



IMPACTS OF THE COMMISSION'S INITIATIVE TO MODIFY THE REGULATION OF CERTAIN PLANT GMOs ON THE APPLICATION OF EUROPEAN PATENT LAW

In this new report, the European Coordination Via Campesina (ECVC), which represents 31 organisations of European small and medium-scale farmers, peasants, and rural workers, analyses the impacts of a potential deregulation of certain plant GMOs on the enforcement of European patent law, and details the concrete consequences that such a deregulation would have on the GMO-free agricultural sector and on the rights of peasants¹ and breeders on seeds.

Patents on seeds² are as sensitive in European public opinion as are genetically modified organisms (GMOs). The adoption of the two European directives on patents (98/44/EC) and GMOs (2001/18/EC) has helped to allay concerns with the following message concerning plants and animals: what is not labelled GMO is not patented, only GMOs are patentable. Countries that have not regulated GMOs have seen patented seeds take over the market, invade almost every field, and remove the rights of farmers to use their own seeds and of consumers to choose their food. Despite some loopholes, the middle ground proposed by the European Union has allowed it to protect the freedom to produce and consume with or without GMOs, to curb the concentration of the seed industry and the drastic erosion of crop biodiversity that it entails, and to maintain an unfortunately still too restricted right of farmers to use their own seeds.

The implementation of the European Commission's current proposals to abolish or ease the regulation of certain plant GMOs would put an end to this balance, which has already been weakened by a deficient implementation. It would annihilate farmers' and consumers' rights by opening the way for the control of the food chain by patents of a handful of multinational companies.

¹ ECVC's demands for the implementation of peasants' rights to seeds in Europe can be found in our 2021 publication: <https://www.eurovia.org/publications/publication-incorporating-peasants-rights-to-seeds-in-european-law/>

² Seeds, seedlings, germs, bulbs...: in legal language, "*plant reproductive material*". In fact, these patents cover both plants and their reproductive organs.

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I. A very incomplete inception impact assessment

1 - On November 8th 2019, the European Council issued a decision (2019/1904)³ “requesting the Commission to submit a study in light of the Court of Justice’s judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study”. **This decision is addressed to the European Commission as a whole and not to DG SANTE alone⁴. It aims to carry out a study on all EU law, without any particular restrictions on the sole GMO regulation.**

To date, only DG SANTE has taken up this issue. After various exchanges with industry stakeholders, European civil society organisations and Member States, it published an initial study in April 2021, followed in September of the same year by an "inception impact assessment"⁵ proposing a change in the European regulation of plants derived from new genetic modification techniques whose commercial development is announced as the most promising: targeted mutagenesis and cisgenesis. It has organised two public consultations in 2021 and 2022, and commissioned consultancies to organise targeted consultations with various stakeholders. The latest consultations in 2022 were considered too biased towards deregulation options by many peasants' and civil society organisations, which therefore refused to respond⁶.

In all its documents and consultations, DG SANTE focuses on the status of new genomic techniques (NGTs)⁷ within the framework of GMO regulation alone, without considering the impact of the developments it proposes on the application of patent law or on other sections of European law that are not developed in this report, such as those concerning the marketing of seeds, genetic resources, etc. In the presentation of its second public consultation opened on 29 April 2022⁸, DG SANTE even specifies that intellectual property rights are not among the issues addressed.

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1904&>

⁴ Directorate-General for Health and Food Safety, one of the many directorates of the European Commission services.

⁵ https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf

⁶ ECVC has expressed in an open letter the reasons for its refusal to respond to the open consultation of DG SANTE: <https://www.eurovia.org/news/ecvc-refuses-to-respond-to-the-european-commissions-biased-consultation-on-new-genomic-techniques/> On the other hand, many environmental, agricultural and GMO-free organisations have expressed in a recent open letter their decision not to take part in the targeted consultation of DG SANTE carried out in partnership with the consultancy Technopolis: <https://www.eurovia.org/news/open-letter-european-commissions-biased-road-to-deregulation-of-new-gmos/>

⁷ New Genomic Techniques have been defined by the European Commission as “*techniques capable of changing the genetic material of an organism and that have emerged or have been developed since 2001*”. This definition is not in line with the definition in the ruling of the Court of Justice of the European Union (CJEU) in Case C-528/16 referred to in the Council decision. The Court of Justice of the European Union (CJEU) defines them as techniques “*which have appeared or were **mostly** developed after 2001*”. This discreet distortion of the CJEU's definition by the Commission, which thus deviates from its task of applying European law, allows it to arbitrarily exclude from the scope of Directive 2001/18 random *in vitro* mutagenesis techniques which, like transgenesis, were **mostly** developed only after 2001, after having been the subject of a few developments shortly before 2001 that did not allow them to demonstrate “a long safety record”. See below, paragraph 11 (p. 12).

⁸ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/F_en

However, the abolition of traceability of plant products currently regulated as GMOs would have a huge impact on the application of European patent law in the agricultural, research and seed industry sectors and, consequently, on farmers' rights, access to plant genetic resources, breeders' freedom of enterprise, the right to food and food sovereignty, to mention but a few. **Any Commission proposal on the legal status of NGTs that is not accompanied by a study of its impact on the concrete application of patent law in the real world would therefore be contrary to the request of the European Council of 8 November 2019.** The same applies to the lack of consideration of other sections of EU law that may also be impacted by this proposal.

