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ALLEA STATEMENT ON MEASURES TO EASE THE IMPACT OF THE IP SYSTEM ON NEW GENOMIC TECHNIQUES FOR CROP DEVELOPMENT

Executive summary

New Genomic Techniques (NGTs), such as genome editing using CRISPR-Cas, can significantly improve the speed and precision with which new plant varieties are created. In Europe, intellectual property (IP) protection of biotechnological inventions, including NGTs, is regulated through the European Union (EU) Biotechnology Directive 98/44/EC. In addition, breeders can obtain single IP rights on both propagating and harvested materials (i.e., 'Plant Breeders' Rights'), but especially the patenting of harvested materials is heavily debated and controversial. Accelerated adoption of NGTs is expected to significantly increase the number of patent applications and the complexity of the patent landscape in the coming years. The patentability of NGTs and their products raises several concerns among breeders and farmers, including (1) possible accidental infringement of patents, (2) monopolisation of technologies and traits, and (3) increased difficulties and costs of obtaining licences for use of these techniques and plant varieties. This statement by ALLEA, the European Federation of Academies of Sciences and Humanities, explores how the current IP system affects the operations of European breeders and farmers. It provides a range of short-, medium-, and long-term recommendations for measures that could help to overcome possible obstacles posed by the current IP system so that all stakeholders can fully benefit from these technologies in the future.

Introduction

New Genomic Techniques (NGTs), such as genome editing using CRISPR-Cas, can significantly improve the speed and precision with which new plant varieties are created[1]. For breeders not using such techniques, developing new plant varieties is generally an expensive and time-consuming endeavour, typically taking up to 15 years to bring a new variety to market. The potential of NGTs is broadly acknowledged by the scientific community, and they are

1 ALLEA. 2020. *Genome Editing for Crop Improvement*. Symposium summary. Berlin. https://doi.org/10.26356/gen-editing-crop. Lead authors: Dima, O.; Bocken, H.; Custers, R.; Inze, D.; Puigdomenech, P.

considered promising tools for contributing to sustainable crop development, environmental safety, and food security through the development of more drought- and/or salt-resilient, disease-resistant, and higher-yielding varieties[2]. However, the patentability of NGTs raises concerns among breeders and farmers – amongst others – regarding the possible monopolisation of traits via the patent system and the possible accidental infringement of patents. Furthermore, due to patent protection of NGTs, many small- and medium-sized breeders fear that it may become impossible to obtain licences for using these techniques and/or to have access to the protected genetic material for breeding on reasonable terms from the patent holders.

IP protection of plants, plant varieties, and breeding technologies in the EU

In general, patent protection can be granted in any field of technology and obliges the patent holder to disclose the details of the invention, while preventing others from producing, using, or selling the invention without authorisation for a period of up to 20 years. In Europe, an application for patent protection of plant-related inventions can be submitted to either national patent offices or to the European Patent Office (EPO), which coordinates patent applications in countries that are members of the European Patent Convention. A European legislative system was introduced in 1998 with the European Union (EU) Biotechnology Directive 98/44/EC, which covers the legal protection of biotechnological inventions[3]. Under this Directive, plant varieties and essentially biological processes for the production of plants and animals, such as crossing or selection, are not patentable[4]. Furthermore, inventions related to plants are patentable when (1) they are not exclusively obtained through essentially biological processes and (2) the technical applicability of the invention is not confined to a particular plant variety[5].

Usually, patent limitations allow for certain activities on or with patented plant-related inventions by third parties without infringing patent rights. The two most relevant ones are the 'research exemption', which allows research on the subject matter of the patent, and the relatively recently introduced 'limited breeders' exemption'. The latter allows breeders to use patented plant material for breeding, discovering, and developing other plant varieties[6]. Several national jurisdictions (such as France, Germany, the Netherlands, and Switzerland) had already introduced the same limited breeders' exemption into their national patent acts well before the

2 European 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*. Available at: https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf.

3 *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0044.

