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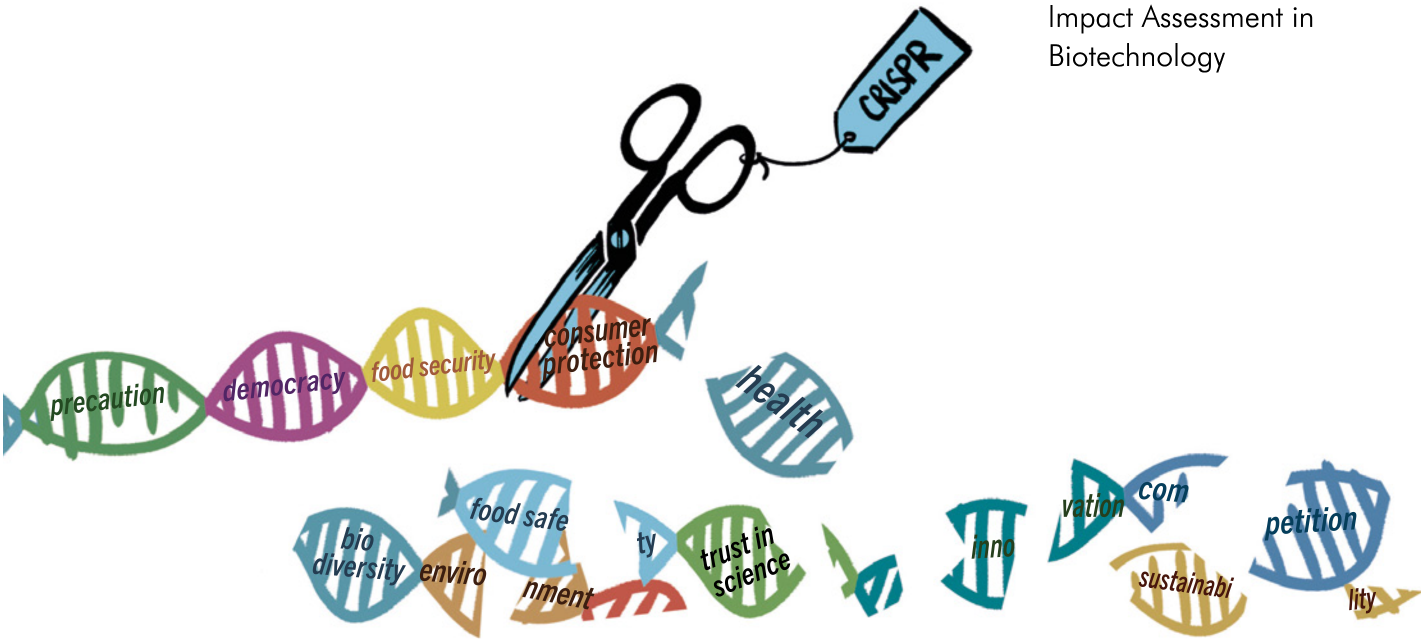

New GE and food plants: The disruptive impact of patents on breeders, food production and society

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Summary

This report discusses the increasing number of patent applications being filed and granted in Europe on New GE in plants (new genetic engineering, especially so-called 'gene-scissors'). The patent landscape is currently dominated by the 'Corteva group' (resulting from a merger of Dow AgroScience and DuPont/Pioneer) which, apart from its own patents, controls access to many other patents needed by breeders who want to use CRISPR/Cas technology. The 'Corteva group' established a patent pool in 2018 which, at that time, already comprised around 50 patents. Other breeders who want to have access to this pool are required to sign contracts; this puts Corteva in an extremely strong market position that could be seen as a 'hidden cartel', with possible implications for competition (the text of the contracts is confidential).

Many of the patents currently being filed intentionally try to blur the fundamental biological and technical differences between genetic engineering and conventional breeding. The purpose is to expand patent monopolies into the non-technical areas of traditional breeding that are excluded from patenting. This can have serious consequences for a properly functioning European market in regard to plant and animal breeding.

A comparable strategy of blurring the differences between conventional breeding and genetic engineering can be observed in the political discussions around EU GMO regulation: the same stakeholders involved in filing the patents are also attempting to blur the differences in GMO legislation. It is undoubtedly an alarm signal that the EU Commission has recently introduced a new term, i.e. 'conventional GMO', which could be understood as defining transgenic plants as conventional.