II. Traceability of GMOs in European law

2 - In addition to the obligation to label marketed GMOs, Directive 2001/18 (Articles 13.f, 19.c, 21, 25.4 and 26 Annex III B and IV) makes it compulsory to publish "*the description of the methods for detection and identification of the genetically modified plant*". Regulation 1829/2003 (Articles 5.3.i, 17.3.i and 30.3 f) is even more precise in making mandatory the publication of "*methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it*". Essential to ensure traceability, control and monitoring of the release of GMOs, **the obligation to publish the description of the methods of detection and identification of the genetically modified plant also ensures consistency between the GMO regulation and the regulation related to the legal protection of biotechnological inventions (Directive 98/44/EC). This obligation enables any user to distinguish any GMO from any other organism or product not subject to the restrictions on use resulting from the patent on that GMO.**

It is thus an essential tool to manage the risks of abusive infringement proceedings that may result from the abusive extension of the scope of patents covering NGTs and their derived products to "native genes" of plants or animals derived from traditional peasant or industrial breeding.

III. Application of European patent law to plants derived from *in vitro* mutagenesis (random or targeted) and cisgenesis

3 - The European Commission's current communication only refers to targeted mutagenesis and cisgenesis techniques. However, its proposal also applies to random *in vitro* mutagenesis techniques, since it considers that they are already excluded from the scope of Directive 2001/18/EC, an exclusion contested, in particular, by the French Council of State. This case is discussed in detail below in paragraph 11, as are the specific features of cisgenesis in paragraph 12.

These techniques, and the seeds and plants which derived thereof, are covered by patents. These techniques all involve a step of genetic modification of plant cells grown *in vitro*. Under European patent law, an isolated cell is a microbiological organism. These techniques are therefore not essentially biological processes ("*consisting entirely of natural phenomena such as crossing or*

selection"⁹) that are not patentable, but microbiological processes of genetic modification "*in a way that does not occur naturally by mating and/or natural recombination*"¹⁰ . They are therefore patentable¹¹, provided that they involve an inventive step, are new, susceptible of industrial application¹² and sufficiently described for a person skilled in the art to carry them out, which implies that they are sufficiently reproducible. The products of these processes are also patentable, as process products or simply covered by process patents.

4 - The claims of the patents resulting from these genetic techniques do not relate to all the phenotypic characteristics or to the entire genome of entire plants: this would in fact amount to patenting a distinct, homogeneous and stable variety made up of all the plants expressing all these phenotypic and/or genetic characteristics, which is prohibited by European law. These patents relate only to the biological material¹³ or genetic information¹⁴ modified (described as a "transformation event") by the claimed process and to the properties, phenotypic characteristics¹⁵ or functions conferred by the claimed process on all the plants that express or contain them, provided that they do not constitute a distinct, homogeneous and stable variety. In general, the claims of these patents cover all plants of the same species bearing the characteristics resulting from the invention, for example all maize plants bearing a gene conferring on them a tolerance character to a given herbicide or producing a given insecticide. Since the decision of the Enlarged Board of Appeal of the European Patent Office (G3/19) of 14 May 2020¹⁶, plant or animal products derived exclusively from essentially biological processes are no longer patentable. **Patent applications for plants or animals must therefore now provide a description of the non-essentially biological process(es) used.**

5 - Any seed, plant, crop or other plant product bearing the characteristics claimed by a patent may be presumed to constitute an infringement. This presumption of infringement allows the patent holder to initiate proceedings, or even to obtain a seizure of the goods¹⁷ without providing formal

⁹ Article 2 of Directive 98/44/EC.

¹⁰ Article 2 of Directive 2001/18/EC.

¹¹ Article 53(b) of the European Patent Convention: "*exception to patentability [...] this provision shall not apply to microbiological processes (for the production of plants and animals) or the products thereof*". The meaning of the terms used in this Article is clarified in the EPO Implementing Guidelines, https://www.epo.org/law-practice/legal-texts/html/guidelines/f/g_ji_5_5_1.htm : "*Microbiological process*" means any process involving or carried out on microbiological material or resulting in such material"; "*Propagation of the microorganism itself is to be construed as a microbiological process*"; "*Isolated plant or animal cells or cultures of plant or animal cells in vitro are treated as microorganisms, as the cells are comparable to single-celled organisms (G 1/98, 5.2)*."

¹² Agricultural cultivation is an industrial application in patent law.

¹³ Biological material: a material containing genetic information and which is self-replicating or reproducible in a biological system: protein... The molecule that constitutes an entire genome is not itself patentable

¹⁴ Gene, nucleotide sequence - DNA or RNA - identified in dematerialized numerical form by successions of four letters A, C, G, T.

¹⁵ A property, character, trait or function observable or measurable in the physical world.

¹⁶ <https://www.epo.org/law-practice/case-law-appeals/communications/2020/20200514.html>

¹⁷ Article 7 of European Directive 2004/48 of 29 April 2004 on the enforcement of intellectual property rights.

proof of infringement. The mere presence of biological material, genetic information or specific properties covered by the patent is sufficient. These procedures certainly entail a risk of compensation for the patent holder if proof of non-infringement is established. But they also entail **a reversal of the burden of proof**: it is indeed up to the alleged infringer who wishes to stop the proceedings or lift a seizure (which is particularly urgent when perishable goods are involved) to prove that his seeds, plants or other plant products are not directly derived from the patented invention, or from the identical reproduction of products derived from it. Without such evidence, the alleged infringer would be subject to the various national laws implementing Articles 8 and 9 of Directive 98/44¹⁸ and/or the decisions of the new Unified Patent Court. Gathering such evidence is often beyond the reach of a farmer, a small seed grower or anyone else who is not a specialist in genetics or the intricacies of patent law, and can sometimes be completely impossible.

