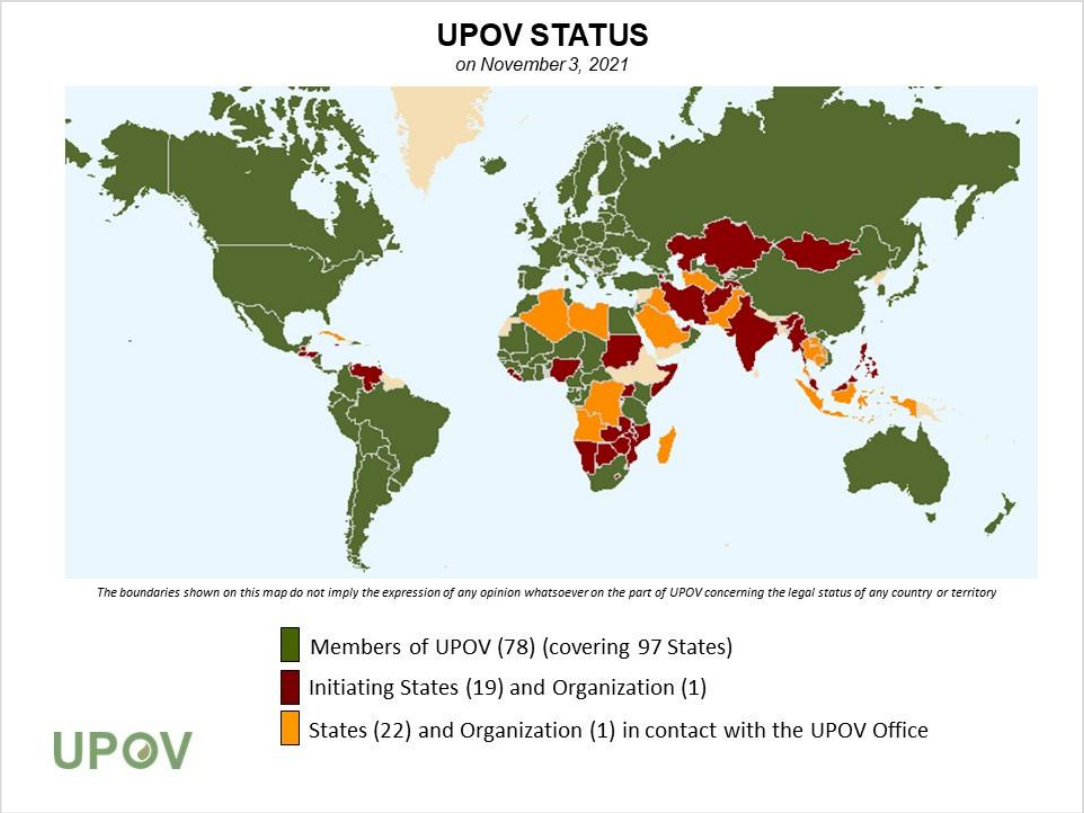
Use of farm saved seeds

The debate often argues that plant variety rights and patents prevent growers from using their own seed. This is a misconception. In fact, there are good opportunities to use farm saved seed and this is particularly true for smaller farms in Europe and especially in developing countries. On the other hand, plant variety rights and patents provide an opportunity to get a compensation for the costs incurred in developing new varieties or other innovations and, at best, making a profit. Smaller farms in the EU are exempt from paying any fee for their use of farm saved seed (see Chapter 4.5.4 of the Report).

This discussion should be focused on the large farms in the EU which today do not pay a fee for their use of varieties protected by plant variety rights or patents. They should also do so without trying to find all possible ways to avoid it. Where the system of fees for farm saved seed works or where the majority of the seed sold is certified, there will be a completely different interest in pursuing plant breeding.