Monopolistic claims on patented technologies and seeds linked to the introduction of New GE crops render disruptive processes in plant breeding, agriculture and food production are a highly likely consequence. This development is in strong contradiction to repeatedly voiced arguments stating that CRISPR/Cas technology would be cheap, and therefore more accessible for smaller and medium sized breeding companies.

At the same time, the interest in proprietary technologies are also having an impact on political decision-making and trust in science. This puts the precautionary principle at risk and increases the pressure on ecosystems: short-term profit maximisation is, amongst others, driven by the duration of the patent and pressure on the companies to sell as many of their patented seeds as possible. This means that ecosystems may be impacted within a short period of time by an increasing number of organisms not derived from evolutionary processes and mechanisms. The pressure to generate profit may therefore also impact food safety.

Recommendations for the EU therefore include:

- Strict limitations on patent protection and, in particular, no longer allowing patents on conventional plant or animal breeding;
- Starting investigations into the potential rise of anti-competitive and cartel behaviour based on the control of access to patented technology in the field of New GE, and investigation into the extension of patent protection to conventional breeding;
- Strengthening political decision-making processes to fully integrate the perspective of the protection goals (health and the environment); avoiding inappropriate influence from companies and experts with a vested interest in patents on the technology, and pushing back against products derived from New GE.

In addition, the EU should re-organise its research strategy by adding a strong pillar of risk research, conducted from the perspective of the protection goals whilst ensuring independence from industry and their affiliated experts.

1. Introduction

New genomic techniques (New GE) or genome editing are immensely controversial. There are conflicting views on the risks, the potential benefits and the regulatory framework. In April 2021, the EU Commission published a report on new genomic techniques in plants (EU Commission 2021). It appears that the intention of the EU Commission is to promote New GE applications in agriculture to support international trade, technology and product development. At the same time, many experts are warning that the precautionary principle must be respected and the risks of New GE organisms not ignored.

Patents constitute a powerful tool in a functioning market. However, a combination of proprietary technology and monopolistic ownership can put that market at risk. Profits are expected to ensue from trade with patented products or selling licences for access to the technology. In the context of plant breeding, patents can have potentially disruptive effects, as they can be used to block, hamper or control access to biological material needed by all breeders.

Some of these problems are addressed in the above mentioned EU Commission (2021) report which *"acknowledges the benefits of patents and licensing in promoting innovation and the development of new genomic techniques and their products. However, these same aspects (together with high business concentration) can also act as a barrier to market entry for SMEs and can limit access to new technologies and to genetic material, e.g. for breeders and farmers."*

This Testbiotech report discusses the issues in more detail, providing recent data on patent applications and the companies involved. It reveals far-reaching and systemic effects beyond those being discussed by the EU Commission. The negative observed or prospective impacts affect conventional breeding, scientific advice, the protection of biodiversity and sustainable food production. In the light of these findings, the EU-Commission should carefully reflect on its approach to new genomic techniques used in agriculture to avoid possible negative impacts on the EU's 'Green Deal' and 'Farm to Fork' strategy.

2. The patent landscape

The following paragraphs give an overview of research institutions and companies involved in filing patent applications on nucleases technology (especially CRSPR/Cas). It shows that although there are many institutions and experts involved in the research, the commercial applications are widely controlled by a handful of companies, dominated by the 'Corteva group' (which resulted from a merger of Dow AgrowSciences and DuPont/Pioneer).

2.1 A brief history of patents and seed market concentration in Europe

Patents create monopoly rights to control the commercial application of technology and marketing of products. If patents are granted on plants and animals, they cannot be used by other breeders, gardeners or farmers without the permission of the patent holder. The patent holder can therefore acquire far-reaching control over breeding and food production. The patents give exclusive rights for the duration of 20 years, and also extends to the offspring as long as the patented genetic traits is present. After the plants have been crossed there can therefore be an accumulation of patents in the subsequent generations. Moreover, patents granted on plants very often also extend to the harvest and processed food.