IV. Interactions between GMO regulations and patents

6 - The "Patent Directive" (on the legal protection of biotechnological inventions, 98/44/EC) was adopted in 1998 at a time when transgenesis, presented at the time as targeted, was the only technique of genetic modification giving rise to GMOs (then regulated by Directive 90/220/EC) widely known beyond small circles of specialists, and therefore the only reference for the legislator. A native gene¹⁹ or any other genetic information obtained by essentially biological processes is easily distinguished from any transgene by a simple genetic analysis (PCR test or sequencing). In the case of a plant modified to contain one or more transgenes conferring a particular property, it is therefore not possible to sue for infringement the holder of plants having the same properties as this patented transgenic plant but not containing the corresponding transgene(s).

7 - This is not the case when it is not a transgene, but genetic sequences or information obtained by NGTs which, according to the claims of the genetic engineering companies, merely "*rearrange DNA that is already there*" and "*accelerate what would naturally occur in conventional breeding*"²⁰. The companies conclude, in a classic circular reasoning, that there is nothing to distinguish their

¹⁸ Article 8:

1. *The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.*

2. *The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.*

Article 9: *The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.*

¹⁹ Native: existing in nature.

²⁰ Statement by Mr Reza Rasoulpour, Head of Global Crop Protection Regulation at Corteva, published in the Politico newspaper on 4 October 2022. There are many other statements such as "*no foreign genes*", "*do the same as nature*", etc.

new GMOs from conventionally bred plants (essentially biological processes under patent law) and that they cannot therefore be regulated differently.

Some researchers and the European Commission have taken up these totally unfounded claims. Any plant derived from NGTs is in fact unambiguously different from any plant obtained exclusively by conventional breeding techniques, if only because of the many unavoidable unintentional genetic and epigenetic modifications, *on* or *off target*²¹, that can only be produced by these NGTs and the associated techniques (*in vitro* cell cultures, selection of modified cells and removal of the markers used, unintentional insertions of vector nucleic acids or other nucleic contaminants from the organisms - generally bacterial - used to prepare the NGT "components"...). The impacts of these related techniques common to transgenesis and NGT techniques are systematically ignored by the assessment agencies who claim that these techniques "*do the same thing as conventional breeding*", **a lie by omission abusing the authority of the expert to mislead public opinion**. But these unintended modifications are not part of the claims of most patents, which are limited to defining only the transformation event (biological material, genetic information) and the particular properties or functions it confers on a plant and/or defining the particular characteristics conferred on a plant by the process covered by the patent. There is then no way to distinguish these definitions from the description of a native gene and/or the same characteristics or properties obtained exclusively by essentially biological processes.

The unintended genetic and/or epigenetic modifications, or sometimes even certain characteristics of the transformation event, which are not described in most patents, nevertheless make it possible to distinguish plants genetically modified by NGTs from any plant resulting from an essentially biological process that cannot be patented (Bertheau 2019, 2022)²². Currently, only

²¹ *On target*: directly linked to the transformation event; *off target*: elsewhere in the genome.

²² The residual genomic and epigenomic biomarkers available on commercial varieties allow us to distinguish:

- Varieties of cultivated and uncultivated species (biomarkers of domestication syndrome),
- The firms (or even the laboratories and technicians with certain AI tools) that carried out the modifications (biomarkers in the genome of the modifiable laboratory varieties and in the genomes of the Elite varieties used for introgression and then commercial developments),
- The fact that the varieties have gone through *in vitro* steps (somaclonal variation, traces of Cre-Lox excisions, inserted nucleic contaminants, chromothripsis...),
- The use of NBT techniques (on- and off-target modified sequence frequencies via RNAi or nuclease NBT, chromothripsis and micronuclei, PAM proximities...)
- and quantify them (quantitative PCR and LCR, NASBA...) or to locate the contents of NBT products in relation to the labelling threshold (sub-sampling methods with AQL and LQL...).

Bertheau, Y. (2019). *New breeding techniques: detection and identification of the techniques and derived products*. In R.H. Stadler, ed. *Encyclopedia of Food Chemistry, Reference Module in Food Science*. Elsevier, pp. 320-336.

<https://doi.org/10.1016/B978-0-08-100596-5.21834-9>

Bertheau, Y. (2022). *Advances in identifying GM plants. Toward the routine detection of "hidden" and "new" GMOs*. In *Developing smart-agrifood supply chains: using technology to improve safety and quality*. L. Manning, ed (Burleigh Dodds Science Publishing), pp. 87-150. <http://dx.doi.org/10.19103/AS.2021.0097.22>.

<https://bdspublishing.com/webedit/uploaded-files/All%20Files/Open%20Access/9781801462044.pdf>

GMO regulation requires the publication of the processes that make this distinction possible, not patent law.

8 - As long as NGTs remain subject to the application of European GMO regulations, any authorisation for release is in fact subject to the obligation to make public "*the methods and plans for monitoring the GMO(s)*", "*the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed*"²³. This information makes it possible to distinguish any plant product obtained exclusively by essentially biological processes from any patented plant product derived from a NGT and thus prohibits the abusive extension of the patent to native genes and to seeds and plants derived exclusively from traditional breeding. The publication of these patents makes it possible to prevent any abusive infringement proceedings. However, if plant products derived from certain NGTs were no longer subject to the European GMO regulation, this public disclosure requirement would disappear and with it the possibility for the alleged infringer to prove that their product is different from the patented product.