4 This has been clarified in EPO case law: processes which comprise no more than crossing whole genomes constitute an essentially biological process. If the process of crossing results in the introduction of a new trait into the genome of the resulting plant, or a trait is being changed, then it is no longer an essentially biological process, but constitutes a patentable invention. See *G 0001/08 (Tomatoes/STATE OF ISRAEL)*, ECLI:EP:BA:2010:G000108.20101209. Available at: https://legacy.epo.org/boards-of-appeal/decisions/pdf/g080001ex1.pdf.

5 *Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions* (2016/C 411/03). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_411_R_0003.

6 See *Art. 27(c) Agreement on the Unified Patent Court (UPCA), OJ 2013/C 175/01*. The territorial scope of this Agreement is at the time of writing of this Statement limited to 17 EU member states: Austria; Belgium; Bulgaria; Denmark; Estonia; Finland; France; Germany; Italy; Latvia; Lithuania; Luxembourg; Malta; the Netherlands; Portugal; Slovenia; Sweden. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:42013A0620(01).

Agreement on the Unified Patent Court (UPCA) came into effect in 17 EU member states. There is currently no universal standard of the limited breeders' exemption in all EU member states, which understandably affects harmonisation efforts and creates uncertainties for breeders.

For plant varieties, an international treaty on the protection of new plant varieties was adopted by a number of countries, which then established the International Union for the Protection of New Varieties of Plants (UPOV Convention) in 1961[7]. This treaty forms the basis of plant variety protection legislations in individual states and intergovernmental organisations. The UPOV Convention specifies the acts that require the breeder's authorisation in respect of the propagating material of a protected variety and, under certain conditions, in respect of the harvested material. Under the UPOV Convention, the breeder's right is only granted when the variety is (1) new, (2) distinct, (3) uniform, (4) stable, and (5) has a suitable denomination.

In addition, the EU has established a separate system that grants intellectual property (IP) rights to developers of new plant varieties, called Community Plant Variety Rights (CPVR, also known as Plant Breeders' Rights). Issuance of a CPVR by the CPVO provides breeders with a single exclusive IP right for the protection of plant varieties, and is valid throughout the EU for a period of 25 or – for some crops – 30 years[8]. This protection is based on the UPOV Convention, but allows for the protection of the plant variety in all EU member states at once.

At present, the aforementioned regulatory systems are applied to plants and plant varieties created using traditional breeding (i.e., through selective and mutational breeding), as well as to those produced using NGTs.

IP challenges related to NGTs

Accelerated technological development

Currently, the number of plants commercialised in the EU that are covered by patents is still limited. According to the PINTO (Patent Information and Transparency Online) database, the total number of varieties registered for commercialisation in the EU is approximately 40,000 and the number of plants also covered by one or more patents is around 1,300. But the complexity of the patent landscape is expected to further increase due to the acceleration of breeding processes and patent stacking (i.e., when multiple patents apply to a single product). In addition, increased use of NGTs is likely to stimulate the number of patent applications and patent stacks in the coming years, as development times and costs are further reduced, and more complex traits can be introduced in a single breeding cycle (see Box 1).

From an IP perspective, the challenges for small plant breeders with patents covering plant-related processes and products are similar to those faced by small inventors working in other fields of technology, be it in high- or low-tech areas. As such, plant breeders need to be aware of the patent landscape in their technological field and either design around or negotiate licenses – both of which may be exceedingly difficult, if not impossible.

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7 For a detailed description of the UPOV Convention, see https://upovlex.upov.int/en/convention.

8 *Plant Variety Property Rights*. Food Safety. Available at: https://food.ec.europa.eu/plants/plant-variety-property-rights_en.

