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Seeds and intellectual property

SEMAE Societal Issues Committee
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The SEMAE societal issues committee

Created in March 2020, the Committee on Societal Issues (CES) has the mission of helping the seeds and plants inter-profession to “carry out the transformations necessary to face new challenges and new problems. Its work therefore aims to
enlighten and challenge SEMAE administrators on certain themes, to change the way the inter-profession views society and, as a corollary, change the way society views it
on SEMAE. » (Extract from the CES internal regulations).

The following personalities sit today on the CES intuitu personae: Anne-Françoise ADAM-BLONDON, Denis COUVET, Michel DRON, Virginie DURIN, Jean-Christophe GLASZMANN, Pierre-Benoit JOLY (President), Marcel LEJOSNE, Antoine MESSEAN, Jean-Martial MOREL, Lorène PROST, Alexandrine REY, Anne-Claire VIAL. Vincent DELAUNAY is general secretary.

In 2022, the CES issued its first opinion on the theme “Seeds and agroecological transition”.1

To prepare this opinion, the CES interviewed experts on the issue of intellectual property, researchers in genetics and plant improvement, representatives of companies in the sector, representatives of regulatory bodies.2 The CES would like to thank very sincerely to all those who took their precious time to help them better understand this complex subject and explain their positions.

[1] https://www.semae.fr/comite-des-jeux-societaux/

[2] See the list of hearings in appendix 1.

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Executive summary and recommendations

Executive summary

• Will we succeed in adapting agricultural and food systems to climate change while preserving biodiversity and natural resources? Scientific expertise leads us to seriously doubt this. Faced with these threats and these challenges, it is essential to mobilize all energies, all research and innovation capacities, in order to increase the diversity of agricultural systems: intra- and interspecific diversity, diversity of production systems, diversity agricultural landscapes, diversity of actors. Faced with these threats and these challenges, diversity in all its forms constitutes the best insurance, the key to robustness and therefore to the capacity to adapt. While the dominant paradigm of distinct, homogeneous and stable (DHS) variety has led to adapting the growing medium to the seed, in many cases it will be necessary to do the opposite: adapt seeds to the characteristics of agroecosystems. Greater integration of varietal creation and system agronomy is essential to bring about such a change and succeed in the agroecological transition. In this context, intellectual protection in the field of varietal selection must support increased and diversified varietal creation activity in the service of

all cultivation systems and not slow it down.

• With genetic engineering techniques, the patent of invention entered the world of seeds. This transformation has been one of the drivers of corporate concentration which has reached worrying levels. This is demonstrated by the situation in the United States where the USDA, Ministry of Agriculture, considers the concentration in market segments marked by widespread use of GMOs protected by patents (corn, soy, cotton) to be very worrying. Europe has until now been relatively protected from this on the use of GMOs in cultivation legislation which prohibits the *de facto* and from the movement due to the embargo of patenting of plant varieties.

• For the vast majority of European stakeholders involved, the Plant Variety Certificate (VOC) must remain the pillar of the protection of the intellectual property of plant varieties, but this VOC is being weakened:

o The VOC allows open innovation, that is to say which results from an intensive exchange of knowledge and genetic resources between a diversity of actors, and it has largely demonstrated its effectiveness. This system is astonishingly modern for promoting combinatorial innovation which is key for areas with high information content. In such fields, it is in fact the original combination of a set of elements which gives the value of the variety.

Also, it is essential to prevent patents on traits from limiting the possibilities for creating original combinations. o Over

time, the VOC has evolved to adapt to technological developments.

In particular, the UPOV Convention of 1991 introduced the concept of essential derivation. The protection granted by a VOC extends to essentially derived varieties (EDV), which makes it possible to take into account the possibilities of more rapid parasitic differentiation with the evolution of techniques. However,

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this conceptual innovation has not been really worked on, in particular to operationalize the concept of “essential character”.

- Although in Europe varieties as such are not patentable, they may be dependent on patents that claim genetic characters or traits. This interference between patent and VOC has been the subject of much attention. In 2016, France introduced into law a ban on patenting so-called native traits (ie which can be introduced by crossing/selection techniques). This provision reinforces the rule of exclusion to patentability. This exclusion has been included in the technical regulations of the European Patent Office (EPO). However, this provision is not systematically applied as evidenced by numerous examples. In addition, it places the burden of proof on the company which does not hold a patent. As a result, genetic resources that are present in countries and obtained by crossing and selection find themselves confiscated by patents.

This situation also worries countries holding genetic resources and has relaunched debates at the Convention on Biological Diversity on the opening of sequence data and the sharing of benefits linked to the use of this knowledge.

- In this context, many actors consider that it is very difficult to ensure freedom to operate () when creating a new variety because: (i) the regulatory framework is vague and subject to interpretations miscellaneous; (ii) patent offices do not have the skills to strictly apply the rules of exclusion to patentability and (iii) access to information on the field of patents is complex and expensive. Industry players speak of a “patent thicket” or even a “minefield” to describe this situation. Various private initiatives have been taken to try to resolve the problem of information and that of access: (i) the PINTO database from Euroseeds where companies owning patents declare the traits and the plants that are dependent on them ; (ii) platforms (ILP- for vegetable seeds) and (ACLP- for large seeds). The PINTO database aims to ensure the transparency of information on the scope of patents essential for the FTO. The platforms facilitate access: participants agree to grant non-exclusive licenses on their patents under fair, reasonable and non-discriminatory (FRAND) conditions. However, these private law systems offer no guarantee in the medium and long term. Furthermore, it is very likely that with technological evolution, the stacking of characters will become systematic. Already, many GMO varieties are modified for two or more traits. Stacking patented traits in the same variety will unbearably increase uncertainty and transaction costs.

Freedom to operate

International Licensing Platform

Agricultural Crop Licensing Platform

As a result, the principle of free access to genetic resources is strongly threatened.

- The last forty years have seen an extension of the field of patentability which leads to a restriction of the space for pre-competitive and public research.
  Observation applies as much to fundamental scientific knowledge as to living organisms. Even if resistance has been organized in Europe and other parts of the world, the patent of life has progressed considerably, imposing in the

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living world of designs borrowed from the world of mechanics and chemistry.
For philosophical, pragmatic and political reasons, the CES considers that it is essential to challenge this development and restore a property regime which truly guarantees free access to genetic resources as a source of variability for creation. new varieties.

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Recommendations

- Integrate new genomic techniques (NTG) European discussions on the issue of intellectual protection into the regulations of

The trajectory of NTG will depend on the contexts of use. Property regimes which oppose the principle of exemption of the breeder and the privilege of the farmer will have strong implications in terms of concentration of the sector, which could lead to a reduction in the diversity of cultivated plants and increase the difficulty of adaptation from our systems to new climate regimes. In order to have an informed political debate on the impacts of NTG, the CES recommends integrating the question of intellectual property into discussions on the regulation of NTG.

- Reinstate the principles of VOC at the heart of intellectual property of plants

Given the importance of the issues, the intellectual property regime for plants must be the subject of an ambitious policy, aimed at maximizing diversity in all its forms. After hearing from numerous stakeholders, the CES considers that plant variety law, because it is based on a principle of open innovation, is particularly suitable. The CES further considers that the multiple attempts to reconcile patents and VOCs considerably complicate the system, do not provide the necessary security for operators and inevitably lead to a questioning of the breeder's exemption and the farmer's privilege. The CES calls for collective awareness and an ambitious political initiative that will put the VOC principles at the heart of the plant ownership regime. In particular, the CES recommends:

- Strictly apply the exclusion of variety protection by patent and extend it to plants and the characteristics they contain, the exclusion of the variety as such being too narrow to be effective. In other words, affirm a new principle of non-cumulative protection between the patent and the VOC.
- Working in law on the notion of agroecological exception.
- Limit invention patents to technologies and prohibit patent protection of genetic characters, whether they are considered native or not. This provision results from strict implementation of the ban on double protection
  extended as we propose above.
- Immediately, given the existence of patents on traits, broaden the provision of compulsory licenses by removing the “considerable economic interest” condition.

- Also immediately, generalize at European level the exemption from
  breeder in patent law (found in French law in particular) and extend it so that it allows the reuse of genetic diversity, under the same conditions as what is permitted by the VOC, in other words without obligation to negotiate a license with the patent holder when the patented element is still present in the new variety.

- Deepen the study of the methods of implementing the concept of essential derivation. Work on the notion of “essential character” in order to find

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compromise solutions making it possible to remunerate the work of invention on traits while maintaining the breeder's exemption.

- Strengthening a public knowledge infrastructure

Strengthening public knowledge infrastructures must be essential in areas where public investment has been restricted for a long time. US government authorities have recently become aware of this. In France (and to a lesser extent in Europe), the situation is less degraded, but it is fragile. It is necessary to strengthen the knowledge infrastructure by developing a set of technologies, methods and genetic resources in an open science framework, in support of the agroecological transition and adaptation to climate change:

- Set up research and development operations in areas with varietal selection of minor species, proof achieved pre-breeding , of concept on risk (“risky” traits or types of varieties, etc.). This can be in part through public-private partnerships that are as broad and inclusive as possible, avoiding bilateral collaborations. In this context, collaboration between public laboratories and companies favorable to VOC will make it possible to document the selection processes for new plant varieties, including when they are based on genetic modification techniques, and thus to limit the filing of patents thanks to scientific publications exposing the research process and the results obtained.

- Develop royalty-free technologies to support varietal selection. As part of this reflection, the dissemination of a scientific publication in a journal accessible to the public can be considered as a solution for disseminating scientific knowledge since a patent filing would be considered blocking innovation and research, this which is the case for patents relating to genes and characteristics in particular “native”. This strategy can also make it possible to maintain technical knowledge in the public domain, provided that the invention is sufficiently described.

- Contribute to the creation and maintenance of common goods: genetic and genomic resources, methodologies for assessing risks and agronomic, technological and environmental value (VATE).

- Establish sustainable and efficient financing arrangements for all of these activities. These financing methods will have to be evaluated in the short term as well as in the long term in terms of their capacity to make agriculture more resilient.

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1 Reference framework and values

The CES opinion is based as much as possible on objective, verified and sourced information. This is not an opinion of specialists, but an opinion produced by an inter and transdisciplinary committee having been informed by a series of interviews with experts on the question of intellectual property, researchers in genetics and plant improvement, representatives of companies in the sector, representatives of regulatory bodies. 3

While it is essential to rely on established facts, such an opinion cannot claim perfect objectivity. It responds to a concern and its preparation was influenced by a point of view and a perspective which led the CES in its investigations and in the interpretation of complex, uncertain and ambiguous problems.

It is therefore necessary to clarify this perspective by explaining the reference values which are shared by the CES:

- The agroecological transition and strengthening the robustness of agriculture - particularly its adaptation to climate change- must be the priorities for the development of plant varieties.
- Diversity constitutes an essential issue, the best insurance in an uncertain world: diversity of agricultural landscapes, diversity of cropping systems, diversity of cultivated species, diversity of genetic resources, diversity of seed actors.
- While the dominant paradigm of the distinct, homogeneous and stable (DHS) variety has led to adapting the growing medium to the seed, in many cases it will be necessary to do the opposite: adapt the seeds to the characteristics of the agroecosystems which they- same are diverse.
- Intellectual property rules must encourage innovation while maintaining access to genetic resources and technologies. Intellectual property must enable open innovation, that is to say innovation made possible and accessible to the greatest number of people through the intensive exchange of knowledge and genetic resources between a diversity of actors.