No information on the existence of patents that may cover seeds is available at the time of marketing, neither in the official catalogue, nor in the patent registers which do not indicate in which varieties patents are developed, nor elsewhere. If labelling and traceability of GMOs is removed, farmers, breeders, processors, distributors *etc.* could in good faith use patented seeds or plants to reproduce their farm seeds and/or to select other seeds, grow them and then develop and sell multiple plant products, without any knowledge of the obligation to negotiate a licence fee beforehand. Such uses are subject to infringement proceedings. Farmers and small seed processing and distribution companies do not have the means to protect themselves from such lawsuits by establishing and using protocols to search for possible biomarkers of patentable genetic modification techniques, nor do they have access to the private databases of very large companies. EFSA's PINTO database only covers commercialised varieties and not all patented transformation events. Moreover, as it is only voluntary, it is incomplete and difficult to access. It is therefore largely insufficient to solve this problem.

Such infringement lawsuits are already a very concrete reality in countries that do not impose any traceability of GMOs. In the USA, Monsanto has hired private detectives to take samples from farmers' fields. The financial penalties for the illegal reproduction of a "patented invention" are so high that no farmer dares to use his own seeds, even if they have not sown GMOs. The penalties are the same in the event of contamination. Therefore, more and more farmers prefer to buy patented seeds every year to be sure that they have paid the licence fees avoiding them an infringement case. This is how GM crops become widespread, and with them, the contamination and conviction of the last farmers who grow non-patented seeds.

²³ Article 25.4 of Directive 2001/18 and Annex III B of Regulation 1829/2003.

This patent jungle, which has been well highlighted by the OECD²⁴, is also at the origin of the very high concentration of the seed industry, which allows six transnational companies to control more than 60% of the world seed market today²⁵, reducing most of the cultivated biodiversity to the very limited gene pool that these companies exploit. The genes of interest for the main agricultural crops are already almost all patented by these transnationals. Any small or medium-sized enterprise that innovates necessarily uses at least one of these genes and thus automatically falls under their dependence: considering the cost of licensing fees, the only choice left to these companies is to disappear from the market or to accept an unbalanced "partnership" followed by absorption.

The management of patent portfolios is also becoming a tool for financial rent like any other, which can be outsourced, as it can be observed in other fields (electronics for example). The purpose of filing a patent is not so much to protect the development of some invention as to limit competitors' access to techniques and/or to be able to negotiate a few royalties with a competitor fearing long legal proceedings. We are then witnessing the creation of a new financial bubble resulting from a few predators taking control of the market, as was the case in electronics and computing at the beginning of the current century. These patents have lost their initial advantage of encouraging innovation and its disclosure and turn out to be more tools for blackmail than for remuneration of a real discovery. Patent trolls are therefore on the prowl in this sector (Check Hayden, 2011), whose abusive lawsuits are estimated to cost²⁶ nearly US\$30 billion annually. They particularly target small innovative firms and start-ups, precisely those whose messages from communication agencies favouring the development of new GMOs would have us believe that they could benefit from new "less expensive" techniques.

By abolishing the traceability of patented GMOs, the Commission would definitely engage the European Union in the generalisation of this drift.

V. The disclaimer: a false solution

9 - The holder of a patent always provides themselves with the means to defend it against possible infringements, and therefore to identify the products covered by the claims of his patent. But in the absence of an obligation to publish these means, they can keep them confidential as an industrial or commercial secret.

Since July 1st 2017, the European Patent Office guidelines require that any patent must additionally be accompanied by a disclaimer "*if a technical feature of a claimed plant or animal, e.g., a single nucleotide exchange in the genome, can be the result of both a technical intervention (e.g., directed mutagenesis) and an essentially biological process (a natural allele)*". A disclaimer "*is necessary to*

²⁴ OECD. (2018). *Concentration in Seed Markets: Potential Effects and Policy Responses*:

<https://www.oecd.org/publications/concentration-in-seed-markets-9789264308367-en.htm>

²⁵ According to a recent ETC Group's report (2022), six multinational companies share nearly 60% of the global seed market (including biotechnology), and two multinationals (Bayer and Corteva) alone control 40% of this market: <https://www.etcgroup.org/food-barons-2022-agrochemicals-seeds>

²⁶ <https://hbr.org/2022/09/its-time-for-the-u-s-to-tackle-patent-trolls>

delimit the claimed subject-matter to the technically produced product"²⁷ (the technical means related to the patented invention). It should remove from the claims what they cannot cover because it is excluded from patentability, where this is not clear from the claims. It should therefore allow the alleged infringer to prove that his product is different from the patented product.

10 - But the description of products not covered by a patent can only be provided if these products exist and are known. However, a patent for a product derived from NGTs aims, according to the companies, to "*accelerate what would occur naturally in the context of conventional breeding*". It must also meet the requirement of novelty and cannot therefore be granted if it aims to reproduce identically what already occurs "*naturally in the context of conventional breeding*". The disclaimer cannot therefore describe what does not exist or is not known²⁸.