There was a long tradition of using farm saved seed, also in Sweden. However, as seed production and treatment became increasingly professional and new varieties were introduced, the use of farm saved seed decreased in Sweden. The insight of the growers about the importance of healthy and high- performing seed without the presence of other varieties or weeds also grew. In the 1980s, the use of farm saved seed increased again as a result of the cost pressure in agriculture. The trend was the same in several other countries in Western Europe. This meant that the volume of certified seed for which licence fees were paid to plant breeders decreased. It was also difficult to increase the level of the licence fee. More expensive commercial seeds led to even more use of farm saved seeds. It was therefore an important objective for plant breeding companies and the seed trade to charge fees for farm saved seed when a revision of the UPOV Convention came into play in the late 1980s, introducing provisions on the use of farm saved seeds (see Chapter 4.5.4 of the Report). The most important argument was that free use of farm saved seed would undermine investments in plant breeding and that it would be more equitable if all farmers contributed to the funding of plant

breeding. In addition, larger farms systematically sold farm saved seeds, which was an infringement of the plant variety right even if it was difficult to prove. Therefore, under the 1991 UPOV Convention, the countries which have ratified this version of the Convention may establish the right of farmers to use their own seed provided that the interests of the breeders have been met, the so-called 'agricultural exemption, but not to sell their harvest of a protected variety for use as propagating material.



Status of memberships of UPOV as of 3 November 2021 (www.upov.int).

Currently, 76 states and the two intergovernmental organizations EU and OAPI (Organisation Africaine de la Propriété Intellectuelle) are members to UPOV, covering almost 100 countries in total. The vast majority of them have joined the 1991 version, but some have not updated their positions but remain affiliated with the 1978 version, especially Latin American countries. Below is an overview of the global situation regarding farmers' ability to use farm saved seeds. It does not claim to describe all aspects of the regulatory framework in the countries concerned, but focuses on the perspective of growers.

In the EU regulatory framework, all small farms are exempt from the obligation to pay a fee for farm saved seed. Smaller farms are defined as those producing less than the equivalent of 92 tonnes of cereals/year of the crops subject to the requirement (grain, legumes, oilseeds, etc.; see Chapter 4.5.4 of the Report). The fee collection systems work well in the Nordic countries, the Netherlands, France and the United Kingdom (even since leaving the EU) with fees equivalent to approximately 0.5 % of the harvest value/ha at current prices.

On the other hand, it is difficult to get large farmers in Germany, Eastern Europe, Italy and Spain to contribute to a system that could provide reasonable remuneration to breeders. In eastern Germany and parts of Eastern Europe, this is related to the very large units that existed in these countries and the Soviet Union before the fall of the Wall. They often produce their own seeds. These large farms remain largely with new owners. It is surprising that farmers' organizations in these countries have not realized that without a functioning system for collecting levies for the use of farm saved seed, the incentive for plant breeders to carry out a more advanced breeding of wheat and barley in particular

is reduced. The motive of the farmers appears to be that all additional fees should be limited because the profitability of crop cultivation is so low.

For maize, rye and rapeseed, it is different because hybrid varieties are used, unlike wheat, barley, oats and vegetables. Although the use of farm saved seeds for these crops are technically possible, the result would be very uncertain as hybrid varieties are not stable. Therefore, it is not attractive for growers to use farm saved seeds for theses crops. When the harvest of a hybrid variety is used as seed, the result is a large number of different offspring plants. Hybrid breeding is therefore more interesting from a financial point of view for plant breeding companies, making it more attractive to invest in these crops. In wheat and barley, the plant breeder can earn, from a combination of sales of certified seeds and fees paid for the use of farm saved seeds, approximatively 100 SEK/ha (approximatively EURO 10/ha). The revenue from the sale of hybrid seed in maize, rye and rapeseed is higher. In potato cultivation, commercial growers increasingly make use of certified seeds to reduce problems with the spread of viruses. Normally, however, farm saved seed is still used on a large part of the area for potato cultivation.

The same rules apply in the EU to varieties that include a trait that is patented, i.e. the possibility for farmers to use farm saved seed in all the crops is covered by the agricultural exemption. No horticultural crops are covered by the agricultural exemption. For most of the horticultural crops, however, this is not attractive with the requirements of commercial growers on seed quality and because seed production of these crops is highly specialized. Moreover, the commercial trade in seeds of horticultural crops is very large. However, anyone who wants to make use of the opportunity to take seeds of various vegetable plants in their gardens for their own cultivation in the coming years can do so without problems. This is defined as a non-commercial exploitation of a protected variety, which anyone can do in any country that is a member of UPOV.

Outside the EU, UPOV countries have introduced different rules on the agricultural exemption and on the private and non-commercial use of farm saved seeds. Definitions of important concepts can be highly variable, such as non-commercial use. This whole area is regulated not only by plant variety rights laws, but also by various other provisions and sometimes by patent laws. In many countries, it is also a very charged political issue. Regulating the use of farm saved seeds has therefore required compromises and adaptation to national conditions, following negotiations or consultations with stakeholders.