3 See the list of hearings in appendix 1.

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2 Problems and questions

2.1 Context elements

In the world of seeds, intellectual property has been governed since 1961 by the Plant Breeding Certificate or COV4 (see box 1). The COV stipulates that if the breeder can oppose his right to the marketing of his variety, it can be used freely to create a new variety. This is called the breeder's exemption. 5 Another important characteristic, the VOC authorizes the farmer to reproduce his seeds. This is called the farmer's lien.

In the 1970s, advances in molecular and cellular biology led to the possibility of using transgenesis in bacteria and therefore the possibility of conducting, in an oriented manner, genetic recombinations. These recombination techniques in vitro have led certain researchers to consider that their work could lead to inventions falling under patent law. Thus, the recombinant DNA technique of Cohen and Boyer (1973) was protected by a patent operated by Stanford University. The question of patent protection of living organisms has been the subject of much debate. Concerning plant varieties, Europe and the United States have taken different trajectories. In the United States, industrial patents () complemented the VOC () and the plant patent () designed for vegetatively propagated species and which has existed since 1930. In Europe, patent law included an exclusion clause (Article 53b of the European Patent Convention) stipulating that plant varieties and animal breeds cannot be protected by patent. This provision was included in the European directive on the patent protection of biotechnological inventions (Directive 98/44/EC). While plant varieties as such cannot be patented, inventions relating to plants can be. For the first generation of GMOs, these mainly concerned herbicide tolerance and insect resistance genes. The varieties in which these characteristics are expressed fall under the dependence of patents (Monsanto/Bayer, etc.). Given the moratorium on the use of GMOs for agricultural production in Europe, this dependence has not had direct effects. On the other hand, this question of dependence resurfaces today with the evolution of genome editing techniques. Assuming that the use of these techniques were intensive, in what way could the rules of the intellectual property game affect access to techniques and genetic resources?

Utility Patent Plant Breeder's Right Plant Variety Patent

de facto

The complexity of intellectual property law rules prevents a good understanding of the implications in terms of access to technologies and genetic resources. In order to contribute to the debates, the CES offers a critical discussion of some frequent assertions (Cf. Box 2).

4 The principle of non-patentability of plant varieties is provided for in Article. L. 611-19, 2° of the Intellectual Property Code.

5 This principle arises from Article 15 of the International Convention for the Protection of New Varieties of Plants (UPOV) and is found in Article L 623-4-1-I-3° of the IPC.

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Box 1. Intellectual property on plants for beginners

The VOC and the patent are two intellectual property rights whose foundations and effects are very different. The VOC can be compared to copyright: it protects the variety (the book) as an original combination of genetic characters (the words). Like words in copyright, genetic traits are freely available to produce new varieties (new books). This principle is the basis of the breeder's exemption, the true hallmark of the COV.

The patent protects an invention. The scope of what is protected by a patent is defined by the claims. Unlike the European situation, in the United States, the variety can be protected by a patent. The patent can therefore claim the variety as such, a modified genetic trait, a method of identifying a character, or a method of selection. None of these items may be used without the permission of the patent owner.

Type of property right	Criteria	Claims	Farmer's privilege	Coach's exemption	Research exemption
Patent of invention	Novelty, Invention, Industrial application	The revendications are function of inventive activity	No	No	Limited
Certificate of Obtainment Plant (VOC)	Distinction, homogeneity, Stability (DHS)	The new variety	Yes	Yes	Yes

In Europe, the variety as such cannot be protected by patent (Article 53b of the European Patent Convention).6 However, an invention patent can claim a new trait as well as microbiological processes and technical processes or not essentially biological, provided that the invention is not limited to a plant variety. In this case, the varieties are dependent on the patent. For example, the owner can object to the use of all plants that use a patent-protected trait. Thus, although the variety as such is not patentable, varieties may be subject to patents which claim characteristics. Characters (words) may be protected by patents, which may preclude the free use of the varieties (books) in which they are used.

Let us add that, still in Europe, selection methods are in principle not patentable. They are in fact considered as essentially biological processes for obtaining plants and animals which are also excluded from the patent by article 53b. However, the definition of “essentially biological processes” is very fragile. With technical advances, particularly in molecular biology and the development of marker-assisted selection techniques, the frontier has been fiercely contested.

Compared to the first techniques used to insert genes, the approaches have evolved considerably. In 2007, the European Commission set up a working group to study a set of plant breeding techniques, N(P)BT (for

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[6] Article 53 of the European Patent Convention:
“European patents are not issued for: a. inventions whose
commercial exploitation would be contrary to public order or good morals (…);
b. plant varieties or animal breeds as well as essentially biological processes for obtaining plants or animals, this provision not applying to microbiological processes and the products obtained by these processes;

vs. methods of surgical or therapeutic treatment of the human or animal body (…). »

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New (Plant) Breeding Techniques) which allow you to obtain plants with new characteristics faster and more accurately.

Among NBTs, mutagenesis techniques directed by oligonucleotides and/or by nucleases are called genome editing techniques, by analogy with text editing because they make it possible to replace one or more bases (letters) of the genome sequence. in a targeted and deterministic manner. The most promising genome editing techniques involve site-directed nuclease enzymes (or “SDN” according to the English acronym). They have the ability to cut DNA strands, hence the expression Site Directed Nucleases “molecular scissors”. There are four families of directed nucleases: meganucleases, zinc fingers (ZFNs), TALENs and CRISPR/Cas type nucleases.

The CRISPR-Cas97 system was developed by researchers Emmanuelle Charpentier and Jennifer Doudna at the end of the 2000s, an invention for which they were awarded the Nobel Prize for Medicine in 2020. The system has the advantage of being simple to use. quick and inexpensive to use.

The prospect of massive application of these techniques - let's call them NTG for "new genomic technologies" - has led different bodies to work on their impacts.
Without concern for completeness and limiting ourselves to France, we can cite the following reports, examined in the preparation of this opinion:

- INRAE-CIRAD-IFREMER8 Ethics Committee
- French Academy of Agriculture9
- CTPS10
- Academy of Technologies11
- Economic, Social and Environmental Council (CESE)12

At the time of writing, the Union Française des Semences (UFS) adopted a new position on intellectual property (October 2023).

For the CES, it is necessary to include reflections on the intellectual property of seeds within the framework of the agroecological transition. The imperative of the agroecological transition requires us to think differently about the objectives, organization and functioning of the seed system.13 This is essential to respond to global challenges.

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[7] CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats and Case CRISPR-associated . In this system, small RNAs guide the Cas9 nuclease to the site of the genome to be cut.
[8] https://www.inrae.fr/actualites/analyser-questions-ethiques-politiques-posees-ledition-du-genome-vegetaux
[9] https://www.academie-agriculture.fr/publications/publications-academie/avis/avis-reecriture-du-genome-ethics-and-trust
[10] https://www.geves.fr/wp-content/uploads/Rapport-du-CTPS.pdf
[11] https://www.academie-technologies.fr/publications/avis-sur-les-nouvelles-technologies-genomics-applied-to-plants/
[12] https://www.lecese.fr/travaux-publies/les-expectations-et-les-jeux-societaux-lies-aux-nouvelles-techniques-genomics
[13] For an explanation of this position, we refer to Opinion number 1 of the SEMAE CES: https://www.semae.fr/comite-des-jeux-societaux/

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and to develop the capacity of agriculture to adapt to environmental fluctuations, the first effects of which we are already seeing with climate change.

2.2 What is the problem with patents in the world of seeds?

In the world of seeds, the issue of intellectual property protection through patents is not new. Defending the breeder's exemption and balancing VOC and patent law are constant concerns. The CES considers that the breeder's exemption, although defended as a principle by most players in Europe14 , is currently threatened by a series of concomitant developments: (i) the concentration of companies and the locking of patents; (ii) the possibility of blocking the free use of genetic resources by multiplying patented characteristics in the same variety; (iii) the fragility of exemptions to patentability intended to limit patent rights in living things.

2.2.1 A problem of business concentration and lock-in

The phenomenon is well known: over the last twenty years, the seed industry has been the subject of a phenomenon of industrial concentration of exceptional magnitude.
Today, the two leaders (Bayer and Corteva) represent more than a quarter of the world markets; the first six around 40%.15 Given the very strong segmentation of seed markets, concentration should be observed market by market. For example, for the corn seed market in the United States (one of the largest segments internationally, all species combined), the first two (Bayer and Corteva) represent 72% of sales.16 We should also take take into account the concentration of the “market” for characters. According to the USDA (2023), the traits held by Monsanto were used in the United States on 95% of transgenic soybean areas, 81% of corn and 79% of cotton.

The situation is such that the OECD and the USDA have requested reports on the risks caused by this concentration.

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14 See for example the position of the Union Française des Semenciers (UFS): UFS position on the property intellectual , October 2023.

15 There are no official statistics regarding the “global seed market”. This notion is itself questionable given the very strong segmentation of markets according to species and geographical areas. However, given that the major leaders measure their activities at this aggregate level, it is necessary to assess their weight in relation to this “global market”. Bonny (2017) discusses the different accessible sources. The valuation of the “global market” is US$60 billion in 2016. We consider the market to be US$70 billion in 2022. To estimate concentration, we use the data in Table 1.

Bonny, Sylvie (2017). “Corporate Concentration and Technological Change in the Global Seed Industry” Sustainability 9, no. 9:1632. https://doi.org/10.3390/su9091632

16 MacDonald, J.M., Dong, X., Fuglie KO (2023). Concentration and competition in US agribusiness ,Washington DC: USDA, Economic Information Bulletin, Number 256, June 2023, p.11.

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Table 1. Main groups in the seed sector

	Seed turnover global (2022 in US$ billion) 9.7	Main sector of activity
Bayer	7.3	(Chemistry)
Corteva	2.5	(Chemistry)
Syngenta	1.3	(Chemistry)
BASF	1.3	(Chemistry)
Limagrain	1.1	(Seeds)
KWS		(Seeds)

Source: Annual reports (Source: https://scienceagri.com/9-worlds-largest-seed-companies/)

The concentration of intellectual property is also very worrying. For the United States, the USDA identified 17,208 industrial patents relating to plants filed at the USPTO between 1976-2021. The first three groups (Corteva, Bayer and Syngenta) hold 71%.
[17]

Specifically concerning the CRISPR-Cas9 technique, the original patents (or basic patents) were filed by the inventors (Charpentier, Doubna, etc.) and the institutions with which they are affiliated (UC Berkeley, MIT/Broad Institute, Vilnius University, University of Vienna…). The battle over patents is still ongoing at the end of 2023. However, large groups like Corteva and Bayer have acquired licenses - often exclusive - for the use of genome editing techniques on plants. Corteva, in particular, has formed a pool of licenses on the patents held by these major research institutions. The basic patents (patents on editing technologies) are supplemented by numerous application patents on plants, both on the development of techniques and on traits.