The fact that plant varieties developed with NGTs may not be easily distinguishable from those generated by traditional breeding techniques is an underestimated problem. Although the immediate product of a process is also covered by the process patent, there is, in many cases, no suitable detection method that can prove that the product was produced by using NGTs (and therefore possibly subject to patent protection) rather than traditional breeding. Breeders are also afraid of unintentionally infringing existing patents covering plants produced using NGTs. Determining what actually falls under the scope of protection of a product patent is not simple or straightforward, and often requires the expertise of a patent expert and sometimes the decision of a court. This lack of clarity and information on the scope of patents leads to a lot of uncertainty, especially for small breeders.

There are four different issues to be addressed:

1. The risk that breeders might not have access to all genetic material for further breeding due to the protection of these materials by patents.
2. The risk that traditional breeders infringe on an existing NGT-plant-related patent because they may develop plants or plant varieties with the same features as the protected ones.
3. The risk that breeders cannot obtain the required licence for the NGT platform technology, either because the patent holder will not grant one or the licence fees are unaffordable.
4. The risk of unintentional patent infringement due to naturally occurring cross-pollination between fields.

Box 1. Regulatory status of NGTs in relation to IP protection

Following the European Court of Justice (ECJ) decision of 25 July 2018, organisms produced by directed mutagenesis techniques, such as genome editing with CRISPR-Cas, should be considered as genetically modified organisms (GMOs) within the meaning of the EU GMO Directive 2001/18, and are subject to the obligations cited therein[9]. The length and cost of the authorisation process for GMO products make it difficult to bring into culture and commercialise plant varieties developed with NGTs, leading to relatively few European patent applications at present.

If NGTs continue to be regulated under the EU GMO Directive, the development of NGTs and their products in Europe will undoubtedly remain limited. However, if the European Commission decides to adopt a lighter regulatory approach in the future[10], it is expected that the development and use of NGTs will substantially increase, resulting in a higher number of patent applications related to NGTs and their products. In principle, this can be dealt with using the existing IP system for plant varieties, but wider adoption of NGTs likely means that the complexity of the patenting and licensing landscape will increase at an accelerated pace.

9 See https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62016CJ0528.

10 *Proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625.* Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52023PC0411.

Legal disputes and lack of clarity

At present, several patents on the CRISPR-Cas9 technology have been filed by American universities that claim priority of invention. These claims have become a matter of legal dispute in the United States (US) and Europe, and the cases have not yet been fully settled. It is expected that it may take years to sort this out, likely resulting in enormous legal fees and possibly different outcomes in different countries. In the meantime, however, licences for the use of the new technologies have been awarded for their use on plants. This continued uncertainty stifles innovation, resulting in some breeders avoiding the technology and moving to alternatives. Other genome editing technologies such as TALEN, ZNF, and ODM have been developed and are nowadays more heavily used in comparison to the CRISPR-Cas system. These technologies may ease the pressure surrounding the battle about the patents for CRISPR-Cas9. Furthermore, a 'Cas' other than 'Cas9' might be used in the future to overcome the claims in the original CRISPR patents.

Monopolisation and exclusive licensing

As new plants produced using NGTs can be protected by patents, and thus could be temporally monopolised by the patent owners, traditional breeders fear that it might no longer be possible to produce plant varieties using traditional methods that have the same features as the protected ones. This might be solved by the EPO disclaimer solution, in which certain things can be excluded from the claimed subject matter. The breeders' exemption, which is in place in countries that are part of the UPCA within the EU, allows the use of patented plant material for breeding new plants or discovering and developing other plant varieties (i.e., allows access to genetic material). On the other hand, the patent owners, in many cases universities and companies, may have complex and exclusive licensing policies including sub-licences. The conditions of these exclusive licences are, in most cases, not publicly accessible, and uncertainty on from whom a licence needs to be obtained persists. Finally, a plant variety might also be covered by multiple patents from different patent owners making the situation even more complex for breeders.

Lack of transparency

In some countries, such as China and the US, a large number of patent applications related to the use of NGTs in plants have been filed. Lack of transparency on the scope of protection, and thus the quality of many of the granted patents, increases confusion on the matter. Additionally, the patent thicket (i.e., the presence of a dense web of overlapping IP rights) in the field of NGTs is not to be underestimated and is growing at a very fast pace.