In many developing countries, the use of farm saved seed is exempted from the plant variety right. This applies, for example, to the 17 African countries that are members of the African Organization for the Protection of Intellectual Property Rights (OAPI). This means that all growers in these countries can use their own seed without restrictions except for fruit, forest trees and ornamental plants (Article 30(d) of the Common Plant Variety Rights Act). The same applies to growers in, for example, Egypt (Article 195 of the Law on the Protection of Intellectual Property Rights), China (Article 10 of the Chinese Plant Variety Rights Act), Mexico (Article 5 of the Mexican Plant Variety Law) and Vietnam (Article 190(1.d) of the Intellectual Property Rights Act).[1] India has applied for membership of the UPOV and has the corresponding provision in the current draft law. The country's current legislation on the rights of plant breeders and farmers allows any use of their own seed and there are no plans to change this.

In Canada, with its large-scale agriculture, there is also an exemption in the plant variety right for farmers to use their own seed without compensation to the variety owners (Section 5.3 (2) of the Canadian Plant Variety Law). This has meant that the sale of certified cereal seed and peas is modest in relation to the large cultivation and that the breeding of these crops takes place at public institutes. In order to stimulate commercial plant breeding in these crops, there is now work ongoing on introducing rules in its Plant Variety Rights Act that would provide an opportunity for variety owners to receive compensation for the growers' use of their own seed, even if there has been a strong opposition to this among growers.

The United States also has an exemption for the use of farm saved seed in its Plant Variety Rights Act (Sections 111 and 113), but it is also stated that growers may sell pure stock of a variety, protected with a plant variety right, provided it is marked that it may not be used as seed. The legislation also provides that the purchaser of pure stock of a protected variety from another grower and uses it as seed infringes the plant variety right. However, in the case of soybean, a large proportion of the seed used was formerly purchased from other farmers and only 15-20 % was certified and sold by the trade. With the development of GMO varieties of soybean, this changed drastically. When farmers purchased patented GMO seed, they had to sign a commitment not to us farm saved seeds but to respect the patents for these varieties. As a result, almost all soybean seed soon became certified and sold by the trade. Now it also became more interesting for plant breeding companies to develop new, and better soybean varieties. As a result, U.S. cultivation and export of soybean have increased while wheat cultivation and exports have decreased.

In Australia, the proportion of certified seeds is low and the agricultural exemption is included in the current legislation based on the 1991 UPOV Convention. When Australia in 1994 introduced a levy on trade of cereals, legumes and rapeseed with 15-30 SEK/tonne of the deliveries of protected varieties, it became interesting for the internationally leading plant breeders of these crops to start breeding programmes in Australia. The system was launched by the Australian state with support from trade and growers. One purpose was to support long-term export of crops that are of great importance to the country's economy.[2] Collected fees correspond to approximately 0.5 per cent of the harvest value and are distributed based on data from growers on the volumes sold of varieties with plant variety rights. Thanks to the size of cultivation, plant breeders' revenues are now roughly the same as in France, the country in the EU where the total royalty earning on cereals is the highest!

The countries of Latin America are party to earlier versions of the UPOV Convention, which means that in some of them farmers can use their own seed of varieties that have plant variety rights. In Argentina, on the other hand, a detailed provision on the right of farmers to use their own seed has been included in the legislation. But as soon as the GMO varieties are concerned, the situation has been different and growers have not been able to use their own seeds if they have valid patents.

As can be seen from the examples set out above it is, as a rule, stated in the national laws on plant variety rights that growers are entitled to exploit farm saved seeds of protected varieties as seed on their farm. The 1978 UPOV Convention does not provide for an agricultural exemption, but in the countries concerned, growers can still use their own seed under varying conditions. Many countries that have acceded to the 1991 UPOV Convention have not yet introduced an agricultural exemption but are able to do so at a later date. This would allow to open up to systems for collecting levies for the use of farm saved seed, at least on larger farms and for certain crops. Functioning such systems exist in several EU countries, the UK and Australia, while Canada is working to implement this. The regulatory framework for plant patents in the EU contains an agricultural exemption for the use of farm saved seed. For Sweden, this is already in place.