The European Patent Convention (EPC), which is the legal foundation of the European Patent Office (EPO), excludes patents on plant and animal varieties (Art. 53(b), EPC). After oppositions, patents on plants and animals were therefore stopped by the Board of Appeal at the European Patent Office in 1995, based on Article 53(b) (case T356/93). However, in 1998 the legal landscape in Europe was changed when the EU-Directive on Legal Protection of Biotechnological Inventions (98/44 EC) was adopted. According to Article 4 (2) of this directive, *"inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."* Following this interpretation, the EPO overturned its previous decision (T356/93) in 1999 and adopted a new Enlarged Board of Appeal (G1/98) decision. As a result, oppositions against patents, such as the Monsanto patent on the herbicide-resistant RoundupReady soybeans (EP 0546090), were rejected.[1]

Patents are frequently not filed directly at the EPO, they are instead filed at the WIPO (World Intellectual Property Organisation), which does not itself grant patents. It is still the EPO that examines and grants the patents. However, not all patents filed at the WIPO enter the so-called European phase. Neither are all the applications examined by the EPO granted. That said, patents on genetically engineered plants and animals have been routinely granted in recent years. From 1999 until the end of 2020, nearly 4000 European patents were granted on plants, most of them genetically engineered. In many cases, the plants and animals themselves were patented. These are patents on a product which confer absolute protection: this means that all plants and animals with the patented traits are covered by the patent, independently of how they are bred. The wording of Art. 4 of EU directive 98/44EG, could be interpreted in a way that it would be sufficient to just grant a patent on the process. In result, the scope of the patents would be restricted to the technical process described in the patent (and to the plants resulting from this process). Therefore if, for example, plants or animals bred from New GE techniques could also be bred from conventional breeding, then the conventional breeding would be free from possible patent claims since 'essentially biological processes', i.e. conventional breeding, cannot be patented (Art. 4 (1) of EU directive 98/44/EG).

Parallel to the increasing number of patents, the international seed market also underwent a process of concentration and restructuring – this is still ongoing. Large seed companies, such as Pioneer, DeKalb and Seminis,

1 For more details also see: https://www.no-patents-on-seeds.org/index.php/en/background/publications

have been taken over, whilst many smaller companies have disappeared. Today, the international seed market is dominated by a handful of big players. Originally, many of these were agrochemical companies, e.g. Bayer (Monsanto), Corteva (former DowDuPont), BASF and Syngenta (ChemChina) (see Figure 1). As a result, only four companies control more than 60 percent of the global commercial seed market.[2]

Patents were a crucial driver in the concentration process since they allow the holders to control, hamper or even block access of other breeders to the biological material they need. From the beginning, the introduction of genetically engineered seeds was strongly connected to the idea of establishing patents in the sector of plant breeding. For example, a 1992 OECD publication on the genetic engineering of crop plants, shows that, even then, the main focus of companies was to re-organise the seed market, leading to a greater integration and dependency with the agrochemicals sector (OECD, 1992).