This situation generates many questions in different circles, and particularly in seed companies which need access to varietal diversity to create new varieties. At the heart of these questions is the subject of cohabitation between VOCs and patents in the field of varietal creation. Based on the interviews we conducted with a wide range of stakeholders, we note that this cohabitation between two intellectual protection systems and two very different industrial cultures is the source of real tensions.

This cultural dimension can explain the too many errors of assessment which lead patent offices to accept certain patent applications (Cf. box 2).
The USDA report highlights that USPTO patent examiners do not have the expertise to properly understand the novelty and inventiveness of some patents, leading to the acceptance of patents that should not be accepted. be. 18 Certainly, opposition procedures can play a regulatory role. But this creates real uncertainty which can dissuade certain companies from investing in these techniques or using certain varieties in their selection scheme. Several interlocutors emphasized this problem which risks becoming even more amplified with the unitary European patent and

[17] Ibid, p.12.
18 USDA (2023). More and Better Choices for Farmers: Promoting Fair Competition and Innovation in Seeds and Other Agricultural Inputs , A report directed by President Biden's Executive Order Number 14036: “Promoting Competition in America's Economy”, Washington DC: USDA, p.4.

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the establishment of the single jurisdiction which will inevitably be in the dominant framework of the European patent culture. This cultural dimension is coupled with a real skills challenge. Only large companies can invest in the legal skills needed to defend their intellectual property interests. From this point of view, those with a long history in chemistry have a real advantage over more traditional seed companies.

To this cultural dimension is added an agronomic and economic dimension. Within the framework of the VOC, even if everything is not simple, the breeder of new varieties can use varieties protected by VOCs to introduce new characteristics and thus continue genetic progress, without requesting a license or payment. royalties. As an example, we can mention a company which would have introduced a gene for resistance to a virus in a variety of pepper that we call A. Suppose that this resistance gene is circumvented in another country. Another company, present in this country,

may be interested in the organoleptic properties of this variety and want to introduce an effective resistance gene into its territory. In the context of the COV, it uses A in its selection scheme to create a new variety, B, independent of A. The number of cases corresponding to this example is endless, which shows the interest in having access to everything relevant genetic material to generate genetic progress. If variety A is dependent on a product patent, variety B cannot be used commercially without the permission of the patent owner19 . The variety thus protected can then only be improved by the company which protected it, if it so decides. This same company can potentially grant a license to the company that creates variety B but there is no obligation to do so. The experience of the first generation of GMOs shows that the level of royalties reached 4-5% of turnover. For most seed companies, this is the amount of profits that can be transferred from the variety B company to the variety A company. Experience shows that this is the case when the company that owns the patent is a competitor of company B for the sale of the variety. Furthermore, access negotiation generally assumes (see in particular our interviews) that the breeder-applicant gives access to the information and to any innovation generated by the patent, which allows the patent owner to capture the knowledge generated .

2.2.2 Blocking the free use of genetic resources

i) Endangering access to genetic resources

A first risk is linked to the digitalization of genetic resources. The increasing production of genomic sequences from collections of genetic resources provides access to data on a very wide diversity of alleles at the same genetic locus, causing different phenotypes. Holders of genetic resources fear that the use of this data to create new varieties of genome editing techniques will completely replace the use in crossbreeding of the genetic resources themselves, thus making it possible to circumvent via the Nagoya principles on access to genetic resources and benefit-sharing rights. Even more, the use of IT tools and now artificial intelligence can make it possible

19 Unless the patented gene is deleted, which is not without difficulty with the stacking of genes (Cf. 2.2.2).

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to identify the link between the sequence and function of a gene, thus facilitating the filing of a patent.

The risk is therefore that the combined development of genomic technologies and patent law will call into question the balance of the Nagoya Protocol, which conditions access to genetic resources on the sharing of benefits arising from their uses.

ii) A blockage linked to the multiplication of patented characteristics in the same variety

French patent law provides for a form of breeder exemption in patent matters21 but it is limited. Indeed, the breeder who wishes to exploit the new variety without having removed the patented element or without having verified that the latter no longer exercises its function, must obtain the agreement of the patent holder.

Now let's assume a scenario of massive use of NTG. With the draft European regulation of July 2023 on the exploitation of edited plants, such a scenario is indeed possible. We may very well find ourselves in situations where a variety will be obtained using three different gene introduction/manipulation technologies making it possible to introduce fifteen edited recombinant genes. In such a case, the stacking of characters makes it impossible to delete them, causing the created variety to fall definitively within the scope of patents. The only possibility for the dependent company is to negotiate licenses with the patent holders, which poses two prohibitive problems. On the one hand, the cumulative royalties (4 to 5% of turnover generated per patent) would be astronomical. On the other hand, such a situation would generate unbearable uncertainty for the companies concerned. How to negotiate with different patent holder companies? Given the information problems, how can we be sure that the varieties we wish to use in a selection scheme are free of rights and that we have freedom to operate (or FTO)?

Aware of these difficulties and the importance of the transaction costs they generate, companies and certain associations (notably EuroSeeds) have created systems to guarantee access to the results of their own efforts (FTO via the PINTO database) and to facilitate access to licenses (platforms -ILP-, which is approximately ten years old, and -ACLP-, which was created more recently).

Concerning freedom of operation (FTO), this means that any actor engaging in a research project is assured that they will have the freedom to use the results of their efforts. However, access to information is not easy given the number of patents and the time between filing, publication and grant. For breeders, the situation can be similar

20 See for example:
Scholz, AH, Freitag, J., Lyal, CHC And al. Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. https://doi.org/10.1038/s41467-022-28594-0 Nat Common 13, 1086 (2022).
Sherman, B. and Henry, RJ Access to biodiversity for food production: Reconciling open access digital sequence information with access and benefit sharing. 14, 701-704 (2021). https://doi.org/10.1016/j.molp.2021.03.003 Molecular Plant

21 Article L613-5-3 of the Intellectual Property Code provides that “The rights conferred by articles L. 613-2-2 and L. 613-2-3 do not extend to acts carried out with a view to creating or discovering and developing other plant varieties.”
Opinion No. 2 of the SEMAE Societal Issues Committee (CES) - The opinions of the CES only bind its members, nor SEMAE, nor their organizations.

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to one which limits free access to genetic resources. To overcome this problem and respond to the need for information and transparency, the European Seed Association created the PINTO database (to provide access to information on commercial varieties Euroseeds Patent Database and Transparency On-Line)[22] dependent on patents. Such information is valuable because it is not easy to identify dependent varieties. However, if the PINTO database can play a beneficial role, its impact will remain limited because it is a voluntary database with no deposit obligation. There is no protective mechanism for the dependent user in the event of absence of information in the database at the time use is initiated. On the PINTO homepage, Euroseeds warns that the database does not provide any guarantee of freedom to operate:

> "PINTO not and will never be an exhaustive and fully correct and date is to up granted patents and, inventory of the varieties concerned by pending gold ace has consequently, cannot serve searches." tool for complete FTO (Freedom to as a Operate)

Concerning the platforms, ILP requires becoming a member to be able to benefit from a license and thus give access to its own patents. Interestingly, this platform imposes on its members the exemption of the breeder by contractual means, which allows access to genetic diversity in the field of patents. However, these systems only constitute centers for the exchange of information and they do not seem to be able to provide regulation. In fact, each licensee sets its licensing conditions and access is not free23. In addition, certain multinationals which hold the largest patent portfolios choose not to join this system.

Although corrective measures such as PINTO or the ILP or ACLP platforms are interesting, they do not provide guarantees that match the challenges. The CES thus endorses the fears of breeders using only the VOC who consider that the cost of patents will represent a fortune while the companies generating patents (thanks to their technology, which is also protected) have free access to the varieties protected by VOC. There is an unacceptable imbalance here. And inevitably, we can fear that this situation will lead to a new wave of acquisitions of seed companies by large groups which, as we have seen, monopolize large patent portfolios. The use of NTG to enrich the diversity of solutions from which agriculture will benefit will be conditioned by maintaining access to technologies and genetic resources. However, the prospect of massive use of NTG, coupled with the patent games monopolized by a few large global groups, goes against this maintenance. This is therefore a critical point that should be examined at the same time as the new regulations on NTG in order to ensure that the trajectory of use corresponds to public policy objectives.

2.2.3 Exclusions from patent law which rest on fragile foundations

In France, patent law has been modified in order to avoid the undue appropriation of natural characteristics (native genes) and to protect the field of plant breeding. Law No. 2016-

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[22] https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/

23 MA Kock, Open Intellectual Property Models for Plant Innovations in the Context of New Breeding Technologies, Opinion No. Agronomy 2021, 11, 1218.

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1087 of August 8, 2016 for the reconquest of biodiversity, nature and landscapes, anticipated the EPO by registering the non-patentability of plants obtained by “essentially biological processes”. A 3°bis has been added to article L. 611-19 of the Intellectual Property Code, worded as follows:

> “ THE products exclusively obtained by processes essentially biological products defined in 3°, including the elements which constitute these products and the genetic information which they contain ".

This law also limited the scope of the patent by adding a paragraph to article L. 613-2-3:

> “ The specific properties do not extend to biological materials endowed with these protection conferred by a patent relating to a biological material endowed, made of the invention, specific properties, obtained independently of patented biological material and by an essentially biological process, nor biological materials obtained from the latter, by reproduction or from multiplication ".

Furthermore, under Rule 28(2) of the Examination Guidelines as amended by the EPO, plants and animals obtained exclusively by means of an essentially biological process are excluded from patentability (for any patent application having a filing and/or priority date after July 1 , 2017). In order to consolidate the exclusion, the EPO requires a limitation of protection to the product obtained by technical means. Otherwise, the claim must be rejected. Despite these developments attempting to clarify the relationship between patents and VOCs, the increase in the number of patents on plants, favored by the deregulation of certain categories of GMOs, on products similar to conventional breeding products, risks put the selectors in difficulty.

disclaimer

For what ?

The problem comes from what the notion of “essentially biological processes” covers.
These processes are defined as follows by the biotechnology directive in article 2.224 :

> “ a process for obtaining plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or theselection ".

The target is therefore processes based on natural and random biological mechanisms which would not allow the reproducibility of the result. Human technical intervention is very present but it is considered not decisive in relation to natural phenomena. The problem is that this definition leaves a lot of room for interpretation.
Let's take two examples to illustrate this. In the cases the Grand Board of Appeals of the EPO25 ruled that if the use of a molecular marking technique makes it possible to characterize the non-biological element, it only makes it possible to

Tomato Broccoli

24 Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 relating to the legal protection of biotechnological inventions.
25 EPO, ch. rec. tech., Dec 9, 2010, aff. G 2/07, Broccoli: JOOEB 2012, p. 130. – And EPO, ch. rec. tech., Dec 9, 2010, aff. G 1/08, Tomato: JOOEB 2012, p. 206.