The purpose of the agricultural exemption provided for in the 1991 UPOV Convention was to clarify the right of growers to use farm saved seeds of important staple crops, while allowing the variety owners to receive a certain amount of compensation. The interests of farmers and breeders should be balanced. We are now seeing that such schemes have been put in place in the EU and a few more countries, but there is still a need to establish a system that allows the collection of fees for farm saved seed from larger farms in many countries.

If it were the case that the use of farm saved seed of important staple crops by subsistence farmers were to be restricted by plant variety rights, this would be ethically difficult to defend. But that is not the case. In fact, many small farmers prefer to buy new hybrid seed of, for example, rice, maize and vegetable crops, or GMO seed of cotton or

eggplant each year, simply because it pays off with the higher yields and lower production costs they can expect. If these seeds were no longer more profitable, they would choose to use their own seed of traditional varieties.[3]

The conclusion of the examination above must be that the farmer's right to use his own seed is satisfied and that a certain levying of fees for this use is necessary to finance the continuation of plant breeding.

Are patents on plants and plant variety rights ethically justifiable?

Is it ethically justifiable that some people can claim ownership of natural resources? Are they not the common asset of humanity? Yes and no. It is ethically justifiable whether it is a matter of protecting an *invention* in the form of a new character that has been added to a plant by a biotechnological method or the development of a new plant variety. There is no fundamental difference between a technical invention, a literary work or an artistic subject matter. The plant breeder, inventor, author or artist has created something that did not exist before and society should, of course, protect such creative activities by ensuring that compensation can be paid. It is equally obvious that a *finding* that a plant species naturally has a certain characteristic, such as a high level of vitamin C, should not be patented.

There are also other ethical questions that should be asked and answered. Would it be ethically justifiable not to contribute to the development and use of urgent research results in society? This is the consequence of the inventor/creator, in this case the plant breeder, not being given the opportunity to act. Why should the plant breeder work without compensation?

The European Commission has a dedicated advisory group, the European Group on Ethics in Science and New Technologies (EGE), which advises the Commission on policy issues on how ethical aspects, societal development and constitutional rights are affected by science and technological development. The group was established in 1991 and currently has 15 prominent researchers as members. EGE published a report in March 2021 on its approach to gene editing applications, Ethics of Genome Editing.[4] This article deals with the application of the new technology to humans, as well as to animals and plants. In its recommendations on plants, EGE writes, among other things, that it is important to evaluate the costs and benefits of gene edited crops at the system level, to explore possibilities to trace such crops and to stimulate a public discussion on the technology. In general, EGE is in favour of applications of gene editing to plants while being more restrained with regard to animals and humans. The only red line that is definitely drawn up is its application to human germ cells unless it concerns serious, hereditary diseases that cannot otherwise be cured.

In a previous report (Opinion on ethical aspects of patenting inventions involving human stem cells, 2002), EGE concluded that diagnostic, therapeutic and surgical methods in medicine cannot traditionally be patented. The same applies to processes involving human embryos under the 1998 EU Directive on the protection of biotechnological inventions. On the other hand, EGE considered that it should be possible to patent inventions based on modified human stem cells, but that the patent review should include an ethical evaluation of the suitability of the specific case.

The Nagoya Protocol (a protocol to the UN Convention on Biological Diversity) was conceived in response to the possibilities for patenting biotechnological innovations (see Chapter 8). Its Article 5 states that indigenous and local communities should receive a fair remuneration when the genetic resources they have taken to preserve and develop are used to develop new plant varieties or plant-based products. In the international negotiations that followed the protocol, it has been established that when the possibility of patenting an invention is based on the exploitation of a certain genetic resource, the company that collects the patent must also pay a compensation for this.

However, this does not apply where genetic resources are exploited in plant breeding since a variety protected by a plant variety right can be used to produce new varieties without any restriction. Discussions continue on how to calculate a fair remuneration in these cases and how it is to be paid collectively by the plant breeding industry or the

countries concerned. Another ethical question that arises in this context is whether it is justifiable that the compensations granted for patents or plant variety rights remain with the heads of state and government of recipient countries without benefiting indigenous and local communities in the regions concerned.

The conclusion is that it is reasonable for the plant breeder, who creates something new, to be able to protect his invention as intellectual property. Another conclusion is that the Nagoya Protocol is complicated to implement and that efforts should be devoted more to ensuring that the compensations end up right and less to discuss intellectual property rights.

Do only large companies benefit from patents and plant variety rights?