Consequences for breeders

For breeders who do not wish to use plant varieties produced using NGTs (such as organic breeders), the burden to test against possible contamination of their material, as well as the risk of unintentionally infringing existing patents, are expected to increase as more NGT-products enter the market. At the same time, breeders who wish to benefit from NGTs and their products may struggle to get access to them as a result of exclusive licences, lack of transparency, and the increasing complexity and costs resulting from the need to negotiate multiple licences for a single variety. To avoid such risks and costs, breeders will be tempted to only use their current genetic pool, thereby preventing the use of the full genetic pool, and slowing down the development of new plant varieties. These various difficulties faced by breeders, particularly small-scale ones, have been picked up by policymakers in several European countries and the EU. But what are the possible measures that could be taken to help them?

The scope of this statement

This statement reflects the considerations of a dedicated ALLEA Task Force. Several stakeholders presented their views to the group and this information was taken into account when drafting the statement (see page 10 and 11 for the members of the Task Force and the stakeholders consulted). The statement presents possible solutions to ease or resolve the issues raised above. The solutions are discussed concerning the small and/or traditional breeders in Europe only, but are in some cases also relevant to farmers and academic researchers. Breeders in other parts of the world may or may not have the same challenges, and therefore may or may not benefit from the proposed solutions.

The following guiding questions were used to craft this statement:

1. What is the current status regarding patents and licences of NGTs and their products in Europe?
2. What is the likely impact of patenting NGTs on small breeders in Europe under the current IP system?
3. Are there measures that could help breeders cope with the current situation?
4. How should the current IP system be applied to NGTs, and would this depend on the regulatory status of NGTs, e.g., being classified as GMOs?
5. Should the European patent system be modified to better serve innovation in plant breeding and, if so, how?
6. What will be the role of the UPOV Convention in the rights system, and should it be the only IP system for plant-related innovations, even patentable ones?

The guiding questions are not answered directly in this statement but were used to discuss the issues. The statement does not touch on environmental, political, ethical, or social issues, or the truly technological and scientific aspects of NGTs. It also does not deal with EU regulations or individual state legislations on NGTs although the IP laws follow these legislations in general. Finally, the statement does not answer questions regarding the conformity of the proposed solutions with international agreements.

The proposed measures

The patentability of food-related technologies and products is a sensitive issue, and some stakeholders therefore consider a different legal treatment of such patents or the patentability of such products to be appropriate. Various proposed ways forward were discussed during the Task Force meetings, ranging from supporting breeders to cope with the current patent system to completely reforming or suspending the patent system for food-related technologies and products. An overview of the most promising short-, medium-, and long-term measures is provided in the sections below. In this context, short-term measures are expected to be implementable within a few years, medium-term measures within approximately 5-10 years, and long-term measures go beyond that timeframe – these definitions are not absolute but rather serve as a rough indication. The order of the measures within each category does not reflect whether they are favoured by the Task Force or any other type of ranking. Finally, the recommended measures were solely assessed in relation to NGTs and their products and cannot, therefore, be automatically extended to other technologies.

Short-term measures

Facilitating access to patent information

To some extent, small breeders and farmers might have difficulties finding sufficient patent information to interpret the findings and avoid infringement. A possible solution could be the example set by the Swiss Federal Institute of Intellectual Property (IPI). The IPI offers a so-called 'assisted patent search' for anybody living or working in Switzerland. This offer includes a thorough search in professional patent databases performed by a patent examiner in the presence, and with the help, of the customer. This search is performed for a small fee of CHF 300 (EUR 322) and for a maximum of eight hours, with certain specific customers getting a considerable discount. The eight hours also allow the customer to ask the examiner questions about the patent system and the relevance of the found documents. A similar assisted search could be introduced in other EU countries, and this service could be offered for free to small breeders and farmers. This measure would not require any change of the patent agreements and legislation and could most likely be implemented rather quickly.