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guide the selection process and that the impact of this technique remained limited. She thus asserts that it would have been possible to obtain the same result by a classical selection process, which therefore makes it an essentially biological selection process26. Conversely, in the case the chamber had specified that:

Plant Genetic Systems ,

> “ a plant production process comprising at least one essential technical step, which cannot be carried out without human intervention and decisive on the Who has an impact final result, does not fall within the scope of the exceptions patentability of Article 53b), first half-sentence, EPC 27 ".

We therefore understand that the boundary between an essentially biological process and a technical or microbiological process is very fragile because it is subject to legal interpretation. Considering that only so-called “traditional” crossing and selection methods () should be excluded from patentability does marking molecular, random mutagenesis, etc. not make sense because what is traditional or considered natural at a certain time can evolve28. The products of genome editing are an example. Given the proximity of these products to natural products, one could consider that the technical step does not have a decisive effect on the result. In fact, it is possible to obtain substantially equivalent plants, either with conventional breeding methods or with methods such as targeted mutagenesis and cisgenesis. In the first case (conventional or “essentially biological” methods), the patent has been ruled out but in the second case (new techniques), it is possible. Such asymmetry of protection will inevitably lead players in the sector who have the means to do so onto the patent path, which will lead to limiting access to genetic diversity and increase legal insecurity.

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26 Borges, Rose-Marie, “Patents and plants: what are the issues? ", International Journal of Business Intelligence , 2013/1 (Vol. 5), p. 9-23. DOI: 10.3166/R2IE.5.11-23.

27 Ch. Rec.tech., February 21, 1995, aff. T 356/93, Plant genetic systems, OJ EPO August 1995, p. 545, point 28.

28 The debate took place in similar terms regarding the GMO Directive (2001/18). Indeed, recital 17 states that the text "should not apply to organisms obtained by means of certain genetic modification techniques which have been traditionally used for various applications and which have long been proven to be safe". The interpretation of this directive led the CJEU to consider that the products of site-directed mutagenesis fell into the category of GMOs since these methods could not, among other things, be considered traditional at the date of the decision (CJEU, July 25, 2018 , case C-528/16). VE Brosset and Ch. Noiville, “Do new genome editing techniques give rise to GMOs covered by Directive 2001/18: the Court of Justice of the Union says yes twice! », Cahiers Droit, Sciences & technologies n° 8, 2019, p. 197-212; E. Brosset, “Biotechnology law (2021-2022)”, Revue sociale de l’environnement, 2023/3 (Volume 48), p. 645-659. However, the European Commission in its report recognizes that the regulations applicable to GMOs are not adapted for these new products (Commission staff working document, Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Box C-528/16, SWD (2021)) and proposes new regulations in July 2023.

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Box 2. True or false? About some preconceived ideas about plant patents

Here are five statements which are at the heart of the debates and for which false evidence circulates which we believe is essential to discuss.

“Breeders will be able to have access to CRISPR Cas technology by negotiating licenses”

A patent is a property right which grants its holder exclusive use of the protected invention.
The holder has the possibility of granting operating licenses to third parties. These licenses may be exclusive or non-exclusive. It is considered that technical inventions with very wide use will be the subject of non-exclusive licenses, which makes it possible to generalize their use and therefore to maximize the income of their owners.

However, the choice to grant non-exclusive licenses depends solely on the will of the patent owners. However, large groups like Corteva and Bayer have acquired licenses -
often exclusive- for the use of genome editing techniques on plants. Corteva has formed a pool of licenses on the patents held by the University of California, the
the MIT/Broad Institute and Vilnius University. These basic patents (patents on technology, process) are supplemented by numerous patents on the application of these techniques on plants and on traits (patents on products, plants which contain the modification).

Breeders who want to work on CRISPR Cas applications without taking the risk of counterfeiting must acquire licenses whose conditions are kept secret.

This worrying situation was highlighted by the European Commission in its report on New Genomic Techniques (NGT).29 This report recognizes the benefits of patents and licenses in promoting innovation for the development of genome editing. It recognizes, however, that property rights, combined with high industry concentration, can create barriers to entry for SMEs and limit access to technologies and genetic resources for breeders and farmers.

The opinion of the CTPS scientific committee of November 2022 expresses serious concern on this subject:

“ Genome editing processes are overwhelmingly covered by patents. Among all
processes, CRISPR/Cas pathways are covered by a large series of processes, deposited the patents on by different operators. But in plant production in Europe, a single
American company, almost all of Corteva's rights, deployment of genome editing techniques raises questions of access to the
has got there technique. of Licence. Situation quasi-monopoly, THE
Indeed,
this technology is affordable patented technology lead to questions about whether expected gains
conditions of access to
rights holder size of potential markets. the license of the and by »[30]

“Competition on genome editing technologies will lead to the emergence of alternative approaches to CRISPR Cas”

There is in fact a fairly large set of genome editing technologies: meganucleases, TALENs, zinc fingers, etc. However, CRISPR Cas technologies provide a gain in efficiency which makes them very attractive, especially when we wish to stack several modifications. The development of alternative approaches that would have comparable effectiveness was discussed during the preparation of the

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29 EU Commission (2021). 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. https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en

30CTPS (2022).
Referral to the CTPS Scientific Committee New genome editing techniques and evaluation of varieties, p.54. https://agriculture.gouv.fr/nouvelles-techniques-genomics-et-evaluation-des-varietes-rapport-du-ctps.

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PEPR SVA.31 The search for alternatives was ultimately ruled out and will not be integrated into this PEPR. CTPS experts explain that:

“ follow, because the international competition is major on this path seems difficult to This subject it and seems difficult to imagine very efficient processes at CRISPR-Cas9 which would be alternatives » (CTPS 2022, p.54)

The CTPS warns of a perverse effect of the tolerance for research put forward by the holders of the Crispr-Cas9 technology: by benefiting from this option, public research strengthens the commercial positions of the patent owners.

“ the use of patents is possible for research purposes and is free for organizations research whether it involves producing knowledge and from publications. In fact, this free access comes strengthen the use of patents held by the aforementioned company. There is therefore a self-effect reinforcement which se gradually puts in place, And all countries Europeans. » (CTPS 2022, p.54)

“It is possible to use patented plants from NGTs as a source of genetic variability to create new varieties”

In support of this assertion, certain actors highlight the specificities of European law which excludes plant varieties from the field of patents (Article 53.a of the European Patent Convention) and point out that access to a variety including a component is patented is possible. This is for example recalled in the position of the French Seed Union (UFS) of October 2023:

“ There France has also adopted a provision which introduces an exemption from the breeder in intellectual property the present in German patent law of Patents (Code of art. L613-5-3). This provision is also laws, Dutch Unified Court the and in the of the Patent. »

The use of varieties including patented components as a source of genetic variability is certainly authorized. On the other hand, the new variety created is dependent on the patent if the patented characteristic(s) are still present. This is a fundamental difference with plant variety law which includes a real exemption for the breeder. Given the uncertainty of obtaining a license, this dependence may discourage a breeder from using the dependent variety in their breeding scheme.

What's more, the NGTs should make it easier to stack modified characters in the same variety and therefore potentially, the stacking of patents. In this hypothesis, it will be very difficult to use such a variety in selection without using the patented characters, which will close of facto access to genetic resources. This possibility is mentioned with fear in the UFS opinion:

“ The UFS will be (…) particularly attentive to the possible restrictive impact that a multiplicity of patented characteristics of the same variety could have with regard to the effective access of a variety without this exemption from the patented characteristics . »

31 The Priority Research Program and Equipment (PEPR) Advanced Plant Selection (SVA) is a major French research system financed by France 2030 and supported by INRAE. It is focused on the development of genome editing techniques for variety creation. It was launched for 8 years in 2023.

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“The PINTO database guarantees transparency of Information for all stakeholders concerned”

As specified by Euroseeds, the PINTO database does not provide any guarantee and cannot be considered as a device to guarantee freedom to operate (or FTO). See our comments in p.14.

32

“European law excludes from patents characteristics that can be obtained by means alternatives »

Since the adoption of the European directive in 1998, legislative and jurisprudential modifications have specified the criteria for exclusion from the patent. We can deduce from this that, in principle, the evolution of the law has reinforced the non-patentability of essentially biological processes and of the genetic characteristics that they allow to introduce into varieties (case of so-called native alleles). In France, Law No. 2016-1087 of August 8, 2016 for the reconquest of biodiversity affirms the non-patentability of products resulting from essentially biological processes and therefore the non-patentability of pre-existing genetic resources since these all come from essentially biological processes, being the result of natural phenomena such as crossing or selection. Article 613-2-3, by explicitly excluding from possible patent claims "biological materials..., obtained independently of the patented biological material and by an essentially biological process", further reinforces this point and prevents a patent claim from covering pre-existing genetic resources. It also excludes alternative selection routes from any patent claim. In Europe, the EPO amended Rule 28 by decision of the Administrative Council of June 29, 2017. The new Rule R28(2) provides that in accordance with Article 53 b)

of the European Patent Convention, European patents are not granted for plants or animals obtained exclusively by means of an essentially biological process. On May 14, 2020, the Enlarged Board of Appeal of the EPO delivered its opinion (G3/19) confirming the impact of Rule 28(2) EPC on the interpretation of Article 53(b) EPC (considering, however, that this rule should not produce retroactive effect with regard to European patents granted before July 1, 2017.

This accumulation of texts can give the impression that clear rules prevent the patentability of pre-existing characteristics or those that can be obtained by crossing or selection.
However, the European Patent Office (EPO) frequently deviates from these rules. To take a recent example, the EPO granted a patent to Seminis (Bayer) covering conventionally bred broccoli with an increased content of healthy compounds (glucosinolates). The patent (EP2708115) was issued on September 13, 2023. The plants were obtained from crosses with wild broccoli originally found in Sicily, which has a naturally higher glucosinolate content. This case is not isolated, as shown by several studies carried out by European NGOs.33

These discrepancies can be explained by the conceptual fragility of what is defined as “essentially biological” and by the culture of patent office examiners who are unfamiliar with the world of plant breeding.34

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32 https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/

33 Then, C., Bauer-Panskus, A., Tippe, R. (2021). New GE and food plants: The disruptive impact of patents on breeders, food production and society, TestBiotech.
Tippe, R., Moy, AC, Eckhardt, J., Bauer-Panskus, A., Then, C. (2023). The future of plant breeding is under threat in Europe - Current interpretation of patent law is insufficient to stop patents on conventional breeding, No Patents on Seeds (www.no-patents-on-seeds.org/en)

34 This problem was brought to our attention in several interviews concerning the European situation. The USDA report on fair competition and innovation in the seed industry also highlights this problem

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The CTPS analysis confirms the problem and emphasizes its effects on access to genetic resources:

“However, and independently of new genome editing techniques, it is useful to remember that the granting of patents on native alleles discovered in accessions of genetic resources is a reality permitted by Directive 98/44, and its application / transposition into EPO texts. This possibility of patenting a published feature generates tension and major difficulty. The EPO's recently introduced disclaimer for patents relating to a characterized native allele specifying that the granted IP right does not apply to
an identical allele discovered by another route (ie by another accession) does not entirely resolve the problem, the initial accession being only partially described/named in the granted patents.
The issuance of such patents de facto reduces the use of these alleles of interest, even though they are native, in other breeding programs, reducing the opportunity for producers and society in general to diversify suppliers of genetics of interest. . » (CTPS 2022, p.54).