While UPOV and ISO are standardising the tools for identifying and distinguishing plant varieties, so that the different techniques used are recognised as compatible, with convergent results and all enforceable in court, one may wonder why the same work is not being done to standardise the tools for detecting and distinguishing GMOs and products containing patented "transformation events".

If certain NGTs are excluded from the scope of the GMO regulation, the scope of a patent on biological material or genetic information obtained by one of these techniques would extend to any plant that contains this biological material or genetic information and expresses the function claimed in the patent, provided that this plant was not known at the date of filing of the patent application, including if it already existed at that time but without any documentation prior to that date to prove it. This may be the case for all plants derived from traditional farmers' or small seed growers' breeding which contain biological material or genetic information and express properties or functions identical to those claimed in a patent without having been the subject, prior to the first application for the latter, of a precise public description of all these elements, or of an official deposit of samples (registration in the catalogue, claim of a plant variety right or a patent, deposit in any other official collection, etc.) enabling these descriptions to be provided subsequently.

This is the case for the overwhelming majority of traditional seeds or seeds from recent farmers' selections because they have never been or are no longer registered in the official catalogue or covered by a plant variety right, have not been the subject of any patent application, have not been described by any public scientific description that accounts for all their properties, functions and genetic sequences and have not been the subject of any deposit of samples in other official

²⁷https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_2.htm

²⁸In patent law, an invention is new if it is not disclosed by the state of the art consisting of the general knowledge of the person skilled in the art, any public disclosure (written or oral), any public use prior to the date of filing of the patent application. Most peasant and indigenous knowledge have never been the subject of any scientific publication or in registers that can be used against third parties. It is therefore not part of the knowledge of professionals, the profession considered here being that of geneticist, commercial seed breeder or plant 'improvement' researcher.

collections before the date of the application for the patent, even when they are still being grown (Villa et al., 2005).

VI. *In vitro* random mutagenesis using chemical or physical mutagenic agents on plant cells

11 - The same patent abuses could also result from the European Commission's refusal to include GMOs obtained by "*in vitro* random mutagenesis techniques subjecting plant cells to chemical or physical mutagenic agents" in the scope of the European GMO regulation.

Although described as random, these *in vitro* mutagenesis techniques used to develop herbicide-tolerant plants are sufficiently reproducible by professionals to be patentable. The extensive control of the *in vitro* plant cell culture medium and the acquired know-how allow the breeder to determine in advance the particular qualities and doses of radiation or mutagenic chemicals used, the pressure, the temperature, the precise moments in the development of the cell culture when they are used and other parameters.... that can reliably produce a sufficiently high percentage of herbicide-tolerant cells to meet the reproducibility criterion by patent review divisions that never verify reproducibility experimentally or through systematic literature reviews.

The French Council of State considered in its judgment of February 7th 2020²⁹ in the light of the judgment of the Court of Justice of the European Union (CJEU) in Case C-528/16, which the European Council asked the Commission to take into account (note 2, paragraph 1), that '*these techniques (of random in vitro mutagenesis) must be regarded as being subject to the obligations imposed on genetically modified organisms by this Directive (2001/18)*'. The European Commission objected to this ruling and the French government did not comply with it. As a result, two new questions have been referred to the European Court of Justice for a preliminary ruling in this case³⁰ and a ruling is expected shortly.

Oilseed rape and sunflower varieties made tolerant to herbicides using these techniques are currently being grown outside the European GMO regulatory framework. These crops are strongly contested because of the increased quantities of herbicides used and the resulting contamination of conventional or organic crops and wild biodiversity.

No attempts to misuse infringement proceedings or to improperly extend the scope of patents on these GMOs to plants that are native or obtained exclusively by essentially biological processes have been successful to date. There are two reasons for the absence of patent abuse in these particular cases: on the one hand, these rapeseed and sunflowers are F1 hybrids, i.e. non-stabilised crosses that do not retain their qualities and give very irregular harvests if farmers reuse their farm seeds; farmers do not reuse the seeds from their harvests of these varieties and therefore do not expose themselves to infringement proceedings; on the other hand, the same two companies hold

²⁹<https://www.conseil-etat.fr/ressources/decisions-contentieuses/dernieres-decisions-importantes/conseil-d-etat-7-fevrier-2020-organismes-obtenus-par-mutagenese>

³⁰<https://www.conseil-etat.fr/fr/arianeweb/CE/decision/2021-11-08/451264>

the patents and plant breeders' rights to these oilseed rape and sunflower plants produced through spontaneous mutations or mutagenesis ; although they both brought infringement suits against their respective patents in the US courts, they quickly withdrew them, presumably after an exchange of licence rights that has not been made public

But plants carrying other patented traits resulting from these *in vitro* random mutagenesis techniques may be commercialised and give rise to such patent abuse. **Another important risk may therefore arise from their exclusion from the scope of GMO regulation: the declaration of use of patentable but non-GMO regulated techniques by companies that have in fact used other genetic modification techniques subject to GMO regulation.** All directed mutagenesis techniques use *in vitro* cell cultures. The genetic or epigenetic signatures (biomarkers) of these *in vitro* cell culture techniques are, by the multivariate approaches used, in particular in the current UPOV and ISO standardisations, univocal and it is impossible to remove them all by backcrossing (Bertheau 2019, 2022, see note 21 paragraph 7). If only directed mutagenesis techniques are maintained within the scope of GMO regulations and not random *in vitro* mutagenesis techniques, it is sufficient for the breeder of the patented plant obtained by directed mutagenesis to declare that they have used a random *in vitro* mutagenesis process and to put forward his biomarkers alone in order to circumvent these GMO regulations.