Mandating patent database registration (improving transparency)

Registration of patented plant varieties in databases, such as the PINTO database, provides transparency regarding plant varieties that might fall under the scope of patents or patent applications. Encouraging registration by patent applicants/holders and licensees would help breeders to make more informed choices when deciding on the varieties to be used in their breeding programme. Under certain conditions, such a registration could be made mandatory to ensure complete records in the database.

Mandating licensing database registration (improving access)

Access could be improved by encouraging participation in voluntary international seed licensing schemes, such as the International Licensing Platform Vegetable (ILP) and Agricultural Crop Licensing Platform (ACLP). Another licensing database registration might be necessary to allow access to platform technologies. A general problem with such initiatives is that participation is currently not mandatory, and thus such initiatives do not cover the whole patent landscape of crops. Registration could however be made mandatory, and access to plant varieties could be further facilitated via the use of standard and transparent licensing agreements. However, it should be noted that this does not automatically lead to free or affordable access to the patented traits and technologies – breeders will still need to obtain licences and patent stacking will continue to create barriers as licensing fees could easily become prohibitive if stacked.

Stricter interpretation of patentability requirements

There could be ways of interpreting the patentability requirements more strictly. This would limit the scope of protection of some NGT patents, in particular with regard to experimental evidence in the patent application. This could be done by interpreting the requirement of an inventive step (European Patent Convention, Art. 56) and enabling disclosure (also called 'sufficiency') (European Patent Convention, Art. 83) more strictly.

Structured licensing schemes of publicly funded research outcomes

Much of the research on NGTs is being performed by academic institutions using public funds. In line with global movements towards Open Science, terms could be included in funding agreements stating that any IP derived from technologies developed with government funding should at all times be made available to any third party under reasonable terms. A more stringent option could be that academic IP holders become subject to a compulsory unified licensing system.

Ethical licensing

A form of self-regulation for the sector could be through ethical licensing, for example, by providing easy access to technologies and seeds for academic researchers, small breeders, and farmers, or for applications with strong societal benefits[11]. However, it remains difficult to define ethical licensing precisely, and whether the patent holders, a governmental, or an international agency should be in control of defining this remains an open question. In any case, private agreements to this effect will not be legally binding and may therefore be of limited effect in practice. However, they could be made mandatory at least for publicly funded research projects, and could be extended to benefit other stakeholders such as small breeders and farmers.

Medium-term measures

Suspending patents related to food plants

It has been argued by several NGOs and breeders/farmers associations that all patents related to food plants should be limited, suspended, or even terminated completely to remove their blocking effect. Although this measure would result in immediate access to existing technologies and plant varieties, the risks of this approach are that it is expected to lead to a shift towards trade secrets, industry consolidation, and in particular innovation slowdown. In a milder form, the underlying technologies could still be patentable, whereas patents of products and the extension of patent protection to the immediate product of the process might no longer be feasible. This would still carry some of the same risks but would most likely avoid accidental patent infringement by traditional breeders.

Introducing patent pools

Patent pools can be defined as an agreement between patent owners to license or cross-license their patents relating to a particular technology to one another and/or to third parties. Pools also frequently represent the basis for industry standards that supply firms with the necessary technologies to develop compatible products and services. Such patent pools could be introduced and made mandatory for NGTs and their products, or even for the food plants sector in general, thereby contributing to the sharing of knowledge, tools, and seeds among breeders.

Standard Essential Patents

By being classified as a Standard Essential Patent (SEP)[12], patent holders have an obligation under EU law to grant licences to any interested party under FRAND terms (Fair, Reasonable And Non-Discriminatory)[13]. There is already a body of national and European case law discussing what FRAND terms are. SEPs are currently largely confined to the telecommunications sector, but it may also be a way forward for NGTs as a compromise between abolishing patent protection and optimising access. Whether platform technologies such as the ones used for genome editing can be considered to be patents relating to a standard will need to be discussed further. However, even if they do not qualify as standard, it may still be possible to force such patent holders to apply FRAND terms to NGT patents – social interest to gain access to NGTs could push towards FRAND terms and could even extend to their products (e.g., seeds).