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and recommends strengthening the cooperation between the USDA and the USPTO.
See: USDA (2023). More and Better Choices for Farmers: Promoting Fair Competition and Innovation in Seeds and Other Agricultural Inputs , A report directed by President Biden's Executive Order Number 14036: “Promoting Competition in America's Economy”, Washington DC: USDA.

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3 Possible solutions

The development of the use of patents in the field of plants implies a much more extensive property right over genetic diversity and has, as we saw in the chapter “Problems and questions”, a significant impact on those involved in the innovation in particular by leading to the concentration of players. Indeed, despite the directive on the legal protection of biotechnological inventions35 which attempted to adapt
the right of patents to life, this property right does not integrate the specificities of the selection work in an equivalent manner to the COV.36 The patent offices know very little about the process of varietal selection. The intellectual protection of varieties generates economic and legal insecurity favorable to the actors who best master patent law.

For a long time, we tried to adapt living things to patents and, in Europe, to find compromise solutions to ensure the coexistence of patents and VOCs. So, as the Vietnamese proverb says, we tried to adapt the foot to the shoe! The system is now reaching its limits. On the one hand, it promotes monopolization of the markets concerned at a time when we need diversity to move towards resilient agriculture. On the other hand, it calls into question the principle of free access to genetic resources, the driving force behind combinatorial innovation. Finally, it is a system of great complexity, based on fragile conceptual foundations, as shown by the debates on the concept of an “essentially biological” process.

It is therefore necessary to review the variety protection system in a holistic manner.37 The design of the protection system aims to promote the diversity of actors involved in innovation by taking into account what the variety selection process is: a process which for centuries has integrated genetic diversity shaped by man, starting (and for millennia) with mass selection, then drawing on new knowledge in genetics and genomics as well as technical developments. This is why we propose that a real reflection be initiated on the concept of agroecological exception (Box 3). This need to review the protection system in an ambitious manner is all the more necessary given that the threats weighing on the future of agricultural and food systems are very serious. The draft scenario proposed in Appendix 3 highlights the importance of regulating the world of seeds favorable to an enrichment of the diversity of systems in order to cope with climate change.

This “holistic evolution” of the intellectual protection system is presented in two parts: the reform of the intellectual protection system of varieties itself and the

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35 Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions.

[36] Hermitte, M.A. (2016). The influence of intellectual rights on the living world. Paris: Quae.

37 Along the same lines, see the report and recommendations of the High Council for Biotechnologies (HCB):
High Council of Biotechnologies (2013). Plant biotechnologies and intellectual property , Paris: (HCB)
The CES also discussed at length the proposals made by lawyer Michael Kock:
Kock, M.A. (2022). Intellectual property protection for plant related innovation, Springer Nature.
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necessary mobilization of stakeholders involved in this reform and its implementation
artwork.

Box 3. For an agroecological exception

The genetic diversity of cultivated plants is a biological, agronomic and cultural asset.

It is a good of spontaneous origin. Its main support, DNA, is the subject of massive and recurrent spontaneous modifications. With solar radiation, every year all the possible modifications to the rice genome are produced - one could say tested - in the Philippine archipelago alone. The natural rate of mutation allows this, because the plants are numerous in the rice fields and the seeds produced are innumerable. In this very recent neo-diversity, natural selection is sorting itself out (many of the mutations are unfavorable), and so are the farmers. The changes that are retained by farmers are those which bring them useful changes and which are identifiable. What can we say about rice all over the world… and all other cultivated plants.
So many attempts attempted, so many opportunities presented!

This is how the first collectors of wild grains were able, over the generations, to accumulate the variations that we classify today as the “domestication syndrome”: synchronous flowers, large and numerous grains, which hold on the inflorescence. This is how the first characteristics of agronomic interest, as they say, were selected and fixed - stabilized - in cultivated varieties. In sugar cane it will be the juiciness and sweetness of the stems, elsewhere it will be the characteristics of the fruits...

To arrive at the varieties cultivated in the modern era, hundreds of generations of farmers transformed the plants, domesticated them and made them more and more efficient in their eyes. The miracles of solar radiation? not only ! Farmers moved, migrated, sometimes very far, taking their seeds and bringing them closer to other cousin plants with which they were able to cross. Plants cultivated or found in the wild. Spontaneous crosses, sometimes simple, and sometimes more complex, combining several species, requiring special care to propagate the descendants. All the variation accumulated at the basic DNA level was able to recompose, recombine, and develop simple functions around genes and their regulations, as well as complex functions based on networks of numerous interacting genes. Certain blends have thus become the heart of adapted, efficient varieties, with pleasant and reassuring products, reflecting the expectations and uses of human societies, even structuring for the human societies which fed on them or traded in them.

Modern varietal improvement, with its sometimes blinding analytical capabilities, has undertaken to dissect the behavior of plants in the form of traits (the English term for characters) that can be identified, transferred, added to already existing varieties. “elites”. A trait is a priori a set of new abilities brought about when a particular segment of DNA is added to a recipient genome. A model of progressive, incremental, directed improvement, which proves itself in many circumstances. And, dazzled by their ability to apparently reduce a trait to a segment of genome, some claim to have made an invention and to be able to promote this invention in the form of a patent, which will oblige all users of the plant to pay a royalty, direct
or indirect.

But what meaning does this have? This relationship “if I add this segment, I modify this character in a desirable direction” can eventually be sold, monetized. If there are techniques for this, it may be advantageous to do it quickly and precisely, and therefore to charge for such a service. But privatizing the product of such progress is simply misplaced pretension. To prevent the free use of such a product to make crosses and continue the process of improvement is to ignore all the generations of farmers who have patiently worked over generations and transformed

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unproductive wild plants into nourishing varieties, to bequeath them to their descendants and their communities. Because there are dozens or hundreds of traits that have been accumulated, shared, and reassociated, thus shaping varieties according to their needs and preferences, and which today constitute our genetic resources.

And it is an insult to collective common sense and human solidarity in the face of imperative emergencies such as that of diversifying varietal forms to stimulate a new agronomy which will be able to buffer the impacts of unprecedented climatic variations and continue to nourish human societies.

So we advocate an “agroecological” exception to the principles of intellectual property for innovation, because it involves applying to agriculture, a global priority, methods based on documented biological phenomena and allowing the greatest mixing of the diversity accumulated today to extract numerous new forms.

3.1. Putting VOC principles back at the center of intellectual property in the field of varietal selection

Faced with the difficulty of maintaining a balance between patent and VOC and the complexity which arises from attempts to make the two systems consistent, we can question the advisability of maintaining two different types of property rights in the field of varietal selection. Indeed, if patent law were sufficiently developed, including a real exemption from selection, plant innovations could be covered by a single property title. This is the analysis also made by jurist Michael A. Kock:

> “ System failure can only be avoided by fundamentally overhauling the intellectual property system for plant breeding innovations and one of a holistic system that combines elements of patent law, plant breeders' rights and the regime of Responsibility (Exclusivity) of the Convention on Biological Diversity within an open innovation framework. A system could also take into account shorter innovation cycles by providing for a shorter duration of protection and the regime of Responsibility (Exclusivity) to inclusiveness, which allows “ access, benefit sharing and ". [38]

3.1.1. Variety is at the center of the intellectual property system

De Kock’s “UPOV 2030” proposal gives a central role to the VOC. Only the use of plant varieties can be the subject of an exclusive right. In this system, in accordance with the UPOV Convention of 1991, VOC holders can oppose their rights to the marketing of any variety which is essentially derived from their variety (essentially derived variety -EDV).

The CES also considers that variety is the real innovation to be protected and not the traits that compose it. In fact, these are only of interest combined with all the rest of the characteristics of the variety and in connection with its use in a given agronomic context. This variety actually incorporates millennia of breeding by different methods (Box 3) and this was consciously facilitated by the breeder's exemption which is integrated into the VOC and must be retained without restriction. This is essential for

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38 MA Kock, Open Intellectual Property Models for Plant Innovations in the Context of New Breeding Technologies, Opinion no. 2 Agronomy 2021, 11, 1218, p.26.

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guarantee a dynamic and inclusive ecosystem, with varietal innovation promoting genetic diversity and use of the varieties created.

3.1.2. Apply the provisions of non-patentability of native traits; extend it to plants and traits in general

Consistent with the previous proposal, traits should not be patented.
Currently, in Europe, only so-called “native” traits are in principle non-patentable and this results from the exclusion of products resulting from essentially biological processes. This principle, as we have seen, is not always applied. The burden of proof rests on the company that uses natural selection methods and challenges the patent.

However, the CES considers that the definition of a native trait or product resulting from an essentially biological process carries uncertainty. Beyond that, this exclusion concentrated on so-called “traditional” selection techniques and which does not take into account the reality of new selection techniques is not satisfactory. The only claims in a patent that should be acceptable are those relating to techniques, excluding traits (or modified alleles), cells and plants. Indeed, how can we be certain that an allele for dwarfism or resistance to a virus obtained by editing a genome and claimed as produced in a patent, for example, could never be found by screening a sufficiently large collection of genetic resources? Alleles leading to this type of phenotype are often present but not expressed in populations. We can cite, for example, a point mutation that appeared perfectly naturally in a vine variety (Pinot Meunier) and is present in a chimera state (only certain tissues of the plant carry the mutation). It is necessary to use a process of regenerating a whole plant from these tissues for this mutation to be expressed and produce a dwarf plant with a modified flowering cycle39. Patenting a trait therefore seems to us to be a source of legal uncertainty, of blocking the use of the diversity necessary for varietal creation and therefore of hindering the necessary contribution of plant improvement to the agroecological transition. The CES proposes to exclude from patentability plants, genes and sequences of plant origin whatever ultimately,

regardless of the technique used. This solution would put the VOC principle back at the heart of plant innovation and preserve access to genetic diversity.

The CES goes further than certain proposals, first and foremost those of Michael Kock who proposes a register system making it possible to manage features under patent: the inventor deposits the feature in a register; companies using the trait must declare it; they are charged a license fee. The system is based on a regime of responsibility and equitable sharing: the user of a trait who does not declare it would be sanctioned; royalties would be established at a reasonable level based on a calculation based on the dynamics of added value. The registry system aims to reestablish the principle of free access to the genetic resource by ensuring remuneration for the inventor who obtains the new traits. It could be appropriate to study the feasibility of Mr. Kock's proposal by specifically studying its compatibility with patents and its conditions of implementation. However, these conditions are probably complex and

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39 Boss PK and Thomas MR (2002) Association of dwarfism and floral induction with a grape 'green revolution' mutation, Nature , https://doi.org/10.1038/416847a

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costly, hence the CES's proposal to strictly limit the scope of patents to technology.