This is already happening. The company CIBUS gave an instructive example: in order to market an herbicide-tolerant oilseed rape on the American continent, which does not subject NGTs to GMO regulation, it declared that it had obtained it by directed mutagenesis (using oligonucleotides), with extensive publicity about its "technological innovation". But as soon as an independent laboratory published and a process allowing the transformation event of this oilseed rape to be identified, and communicated to the authorities which control GMOs introduced into the European market, CIBUS went back on its initial statements. It then stated that it had in fact obtained the oilseed rape by "soma-clonal variation", which is a random mutagenesis technique applied to *in vitro* plant cells that the European Commission refuses to submit to GMO regulations. If the CJEU were to follow the Commission's opinion, this type of circumvention of the GMO regulation allowing native genes to be patented could become widespread. This is especially true since it allows GMO labelling to be circumvented while retaining the patents claimed. Soma-clonal variation could then be invoked at any time, whatever the NGT technique used, without any risk regarding the legislation, since **neither the variety evaluation services for registration in the catalogue nor the patent examination divisions analyse the plant products submitted to them to look for markers of the breeding technique used.**

VII. Cisgenesis

12 - The same abusive infringement lawsuits by many operators could also result from the Commission's proposed exclusion of cisgenesis from the scope of the GMO regulation. Of course, cisgenesis is a transgenesis technique. It inserts a sequence homologous to a gene from plants that can be crossed with the recipient plant using traditional breeding methods: this modified gene alone does not therefore make it possible to distinguish the cisgenic plant from any other plant

containing the same genetic sequence obtained exclusively by essentially biological processes. If described in the patents by this one gene, the transformation event of a cisgenic plant is not distinguishable from the same "native" gene or gene inserted exclusively by essentially biological processes such as crossing.

Beyond this gene, the cisgenic transgene also necessarily contains other biological material that cannot be found naturally, or by essentially biological processes, in the plant into which it is inserted (bacterial vector, viral promoter, terminator...). But the unquestionable detection and identification of these exogenous genetic materials not described in the patent is not within the reach of farmers or small seed breeders who do not have access to the necessary databases or sequencing techniques. Moreover, they often cannot afford the cost and commercial losses associated with lengthy and unjustified infringement proceedings. **Excluding cisgenesis from the scope of GMO regulation would remove public access to techniques for identifying and distinguishing these GMOs. Farmers and small seed companies would then become easy prey to abusive lawsuits for counterfeiting cisgenic plants.**

VIII. Digitising seeds to escape the laws of the real physical world

13 - When it comes to reinforcing the rights of a patent holder, European regulations establish a direct link between genetic information and the physical seeds ('biological material') that contain it (Article 9 of Directive 98/44, see note 17 in Chapter 5). However, when it comes to accessing the 'digital sequence information' (DSI) contained in the millions of physical seed samples collected from farmers' fields and stored in public collections and other 'germplasm banks', the European Union representatives in the European Parliament and the Council of Ministers have not been able to make any such link : EU representatives in international discussions on biodiversity believe that this digital sequence information is not genetic resources and would therefore not be subject to the prohibition, for those who have access to it, to claim intellectual property rights limiting access to the physical plant genetic resources within which it has been identified, to its genetic part or components³¹ .

Beyond the gross contradiction revealed by this misleading rhetoric, this position opens a limitless road for the generalisation of patents on native genes. Large industrial foundations and numerous public research programmes have in recent years funded the genetic sequencing of the majority of these model plant genetic resources, currently including the sequencing of species pangenomes. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which is responsible for access to most of the world's collections of plant genetic resources, is involved in these programmes. Digital sequence information is becoming increasingly accurate. Public research information is now freely available on the Internet, which is hardly the case for sequencing by private companies. The so-called 'traditional' knowledge of the farmers who selected and saved

³¹Article 12.3.d) of the Seed Treaty (ITPGRFA) ratified by the European Union: "*Recipients [of a plant genetic resource] shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System*".

the seeds from which these DSI were identified is also freely available in the publications of the researchers who identified them and reports on the specific properties of each of these seeds (Casañas et al., 2017; Kliem and Sievers-Glotzbach, 2022; Raggi et al., 2021; Raggi et al., 2022). Powerful computer algorithms can be used to cross-reference these millions of publicly available or company-held data to identify which properties or functions correspond to which genetic information. Digital machine learning and multiplex genome editing (MGE) technologies can then be used to program NGTs to incorporate this genetic information into new plants by describing them as "identical to what conventional breeding could produce" and, of course, after a formal patent application has been filed. Knowledge and possession of the genetic backgrounds that enable these transformations (transformable "laboratory varieties") and their subsequent expression in elite variety backgrounds, all derived from plant genetic resources, are certainly prerequisites. But it is not necessary to hold or have access to the physical genetic resources within which the DSI used were originally identified.