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11 Guerrini, C., Curnutte, M., Sherkow, J. et al. (2017). *The rise of the ethical license.* Nat Biotechnol 35, 22–24. DOI: https://doi.org/10.1038/nbt.3756.

12 See https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/standard-essential-patents_en.

13 EU Joint Research Centre (2015). *Fair, Reasonable and Non-Discriminatory (FRAND) Licensing Terms.* Available at: https://publications.jrc.ec.europa.eu/repository/bitstream/JRC96258/jrc96258.pdf.

Long-term measures

Compulsory licensing

The existing cross-licensing regime in Article 12 of the EU Biotechnology Directive is not considered workable in practice, predominantly because the meaning of one of the basic requirements is unclear: "*the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety*". In addition, compulsory licensing happens on a case-by-case basis and the most likely outcome is uncertainty, which is expected to result in considerable innovation slowdown. An alternative solution, but one that is hard to implement, is to make it a condition that the patent holder is willing to grant a 'licence as of rights'. A 'license as of rights' is not a compulsory license, but a commitment from the patent holder to grant any interested party a licence under reasonable terms.

Amending the EU Biotechnology Directive

Making more substantial changes or introducing a completely new EU Biotechnology Directive that includes the proposed measures could be advisable, but (a) this is not expected to happen in the short- or medium-term, if at all, and (b) opening up the EU Biotechnology Directive to changes is akin to opening Pandora's box and might not be something that legislators want to pursue. A complete overhaul of the Directive is unlikely to happen without pressure from an immediate crisis – but if there is a crisis, the solution would likely be through faster measures such as compulsory licensing.

A new type of IPR for plants

Alternatively, separate types of IP rights protection could be developed for food plants, integrating patents and plant breeding rights with EU biodiversity, sustainability, and regulatory legislation. Such a system could enforce standardised protection for new varieties and traits using limited exclusive rights, enable fair benefits-sharing based on a variety's added value, and include provisions that may protect traditional breeders in cases of unintentional patent infringement. However, to be effective, such a system would need to be established on a global scale. Ultimately, it is not clear what such a system would look like and how it would work at the international level.

Stakeholder contributions

During a series of online hearings, the Task Force consulted a variety of stakeholders for their perspectives, including patent holders, small breeders, farmers, and researchers. The Task Force is grateful to the individuals and organisations listed below for sharing their views:

- Marc Cool – Corteva
- Martin Ekvad – Royal Swedish Academy of Agriculture and Forestry
- Rasmus Hjortshøj – Sejet Plant breeding
- Michael Kock – Independent consultant
- Duncan Matthews and Hanna Ostapenko – Queen Mary University of London
- Grietje J. Raaphorst-Travaille – Nordic Maize breeding
- Marion Ramp – Schweizer Bauernverband
- Olivier Sauvageot – Syngenta
- Jens Sundström – EPSO/EMBO IP Genome Editing Task Force
- Bettina Wanner and Martin Quanz – Bayer

About ALLEA

ALLEA is the European Federation of Academies of Sciences and Humanities, representing more than 50 academies from about 40 EU and non-EU countries. Since its foundation in 1994, ALLEA speaks out on behalf of its members on European and international stages, promotes science as a global public good, and facilitates scientific collaboration across borders and disciplines. Learn more here: http://www.allea.org.

About this statement

This ALLEA statement has been prepared by a dedicated ALLEA Task Force concerned with the Intellectual Property System for New Genomic Techniques, with further input from members of the ALLEA Permanent Working Group on Intellectual Property Rights (PWGIPR). Through its working groups and task forces, ALLEA provides input on behalf of European academies to pressing societal, scientific, and science-policy debates, and their underlying legislations. With its work, ALLEA seeks to ensure that science and research in Europe can excel and serve the best interests of society.

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