It may be argued that, in the VOC system, the protection of features is not sufficient to encourage investments. The VOC only protects the original combination, the trait - for example a new resistance of the tomato to a virus - is accessible to competitors who can freely introduce it into their varieties. However, with the progress of selection techniques, the introduction time is shorter, which reduces the temporary monopoly of the inventor. Breeder's rights are not without resources to take this concern into account. The 1991 UPOV convention indeed introduces the concept of essentially derived variety (EDV) (See Box 4). The exclusive right of the breeder (possibility of opposing the marketing of the protected variety by a third party) extends to essentially derived varieties.

The notion of “essential character” is defined as follows:

> “ “Essential characteristics” are characteristics that are fundamental to the variety as a whole. must contribute to the main characteristics, They to the performance or use value of a variety be important for one and of the following stakeholders the producer, the seller, the supplier, the buyer, the: recipient material, reproduction or multiplication, harvest of products obtained directly or even product chain of the of the user of the of the of value.
>
> »40

This notion could be used, while respecting the principle of free access to the genetic resource which remains the central pivot of the VOC, to take into account the particular importance of certain essential characteristics.

Box 4. Definition of essentially derived variety (Extract from the 1991 UPOV Convention

Section 14(5)(b)

b) For the purposes of subparagraph has(i), a variety is deemed to be essentially derived from another variety (“initial variety”) if:

(i) it is mainly derived from the initial variety, or from a variety which is itself mainly derived from the initial variety, while retaining the expressions of the essential characters which result from the genotype or combination of genotypes of the initial variety ;

ii) it is clearly distinguishable from the initial variety; And

(iii) except for differences resulting from derivation, it conforms to the initial variety in the expression of the essential characters which result from the genotype or combination of genotypes of the initial variety.

The necessary strengthening of the public knowledge infrastructure constitutes a complementary response (Cf. 3.2).

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40 UPOV (2023). Explanatory notes on the 1991 varieties essentially derived according to the act of the UPOV convention , UPOV/EXN/EDV/3 Draft 4 (https://www.upov.int/meetings/en/doc_details.jsp?meeting_id=77231&doc_id=620274)

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3.1.3. Develop the compulsory licensing system

The establishment of licensing platforms demonstrates a need for regulation in areas where patents are booming. It attempts to respond to the problem posed by the accumulation of patents in a process (of patents), here the selection process. These patent bushels are inevitable, particularly if we continue to patent features, which the CES does not recommend. In the CES recommendations, in the context of varietal selection, patents must be limited to the protection of an innovative technique or process combining several techniques and not extend to the product of these techniques. It is possible that with the acceleration of technical developments, such patent bushes will nevertheless appear, even if the ban on patenting the products of these techniques is effectively applied.

bushes

The use of “compulsory licenses for dependency” could have constituted a useful mechanism of internal regulation of patent law. However, as it stands, it is difficult to mobilize given the criteria adopted[41] . Indeed, according to articles L. 613-15 and L613-15-1 of the Intellectual Property Code[42] , it is up to the applicant for a compulsory license to prove that this invention constitutes, with regard to the earlier patent, an important technical progress and is of considerable economic interest. The judicial court may grant the applicant a license to exploit the prior patent to the extent that this is necessary for the exploitation of the patent. Beyond the difficulties in providing such evidence, the length of legal proceedings is likely to discourage breeders.

Reflection is underway at European level following the compulsory Covid epidemic in [43] on licenses a crisis context. This reveals avenues for improvement which could inspire the general framework of compulsory licenses, in particular via the granting of licenses under fair, reasonable and non-discriminatory conditions (FRAND), but also negotiation in good faith rather than contentious procedures in to the extent that regulation could be organized.

Immediately, during the time necessary to reform the entire intellectual property system, the CES recommends that these compulsory licenses be effective by removing the condition that the dependent invention presents “considerable economic interest”. This measure will make it possible to avoid the capture of native genes and to counter the fragility of the notion of “essentially biological process”. The CES considers that patent holders should also have to provide proof, at the time of filing, that their patents do not relate to products resulting from essentially biological processes, thus reversing the burden of proof which currently weighs on breeders in the conventional sector.

3.1.1 Introduce a real breeder’s exemption in patent law

In the immediate future and while awaiting the overhaul of the plant protection system, it appears essential to introduce a real exemption for the breeder in patent law. In

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41 B. Humblot, Patent law: posthumous praise of the compulsory dependency license, 42 Complies with Article RLDI, June 2012 n°89. 31 of the TRIPS agreements.

43 Proposal for a regulation of the European parliament and of the council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006, 27 April 202, COM(2023) 224.

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Indeed, as we have explained, only certain national laws recognize this exemption in patent law, without giving it the same scope as in the context of the COV. It is therefore appropriate to reaffirm a general principle of access to genetic variability
for research and selection purposes, without financial compensation, whether in the
field of VOC or patent.

In conclusion on this first part of recommendations, the CES considers that only a system which reinforces the principle of the VOC (by affirming that only the variety can benefit from an exclusive right and that the traits cannot be patented) will make it possible to put back in place the exemption of the breeder without legal uncertainty or inequity in the exercise of varietal selection.
This protection system should also go through an arbitration system under the aegis of public actors and experts in the field rather than through courts.

This is certainly a bold proposal, but we have seen that the current system is both complex and very unsatisfactory. It certainly leads to a concentration, already underway, of those involved in varietal selection. It generates legal uncertainty and a diversion of funding from varietal selection to the legal sector when we need innovations in the fields more than ever. The system proposed here allows all farmers, breeders of peasant varieties, academic breeders and private breeders to continue to work peacefully.

This VOC revolution will, however, require time and mobilization of stakeholders around the necessary trajectory to complete and implement it: this is the subject of the second part of our proposals.

3.2. Mobilization of stakeholders

To develop the intellectual protection system associated with varietal selection, it will be necessary for all stakeholders involved or impacted by this development to be able to contribute to the debates in an informed manner, that is to say by understanding the issues in all its facets. This will require training and acculturation efforts for these stakeholders: politicians, those responsible for implementing intellectual property rights, private and academic breeders, civil society, etc.

Furthermore, public infrastructure and research in particular will play a crucial role, both in the transition period to a new VOC and afterwards.

3.2.1. Train all stakeholders in the evolution of the system of intellectual property

To carry out this ambitious reform, it is necessary for all stakeholders to understand both the issues of varietal selection and those of associated intellectual property. We saw in the problematic and questioning chapter that this lack of common culture already leads to bad practices in the application of the texts. This results in an extension of patents on varietal creation and ultimately also a weakening of the VOC and its fundamental principles.

To progress in this area, it will be important to produce educational materials intended for various audiences (public policy managers, directors of research institutes).

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research, researchers and teacher-researchers, breeders but also farmers, managers of genetic resources, lawyers) and to communicate them widely. We also hope that elements of this opinion will contribute to the development of such supports.

3.2.2. Strengthen public infrastructure of the seed system

The varietal improvement environment is made up of a multitude of actors of varying sizes, farmers, seed companies, associations, public establishments, etc. Intellectual property strategies are also very contrasting depending on the culture of these actors, whether they come from the world of varietal selection or agrochemistry44. In this context, we can question the role of public research which simultaneously pursues a mission of general interest, the dissemination of scientific knowledge and the economic valorization of research results. The USDA Report (2023) More and Better Choices for Farmers also underlines the importance of public knowledge infrastructures and insists on the need for increased investments. This infrastructure is based in the United States on solid public organizations:

> " This public infrastructure, which is largely a partnership between the federal government, involving the states and the USDA research centers, the Land Grant Universities State Agricultural Experiment Stations, has long supported fair competition among private entities by disseminating cultivars that farmers can use as they wish and crops and crops. and key traits varieties for geographic areas served. »[45] (Our translation)

We can largely adopt this description at the national and European level. However, since the 1980s, public budgets have been compressed, under the pretext that the market would serve the needs of agriculture more effectively. This results in a worrying weakening of public infrastructure in the United States:

> " Decades of underinvestment have considerably reduced this ability. With fewer varieties adapted to local conditions, farmers risk losing potential income. Additionally, of decentralized capacity for variety development and loss of other materials And there production and planting chains means that seed supply is vulnerable to disruption. »[46] (Our translation)

Fortunately, in France, public policies have been less sensitive to market promises. The law affirms the missions of public research, not only in terms of production of scientific knowledge but also in terms of technological development. Thus, public research:

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44 See our comments on this point in part 1. We can also refer to:
Girard Fabien, Noiville Christine, "Industrial property and plant biotechnologies: Nova Atlantis. About the recommendation of the High Council for Biotechnologies", 2014/1 (t. XXVIII), p. 59-109. DOI: 10.3917/ride.281.0059. International Journal of Economic Law ,

45 USDA (2023) More and Better Choices for Farmers, p.5.
[46] Ibid, p.5.

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> “ focuses on the development of innovation, technology transfer when possible, the capacity of expertise foundations, recognized as being of public And support for associations and utility, responding to societal challenges, And to public policies carried out to social and economic needs, sustainable development And of »(Article L.111-1 of the Research Code).

It therefore seems that public actors in their choices of valorization of research results cannot avoid a real reflection on the advisability of resorting to patent law in the general interest and, on a case by case basis, choose to disseminate knowledge via scientific publication or register an intellectual property title. In fact, the CES considers that public research infrastructures will continue to have an important and ideally reinforced role for:

- set up research and development operations in areas with varietal selection of minor species, proof achieved pre-breeding , of concept on risk (“risky” traits or types of varieties, etc.). This can be in part within the framework of public-private partnerships but these must be as broad as possible (avoiding bilateral) and aim at the development of commons. In this context, collaboration between public laboratories and certain companies that protect the results of their research through the VOC can make it possible to document the selection processes for new plant varieties, including when they are based on genetic modification techniques, and thus limiting the filing of patents thanks to scientific publications exposing the research process and the results obtained. It should be noted that the appreciation of novelty in the field of VOC is not an obstacle to this type of scientific publication, insofar as only a handing over of the material for commercial exploitation purposes can constitute an act of a nature to destroy the novelty of a plant variety47 . - develop knowledge and methods in an open science framework to support the agroecological transition and adaptation to climate change

- develop technologies to support copyright-free varietal selection. As part of this reflection, the dissemination of a scientific publication in a journal accessible to the public can be considered as a solution for disseminating scientific knowledge since a patent filing would be considered blocking innovation and research, this which is the case for patents relating to genes and characteristics in particular “native” 48. This strategy can also make it possible to maintain technical knowledge in the public domain provided that the invention is sufficiently described49. However, we must be vigilant because too rapid publication of results that do not yet address a particular technical problem will only have a limited effect on the novelty of the inventions that could result from it and be claimed by third parties. Indeed, case law recalls that “

to be included in the state of the art and be deprived of

47 Art. L. 623-5 of the Intellectual Property Code. N. Bouche, Obtaining plants , Law Directory commercial, September 2019, n°56.

48 High Council for Biotechnologies, Plant biotechnologies and industrial property , Report of the group of work implemented by the Economic, Ethical and Social Committee (CEES), 2013, p. 43.