It is a simplification to say that only large companies benefit from patents and plant variety rights. The majority of applicants for plant variety rights for new varieties are SMEs, individuals or institutes. They account for about 90 % of all applications and 60 % of all plant variety rights valid in the EU (see Chapter 3.3) are listed in these categories. In some cases, small breeders of fruit and other horticultural crops may nevertheless waive the protection afforded by the plant variety right, depending on the overall costs of protection in crops where propagating material is sold in small volumes and with low licence levels.

There are differences between patents and plant variety rights. It is the large, global companies that hold most of the patents dealing with GMO plants, but there are also leading universities and institutes that have important patents.

It is unequivocally that initially it was only the really big companies that could commercially exploit the opportunities offered by patents for genetically modified or GMO plants. It was linked to the fact that less than ten large multinationals initially acquired and collected the basic patents on technology and the first developed properties. After a few years, Monsanto came to have a completely dominant patent portfolio in the field. This meant that the opportunities for small and medium-sized enterprises to exploit the technology were blocked. This also contributed to the high costs of developing the necessary information package and test protocols to gain market access, not least for imports into and cultivation in the EU. The EU's very rigid regulatory framework has benefited large global companies and hampered the opportunities for smaller players to participate in development.

In the 1990s, a major structural change in the plant breeding industry started with acquisitions and mergers. It was driven by Monsanto, but other global plant protection companies that wanted to enter the market for GMO seed were also involved. The merger process led to three global companies now dominating the market for seeds: Bayer that bought Monsanto; Corteva, after the merger of DuPont and Dow Chemical; and state-owned ChemChina that bought Syngenta. These three are followed in size by BASF, French Limagrain and German KWS.

The OECD published a report in 2018 on the concentration of seed and plant breeding markets, its background and the relevant requirements of authorities. The report states that the market for GMO properties is dominated by few operators, unlike seeds in general, but also that patents on new technologies such as CRISPR/Cas9 and its applications are dominated by universities. The report recommends avoiding unnecessary regulatory barriers for new technologies, facilitating access to genetic material and licensing of technology, and stimulating both public and private R & D.

It was only when the basic patents were no longer in force that it became possible to use the first generation of GM technologies to develop improved crops for developing countries. A typical example is Bt-resistant eggplant for Bangladesh that could be developed when the basic patents on the technology had expired. Eggplant is a staple crop for many poor subsistence farmers in Bangladesh and is an important part of the household of the country. With Bt resistance the harvests became much safer and, above all, these farmers did not have to use the back sprayer in the field

once a week. Another example is the development of Bt-resistant cowpea for Nigeria and other countries in West Africa, where cowpea is an important staple crop, and potatoes resistant to late blight in Rwanda.

With new gene techniques like gene editing, it is different. Hundreds of patents on the technologies and their use have been applied for and in many cases already granted. What differs from traditional gene modification is that now a large number of universities, research institutes and start-up companies are responsible for the applications.[6] In Sweden, the regulatory framework says that it is the individual researchers who own the results of their research while in the vast majority of other countries it is the universities and institutes that own the results of the research. This means that there are better conditions for the individual researchers to commercialize their results. SolEdits[7] and SweTree Technologies[8] are examples of this.

The plant variety rights are spread across 100s of companies, as described above. For small and medium-sized plant breeding companies, it is now a matter of having access to the skills necessary to deal with these complex issues and knowing which patent right holders they need to enter into agreements with in order to take advantage of the new technologies. Euroseeds has collected information on plant patents in a dedicated open database.[9] The spread of these patents does not make it possible for the large multinational companies to dominate the development of gene-edited crops.

But the regulatory framework for the technology itself continues to be an obstacle that can make this financially impossible for many companies. As many non-EU countries have already taken decisions to handle gene edited new plant varieties in the same way as traditionally bred varieties, this problem does not exist in many non-EU countries.

The ongoing process within the EU with discussions on possible regulatory changes to enable the development and use of genome editing and other new breeding technologies will determine the opportunities for SMEs in the EU. This is a matter of destiny for agriculture in the EU, as also highlighted in the Ekvad report (see chapter 9.6).

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THE ROYAL SWEDISH ACADEMY OF AGRICULTURE AND FORESTRY

The Royal Swedish Academy of Agriculture and Forestry • Drottninggatan 95 B, P.O Box 6806 • SE-113 86 Stockholm • SWEDEN
Tel + 46 8 54 54 77 00 • akademien@ksla.se • www.ksla.se