The assertion that these patented DSI are not genetic resources but "products of research" extends the scope of these patents to all plants that contain them and express their function, including those that are not the result of the patented invention or its reproduction, including those in which these DSI were initially identified if they were not known at the time of the patent application. **Today, the last barrier to the spread of this widespread biopiracy in Europe is the obligations arising from the GMO regulation to publish the procedures for identifying, distinguishing and labelling GMOs and the products derived from them.**

Before wanting to remove this barrier, **the Commission services responsible for GMOs (DG SANTE) should first meet with their colleagues who deal with agricultural genetic resources (DR Agri), patents (DG Grows) and wild genetic resources (DG ENVI) in order to resolve the contradictions resulting from their respective positions and to avoid committing the European Union to such a privatisation of all available seeds through digital and genetic techniques.**

IX. Examples of abusive extension of the scope of patents

14 - There are currently no examples of patent abuse in the European Union of plants derived from NGTs that would not be subject to GMO regulation because they are all subject to GMO regulation today. The reasons why the few plants derived from *in vitro* random mutagenesis that are abusing the GMO regulation have not yet given rise to patent abuse have been discussed in paragraph 11 above.

However, the misfortune that befell the French company Gauthier Semences shows what could happen if the labelling and traceability of certain GMOs were to be abolished. In 1997, the Dutch company Rijk Zwaan applied for a patent on a lettuce carrying an 'Nr' gene conferring resistance to an aphid and characterised by the absence of the genetic information responsible for the dwarfing character ('CRA phenotype'). According to the state of the art described in the patent, resistance to this aphid is inseparable from the dwarfing trait. It is therefore the separation of these two genes to obtain an aphid-resistant lettuce that does not express the dwarfing trait that is presented in

the patent to justify its inventive character. The company Gauthier Semences was already marketing lettuces resistant to the same aphid and not expressing any dwarfing character. These characteristics are not among those that must be verified and recorded when registering in the catalogue or obtaining a plant variety right and are therefore easily verifiable by the patent examination divisions. Having obtained these lettuces by an essentially biological process that cannot be patented (crosses of commercial lines with a dwarf wild lettuce resistant to this aphid, carried out in collaboration with the French public institute for agronomic research, INRA), the company Gauthier Semences had not filed a patent application. Instead, in 2004 it filed an opposition to Rijk Zwaan's patent. Sometime later its regular customers began to refuse to continue buying its seeds because they had been threatened with infringement proceedings by Rijk Zwaan. In contrast to Rijk Zwaan, which is a large, so-called "mid-sized" seed company, Gauthier Semences is a small seed company that does not have sufficient financial means to support a long legal procedure while being deprived of the possibility to sell its seeds. It therefore withdrew its opposition and the patent was finally granted to Rijk Zwaan in 2007³². Gauthier Semences had to negotiate a licence fee to be able to continue to market its lettuce seeds, just like other seed companies that market a large number of other lettuce varieties that are resistant to this aphid.

As the opposition procedure was not completed, it is quite possible that the Rijk Zwaan patent is not valid. The patent examination divisions rely on the adversarial process and therefore on the possibility of opposition by professionals and 'men of the trade' to decide on possible non-conformities that they have not identified. They do not have knowledge of the entire state of the art or the means to reproduce the claimed invention themselves in order to verify the truthfulness of its description, its inventive character or its reproducibility³³. **In fact, it was primarily the economic inequality between the two protagonists that allowed the one with the stronger economic backbone to "conclude" the dispute in its favour and not the indisputable validity of its patent.** This example is representative of the current situation where financial power plays a determining role in the monopolisation of a common good. It will only increase with the growing pressure of patent trolls as already observed (Check Hayden, 2011).

The Rijk Zwaan lettuce was obtained by a non-patentable essentially biological process (successive crosses) described in the patent claims. In 2007, only essentially biological processes were unpatentable and not the products derived from them. Since 2019 (see note 15 paragraph 4), patents on products derived exclusively from essentially biological processes are no longer granted. However, as this decision is not retroactive, Rijk Zwaan's patent is still valid.

³²Patent n° EP0921720 B2.

³³Reproducibility is one of the major concerns of the current crisis in science and thus in technological developments and mutual trust between socio-economic actors (American Society for Cell Biology (ASCB), 2015; Begley and Ioannidis, 2015; Boy, 2012; Hirsch and Schildknecht, 2019; Mehta and Vanderschuren, 2021; Morozov, 2013; Oreskes, 2018; Saltelli and Giampietro, 2017; Saltelli and Stark, 2018; Stark, 2018). This lack of reproducibility in science has unhappily rubbed off on that of patents and their claims, when results are not simply invented or maintained despite known retractions by examiners (Freilich, 2020; Freilich and Kim, 2022; Freilich and Ouellette, 2019; Sherkow, 2017).

However, a patent claiming 'native' characteristics, such as that of Rijk Zwaan, can now be granted based on the claim that it's using a patentable NGT '*doing the same thing as traditional breeding*', and thus resulting in a product described in the patent in a way that does not allow it to be distinguished from plants derived exclusively from essentially biological processes but not known in the 'state of the art'. If the obligation to publish the processes for identifying and distinguishing products obtained by certain NGTs is removed, the same misfortune as that which penalised Gauthier Semences could happen to any breeder who wants to market new seeds resulting from traditional breeding after the filing of an application for such a patent, as well as to any farmer who grows traditional seeds or seeds from their own selections which have not, before the first application for such a patent, been registered in the catalogue, deposited in an official collection or been the subject of a description in an official publication indicating that they express the properties claimed in this patent.