49 See art. L. 611-11 of the Intellectual Property Code.

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novelty, the invention must find its entirety, in a single prior art with certain character, with elements of the same form, even the elements which constitute it in the same functioning with a view to the same technical result arrangement, 50 ".

- contribute to the management and provision of commons: genetic resources, data and knowledge; establish sustainable and efficient financing arrangements for all of these activities, taking into account the long time required for certain experiments. The INRAE-CIRAD-IFREMER ethics committee underlines in its opinion on the editing of plant genomes: “To replace these archived memories with genomes made to order, it is important not to be blinded by the short-term benefits and take the time to assess long-term risks. However, carrying out this type of study requires patience and a long time: ten, twenty, thirty years of research and testing. »

50 Com. March 12, 1996: PIBD 1996.III. 273; Paris, Jan. 6, 2006: PIBD 2006. III. 160.
Opinion No. 2 of the SEMAE Societal Issues Committee (CES) - The opinions of the CES only bind its members, SEMAE, nor their organizations.

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Appendix 1. List of people interviewed

Amelot, Nicolas, Syngenta

Bradford, Kent, UC Davis

Button, Peter, International Union for the Protection of New Varieties of Plants (UPOV)

Clément-Nissou, Isabelle, SEMAE

Csorgo, Szonja, Euroseeds

Dereudre, Eric, Corteva

Desprez, François, Florimond Desprez

Devaux, Pierre, Florimond Desprez

Gautier, Jacques, Ets Gautier

Kock, Michael, Patent Attorney

Mattina, Francesco, Community Plant Variety Office (CPVO)

Marchive, Chloé, INRAE

Monconduit, Hervé, Bayer

Rivoire, Benjamin, International Seed Federation (ISF)

Tabel, Claude, RAGT (currently retired)

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Appendix 2. List of abbreviations

ACLP : Agricultural Crops Licensing Platform

DNA: Deoxyribonucleic acid

Cas9: CRISPR associated protein 9 or “CRISPR-associated protein 9”

CJEU: Court of Justice of the European Union

VOC: Plant Variety Certificate

CRISPR: *Clustered Regularly Interspaced Short Palindromic* Repeats

CTPS: Permanent Technical Committee for the Selection of Cultivated Plants

DUS: Distinction Homogeneity Stability

FRAND: (licensees granted under conditions) that are fair, reasonable and non-discriminatory

FTO: Freedom to Operate

ILP: International Licensing Platform

NBT or NGT: *New Breeding Techniques (New Genomic Techniques),* new plant breeding techniques based on genome editing.

NTG: New Genomic Technologies

EPO: European Patent Office

GMO: Genetically Modified Organism

PEPR : Priority Research Program and Equipment

PINTO: Patent Database and Transparency On-Line

SDN: *Site Directed* Nucleases

TALEN: Transcription activator-like effector nuclease

UPOV: Union for the Protection of New Varieties of Plants

USDA : United States Department of Agriculture

VATE: Agronomic, Technological and Environmental Value

ZFN: Zinc-Finger protein

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Annex 3. Future scenarios – The worlds of seeds by 2050

What world will we live in in 2050? What will be the main characteristics of the world of seeds?

Although it is not possible within the framework of this opinion to carry out a real foresight exercise, it seems necessary to us to outline proposed answers to these questions. This projection into future worlds is in fact to shed light on the issues of current debates on intellectual property.

Any projection into the future world requires clearly identifying the processes at work, the emerging trends and the weak signals likely to affect our future. If the globalization of trade and a certain standardization of agricultural models have characterized recent decades, climate change, which began many years ago but is now perceived by everyone, constitutes a major determinant of the evolution of our world. Its environmental, economic and social consequences are major and call into question our economic development models and our lifestyles. By 2050, the systemic consequences are for the most part difficult to predict.

What will be the consequences of the growing flow of climate migrants (216 million by 2050 according to the World Bank)? 51 What will be the new geopolitics of agriculture and food? Will Russia or the pampas of South America be the new breadbaskets of the world? ... We must therefore envisage major shifts in the global political and economic order.

Climate change and the collapse of biodiversity also require us to fundamentally review the techno-scientific development paradigm. Indeed, climate change causes increased fluctuations in environmental conditions (not only increased frequency of extreme events but also more extreme events and greater unpredictability). The widespread collapse of biodiversity can generate unfavorable agricultural environments (without auxiliaries, without pathogen competitors). Developing models optimized with respect to a relatively stable environmental context has been the general norm in recent decades, even in agriculture. The uncertainty that now characterizes our environment invites us to change paradigm. Adaptation to climate change but also to profound changes in biodiversity in environments comes up against this unpredictability and it is this uncertainty that new agricultural models must now take into account. This requires us to review our production systems with greater emphasis on their robustness in the face of environmental fluctuations and their ability to respond to current challenges, particularly in terms of mitigating climate change and restoring biodiversity. , rather than on production.

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51 Mobilization is necessary to imagine futures that shake up our certainties and our frames of reference. See the mission entrusted by the Ministry of the Armed Forces in 2019 to a group of science fiction authors: Éditions des Red Team, These wars that await us 2030-2060 , Équateurs, January 5, 2022

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In this context, the world of seeds will also have to adapt to this paradigm shift, the characteristics of the varieties will be significantly different from those having prevailed until now and, consequently, the selection strategies as well as the current methods of diffusion and protection will have to evolve to meet the challenge.

The future world of seeds can thus be described by the intersection of two major axes of uncertainty, that of the modalities of adaptation of agriculture to climate change (we focus on this emblematic change from which the evolution scenarios are produced and documented by the IPCC) and that of the regulation of seed activity. The concept of regulation is used here to designate the emerging forms of operation of complex systems and not in the sense of the Anglicism which means regulation. Thus regulation is only a specific component of regulation.

We offer here a brief description of these two axes before crossing them to obtain four scenarios which will be told.

Adapting agriculture to climate change

The work of the IPCC highlights different components of climate change:

- The increase in average temperatures, changes in rainfall, length and timing of seasons, etc., with associated variations in living things, soil fauna and flora, pests and auxiliaries, etc. For the regions of southern France and the countries of southern Europe[52] , the different IPCC scenarios predict a shift towards arid and semi-arid climates, with a sharp reduction in the quantities of available water and episodes of heatwaves. frequent;

- The increase in the frequency of extreme events: late frosts, torrential precipitation, hail, violent winds…

If we focus on the adaptive capacity of agriculture, the intensity of changes in climate regimes - which the IPCC scenarios attempt to understand (and have often been underestimated, for procedural reasons , need for approval by the oil-producing States) - will play a determining role. It will lead in particular to a movement of cultivated species towards the polar regions, but this simple extrapolation could hide the fact that agricultural modifications will be much more complex and less predictable. Obviously, adaptive capacity will be linked to how these regime changes are anticipated. The challenge will also be to increase the adaptability and robustness of production systems given the foreseeable increasing scale of fluctuations. A territorial focus is obviously necessary because the implications will be very different depending on the territories considered.

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[52] The impact of climate change is so even more much more worrying for the Mediterranean countries, for the Maghreb, for the Middle East and for the Sahel - to stick to the regions close to Europe. We are already seeing various effects, notably conflicts over the use of water and land resources or the collapse of agricultural systems linked to climate change which, by generating insecurity or extreme poverty, are a source of migration. human.

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Let us first note that the adaptation of agriculture will require profound changes in agricultural and food systems. On the one hand, it will be a question of better integrating animal and plant production in order to complete the cycles (of carbon, nitrogen and phosphorus) and to replace from plant proteins to animal proteins in diets. [53]

The mobilization of biological diversity within the framework of agroecological practices constitutes one of the major levers for the adaptation of agriculture to climate change.[54] It will indeed be a question of playing on diversity at different scales: varieties tolerant to water stress (see for example the work on sunflowers); species whose biology is adapted to drought (sorghum, millet, miscanthus, etc.); associations of complementary species for the management of water and excess temperatures (particularly in agroforestry); associated crops which increase the level of organic matter in the soil; symbiotic interactions between plants and mycorrhizae…

Without denying that the adaptation of agriculture is more a matter of gradient than of a binary situation, without denying either that it will probably be very different depending on the territories considered, we stick here, for didactic purposes, to an opposition of two states of world : [55]

- A situation of climato-agricultural chaos : the instability linked to climatic events is not controlled and agriculture is unable to adapt to this climatic chaos; food prices are very fluctuating; insurance systems no longer make it possible to cover climate risks, which increases farmer bankruptcies; we are witnessing the return of hunger riots (Cf. 2008 and the “Arab Spring” but on an unprecedented scale); the food weapon is at the heart of major international issues; the political order is transformed and sets up a “war economy”

- A situation robustness of agri-food systems : biological diversity and the diversity of production systems mitigate the impact of climate shocks; Partial substitution of plant proteins for animal proteins provides room for maneuver for the adoption of more resilient production systems.

Regulation of the world of seeds

The current organization of the world of seeds shows that very different forms of regulation can be imagined. A comparison between Europe and the United States leads us to focus on the effective role of intellectual property rights. In Europe, the VOC remains the primary reference, both for historical and regulatory reasons but

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53 See in particular Food in the Anthropocene: the EAT–Lancet Commission on healthy diets from sustainable food systems (https://www.thelancet.com/commissions/EAT).

54 See Opinion No. 1 of the SEMAE CES.

55 For the record, like major international organizations, the IPCC uses reference scenarios, shared socio-economic pathways (Shared Socio-economic Pathways -SSP). Only SSP1 (sustainability scenario) makes it possible not to exceed the average temperature increase of +1.5°C by 2050 (less than +1.5° in 2100). In the case of SSP5 (rapid development scenario based on fossil fuels), the predicted increase in 2050 is +2.5°C (+4.5° in 2100). It is clear that these differences in the magnitude of change will be decisive.

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also because, due to the de facto moratorium on GMOs, patents on new traits have had no direct economic impact on agricultural production.

In the United States56, patents play an important but differentiated role depending on the species. This concerns species for which industrial patents play an important role (Utility Patents, as opposed to Plant Patents which have existed in the United States since 193057). For these species (mainly corn, soya, cotton, rapeseed), industrial concentration is very high, the role of universities and the USDA is marginal, and territorial anchoring is very weak.

For other species (straw cereals, fodder, many vegetable species, fruit species, etc.), the situations are very different: varying levels of industrial concentration, role of public research including in varietal creation, strong territorial anchoring. We therefore find, in the United States, situations comparable to the European “model” in areas where patent law plays a marginal role.

It is by extrapolation from such observations that we construct the vertical axis which aggregates the following components: Business diversity; Sharing technological innovations; Opening of access to genetic resources; Territorial anchoring.

For each dimension, we observe a gradient between two modalities (weak/strong). At the bottom of the axis, regulation "" is marked by a strong concentration, even a form of oligopoly of large globalized groups without territorial anchoring, a confiscation of intellectual property which leads to a privatization of genetic resources. At the top of the axis (“”), forms of agile, open and distributed innovation supported by public research make it possible to maintain the diversity of the industrial fabric and therefore of companies with strong territorial roots.