X. Patent infringement due to contamination with patented genetic information

15 - The most widely publicised case of the catastrophic consequences for a farmer of the contamination of his fields by patented genes is that of Percy Schmeiser, a farmer who was definitively convicted in 2004 by the Supreme Court of Canada for the unauthorised use of a patented invention (the Round'Up[®] tolerance gene), after a lengthy procedure initiated by Monsanto in 1998³⁴. This example reveals the impact of the lack of legal protection for farmers against such contamination in the absence of the coexistence rules required by the European GMO regulation. It could not have been concluded in the same way in many European countries where the national implementation of Directive 2001/18 establishes that GMOs can only be cultivated if they do not harm traditional agricultural structures and/or GMO-free production channels³⁵. **But if patented GMOs were to be exempted from the scope of this directive, European farmers would all be threatened with the same misfortune that led Canadian farmer Percy Schmeiser to mortgage his farm and abandon the rapeseed crop he had been growing for 50 years.** Rape is a plant from which it is technically impossible to harvest all the seeds. About 10% remain in the field when harvested and constitute a "bank" of viable seeds for more than 10 years. These very light seeds are carried by the wind, fall off trucks and tractor trailers and germinate in other fields several years after harvest. Viable pollen is capable of spreading between 2.5 and 26 km, depending on

³⁴ https://en.wikipedia.org/wiki/Percy_Schmeiser

³⁵For example, Article L. 531-2-1 of the French Environmental Code: "*genetically modified organisms may only be cultivated, marketed or used in a manner that respects the environment and public health, agricultural structures, local ecosystems and production and marketing channels qualified as "free of genetically modified organisms", and in full transparency*".

See also: Italian Legislative Decree no. 224 of 8 July 2003 (Last update published on 07/10/2019), Art. 8. Notification:

1. Any person intending to carry out a deliberate release of a GMO into the environment is required to submit a prior notification to the competent national authority.
2. The notification shall include (...) (c) the risk assessment for agrobiodiversity, agriculture and the agri-food chain, in accordance with the requirements established by the decree referred to in paragraph 6.

experimental conditions (Klein et al., 2006). Contamination is so high in Canada that most organic farmers have had to give up growing this plant in order not to lose their certification³⁶. This example explains the conclusions of the European Co-Extra programme³⁷ (2005-2009), on the coexistence and traceability of GMO and non-GMO sectors, which concluded that 'flexible' coexistence was impossible and recommended at the very least dedicated GMO or non-GMO zones, which no political body has dared to attempt to define (Bertheau, 2012; 2013).

XI. Patent clubs: false solutions

16 - Many voices are raised against the risk of these patents paralysing research and innovation. Seed companies are proposing to solve this problem through private initiatives such as the Agricultural Crop Licensing Platform (ACLPL). These platforms or patent clubs aim to facilitate the exchange of licenses and genetic material covered by these patents. However, in order to be part of the club, one must have something to exchange and therefore be a patent holder. This excludes small seed companies, farmers, researchers, *etc.* who do not have or do not want to claim patents and who, in the event of an infringement dispute, will not have to face a single patent holder, but a coalition of companies grouped together in these clubs and all holding on to each other through this inextricable patent jungle.

XII. What solutions?

17 - For ECVC, there is no sustainable solution other than banning all patents on living organisms, the maintenance of the obligation to publish the techniques for identifying and distinguishing any GMOs released into the environment and a ban (mentioned in note 21, paragraph 15) on the release of GMOs that could harm traditional crops and GMO-free sectors. Various other initiatives have already been taken by some Member States or are under discussion. They are partial solutions that could be improved and incorporated into European law.

a) Prohibit the extension of the scope of patents to "native genes" and the plants and animals that contain them

18 - In 2016, France adopted a law stating that "*the protection conferred by a patent relating to a biological material endowed, as a result of the invention, with specific properties shall not extend to biological materials endowed or capable of being endowed with the said specific properties, by an essentially biological process, or to biological materials obtained from the latter, by reproduction or multiplication.*"³⁸

Unfortunately, it stopped short of prohibiting the extension of patent protection for a product containing or consisting of genetic information to plants and animals obtained exclusively by

³⁶<https://cban.ca/wp-content/uploads/GM-contamination-in-canada-2019.pdf>

³⁷ <https://www.wiley.com/enie/Genetically+Modified+and+not+Genetically+Modified+Food+Supply+Chains:+Co+Existence+and+Traceability-p-9781444337785>

³⁸Article L613-2-3 of the French Intellectual Property Code.

essentially biological processes and containing the same genetic information and expressing its function.

b) Cancelling patent protection in case of accidental contamination

19 - Article L 613-2-2 of the French Intellectual Property Code states that "*the protection conferred by a patent on genetic information shall not apply in the event of the fortuitous or accidental presence of patented genetic information in seeds, plant propagating material, seedlings and plants or parts of plants.*

These regulatory amendments do not require either a revision of Directive 98/44/EC or an amendment of the European Patent Convention. They could be the subject of simple decisions concerning the application of these legislative texts, on the one hand by the Council and the European Parliament, and on the other by the Administrative Council of the EPO. The next report on the application of Directive 98/44/EC, which the Commission is obliged to produce every two years, could initiate such an approach, as was done to prohibit patents on products derived exclusively from essentially biological processes.

c) Bringing consistency to the EU's messages on DSI and patents

20 - Finally, the European Commission should take an initiative on DSI allowing European law to regain a minimum of coherence:

- either the scope of a patent on genetic information extends to the physical products containing it, in which case the genetic information (DSI) is subject to the same obligations as the physical genetic resources;
- or the genetic information (DSI) is exempt from the obligations of physical genetic resources, in which case the scope of a patent on genetic information does not extend to the physical genetic resources containing it.

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