Closed innovation and concentration

diversity open innovation and

The nature of intellectual property rights contributes massively to this axis, to the point that the simple uncertainty about these rights, which certain actors can maintain, strongly pushes towards the concentration of companies and the closure of innovation. At present, the situation is particularly complex: conflict over priority patents on genome editing, flexibility in interpreting patentability rules, multiplication of patent filings whose scope of protection is uncertain... For small companies and medium, this strong uncertainty poses (sometimes unknown) risks to the freedom to operate.

How can we be sure not to find ourselves dependent on a patent whose owner could oppose the valorization of results resulting from long and costly research efforts?

Given that NTGs considerably shorten the time between two innovations, it is very likely, as indicated previously, that we will end up with frequent situations of stacking of patents in the same variety. This could lead to a lock in access to genetic resources and an end to the breeder's exemption.

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56 See the two recent USDA reports on consolidation in the seed industry:
USDA (2023). More and Better Choices for Farmers: Promoting Fair Competition and Innovation in Seeds and Other Agricultural Inputs , A report directed by President Biden's Executive Order Number 14036: “Promoting Competition in America's Economy”, Washington DC: USDA.
MacDonald, J.M., Dong, X., Fuglie KO (2023). Concentration and competition in US agribusiness ,Washington DC: USDA, Economic Information Bulletin, Number 256, June 2023.

57 Utility Patents, as opposed to Plant Patents which have existed in the United States since 1930

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The position on this vertical axis is therefore very strongly influenced by political measures (concerning IP, the role of public research, seed regulations, etc.), some of which may be the subject of recommendations.

The four scenarios

1. Scenario 1- Sharing company (axis 1: robustness of agri-food systems, 2: open axis innovation diversity) And

In this scenario, a network of companies with strong territorial and diversified roots has developed, benefiting from the common good nature of advanced technologies and genetic resources. Public research has the mission of maintaining and developing this common good, in relation to this network of businesses.

We therefore observe a diversification of species and varieties in the context of complex agricultural landscapes closely coupled with regional food chains (Cf. Box 2). The varieties themselves are of diverse types and in particular the population varieties develop thanks to seed networks on the farm and a diversified network of players in varietal selection. Agriculture is multifunctional and integrates the management of biodiversity (model of Land sharing).

The market and private initiative go hand in hand with cooperative approaches promoted by inter-professional organizations, which makes it possible to mobilize decentralized and bottom-up approaches to respond to major challenges. All of these elements contribute essential to the adaptation of agriculture to climate change.

The relationship between the world of seeds and civil society is peaceful and confident. Regulatory barriers are based on multi-criteria evaluation and traceability; they do not act as a barrier to entry. The application of new techniques to minor species is encouraged.

The VOC has evolved to remain the cornerstone of intellectual property protection and it guarantees the exemption of the breeder and farm seeds; “essentially agroecological” characteristics (see our proposal in the Solutions section) are excluded from the patent. European initiatives to renovate UPOV were followed by China and India, which led the United States to soften its positions on intellectual property rules so as not to find itself isolated.

Box 4. Scenario 1 agriculture: Complex and diverse landscapes and regional food chains

The INRAE prospective “European agriculture without chemical pesticides in 2050” builds an agricultural and food future from which this scenario 1 could draw inspiration:

“Crop systems and crop protection rely on biological regulatory mechanisms at landscape and soil level, with few exogenous inputs. In living () territorial laboratories, different actors, notably farmers and researchers, have co-designed and tested cultivation systems aimed at strengthening biodiversity and regulating pests, in particular through crop diversification strategies and redesign of landscapes.

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This diversification was achieved through participatory selection, and the selection of varieties adapted to diversification (mixture of species and varieties), through the development of semi-natural habitats (20% of land dedicated to natural habitats and semi-natural), and by the partial development of mixed agricultural systems reintegrating animal production into farms.
Extensive livestock farming contributes to completing the biogeochemical cycles essential to European agriculture.

The mosaic of cultures is adapted in its composition and configuration to the challenges of crop protection; it is diversified in space and time, and the size of the plots
has reduced. »

Source: Olivier Mora, Jeanne-Alix Berne, Jean-Louis Drouet, Chantal Le Mouël, Claire Meunier.
Foresight: European agriculture without chemical pesticides in 2050. Summary. INRAE. 2023, 14 p.
hal-04147168

2. Scenario 2 – An unequal and ordered world 1: agri- robustness of systems (axis food, axis 2: closed innovation concentration) And

The concentration of the seed industry has continued, influenced by the increasing privatization of scientific knowledge, technological resources and genetic resources. Economies of scale in research came into play.

The trend towards genetic erosion continues, due to a concentration of research resources on the main species which thus benefit from increasing adoption returns. Despite this, major seed players are managing to find solutions to help large-scale farming to adapt to ongoing climate change.

Market mechanisms dominate. They integrate environmental values through branding and certification strategies. The role of interprofessional organizations is limited. It is the research power of large companies that makes it possible to respond to the major challenges facing agriculture. Agriculture can promote its environmental services but the biodiversity management model corresponds to the specialization of spaces (
Land sparing).

The relationship between the seed world and civil society remains conflictual given the “trolling” effect of conflicts around Monsanto and the fear of dependence on seed monopolies. In this context, in Europe, regulatory barriers are mobilized by political actors to maximize the protection of consumers and the environment. The cost of regulation reduces the possibilities for using technologies on minor species.

The patent is the cornerstone of intellectual property protection. The VOC still exists and is an illusion. de facto
However, the coach's exemption is no longer guaranteed; of privatized genetic resources. The large decrease in genetic progress. The closure of pools groups relying on genetics contributes to a aligning itself pools UPOV's European renovation initiatives has failed. The world is gradually with the American model.

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3. Scenario 3- War economy (axis 1: climatic-agricultural chaos, axis 2: innovation open and diversity)

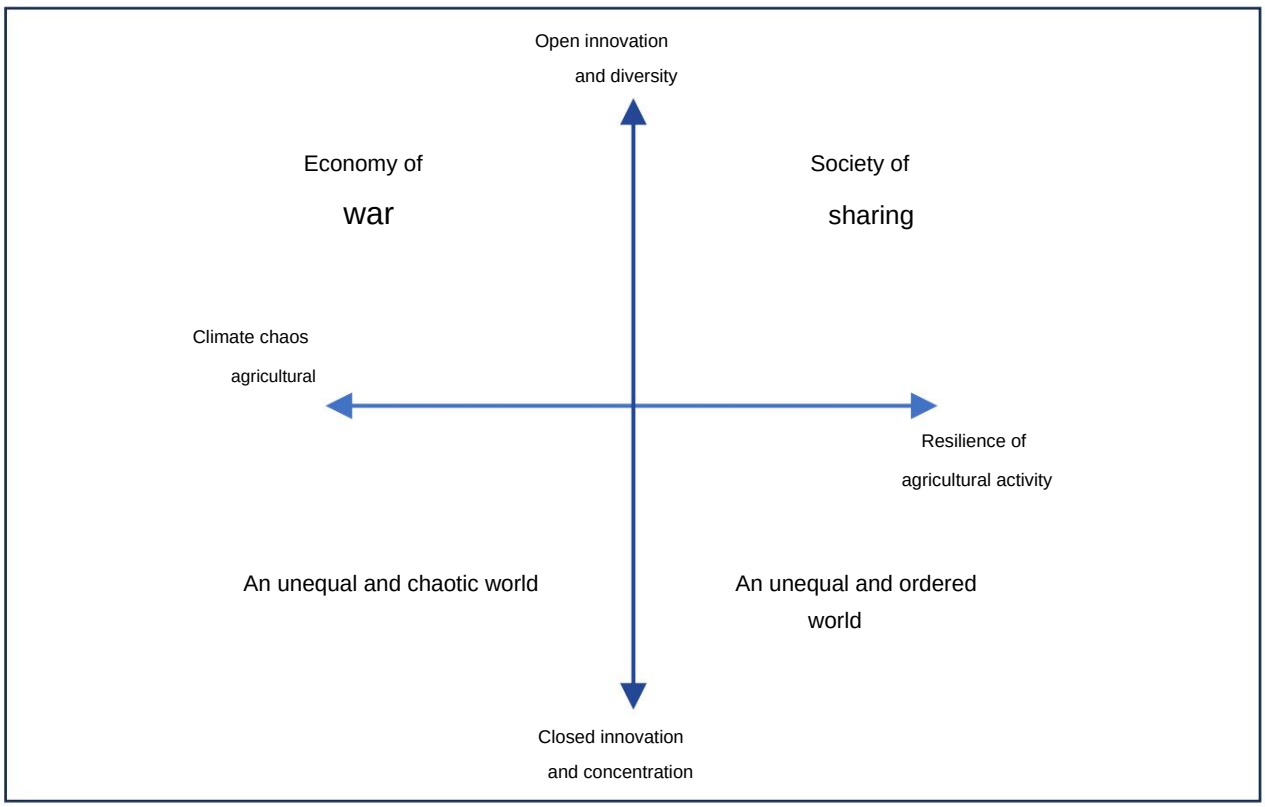
As in scenario 1, a network of businesses with strong territorial roots has developed, contributing to a diversification of species and varieties within the framework of complex agricultural landscapes closely coupled with regional food chains. Public research supports the commons of advanced technologies and genetic resources. However, despite these elements which contribute to the robustness of agriculture, the pace of innovations (and in particular of varietal creation) is a brake in the process of adaptation of agriculture to climate change.

At different scales, we observe major crises that call into question food security and political order. The fabric of territorialized businesses and the coupling with regional food chains mitigates the effect of these crises.

Faced with these major threats, States are returning to redistributive, authoritarian planning and rationing systems. A “war economy” is being established in which certain rules of the rule of law are modified, so as to facilitate cooperation and access for all to the resources and knowledge necessary to achieve, with difficulty, adapt, in order to guarantee the essential needs of populations. Intellectual property rights linked to essential needs are requisitioned, the use of compulsory licenses (or ex officio licenses) having been relaxed.

Regulatory barriers are also being relaxed to accelerate the innovation chain. Seed technologies and genetic resources fall within this scope. At the international level, multilateral agreements make it possible to maintain a cooperative game and orchestration of research efforts.

Given its protective role, the authoritarian policy of the state is well accepted. The social climate remains peaceful despite the major difficulties caused by the changes.



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4. Scenario 4- An unequal and chaotic world (axis 1: climatic-agricultural chaos, axis 2: closed innovation and concentration)

Due to a strong industrial concentration, the French farm has lost its technological sovereignty in the field of seeds. It therefore finds itself heavily dependent on global monopolies which escape political power, both national and European. Nor can public research play a buffering and protective role on

resources.

Due to the reduction in the number of species and the “McDonaldization” of food, agricultural and food systems are not resilient, which increases vulnerability to climate crises.

Major crises that challenge food security and the political order are amplified by powerful actors who use their market power to speculate on these crises. The social climate is explosive due to massive inequalities. Public institutions are deteriorating due to constraints on public budgets and a general rise in distrust.

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semae

Toutes les semences pour demain