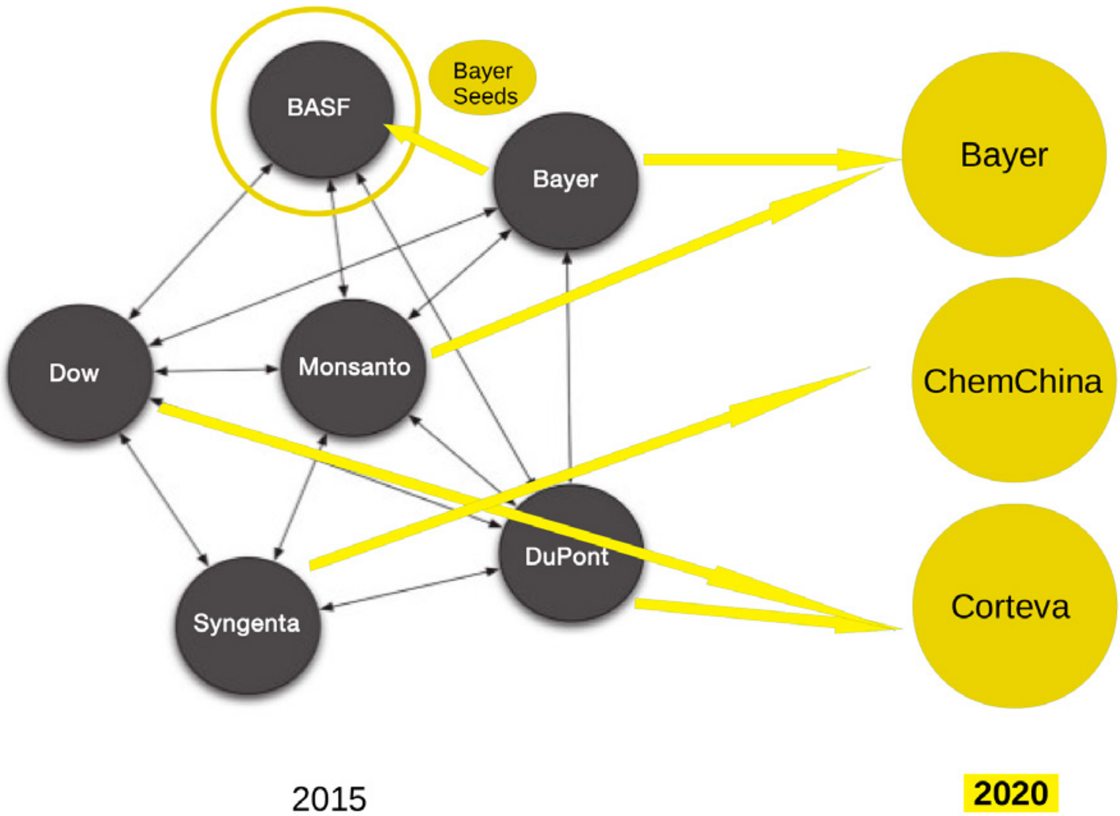


Figure 1: Seed market concentration: Developments between 2015 (Howard, 2015) and 2020 (see also https://philhoward.net/2018/12/31/global-seed-industry-changes-since-2013/). Yellow: Developments between 2015 and 2015. Bayer acquired Monsanto but was obliged to sell its seed sector to BASF. ChemChina acquired Syngenta. Dow and DuPont merged and then jointly created a new company, Corteva, to combine their agro-businesses.

2 https://philhoward.net/2018/12/31/global-seed-industry-changes-since-2013/

2.2 The 'inventors' of CRISPR/Cas

The first European patent application for CRISPR/Cas was filed in 2006 (EP2341149). This patent claims the role of CRISPR/Cas in the immune system of bacteria - this is also considered useful for food production. It was filed by the Danish company Danisco, which specialised in food additives. It was taken over by DuPont in 2011. The EPO granted the patent in 2016.

In most cases, Nobel prize winners, Jennifer Doudna and Emanuel Charpentier as well as Feng Zhang from the Broad Institute (MIT/Harvard), are named as the 'inventors' of the CRISPR/Cas technology. Virginijus Šikšnys (Vilnius University) and George Church (Harvard University) also contributed to the technological development at an early stage.

Around 2012, these researchers were able to develop the CRISPR/Cas system beyond the mechanisms detected in bacteria: by combining the Cas protein with a guide RNA, it became possible to apply the CRISPR/Cas machinery to achieve a targeted change in cells of plants and animals.

CRISPR/Cas enables the user to alter a specific target region in the genome. DNA-cutting enzymes are generally called nucleases. Enzymes such as CRISPR/Cas are known collectively as 'site directed nucleases' (SDN) since they can target specific sites in the genome. CRISPR/Cas is not the only SDN, there are others known as meganucleases, zinc finger and TALENs. However, CRISPR/Cas is so far the most relevant nuclease in terms of publications, applications and patents. CRISPR/Cas became the most important technology in the context of New GE in crops by a long way, followed by TALENs and ODM [3](see Figure 2).[4] In comparison to previous methods of genetic engineering in plants, CRISPR/Cas is not only more flexible and precise, it also makes the genome available for changes to much greater extent (Kawall 2019). At the same time, it poses new challenges in risk assessment because of the specific generic intended and unintended effects inherent in the technology (Agapito-Tenfen et al., 2018; Eckerstorfer et al., 2019; Kawall et al., 2020).

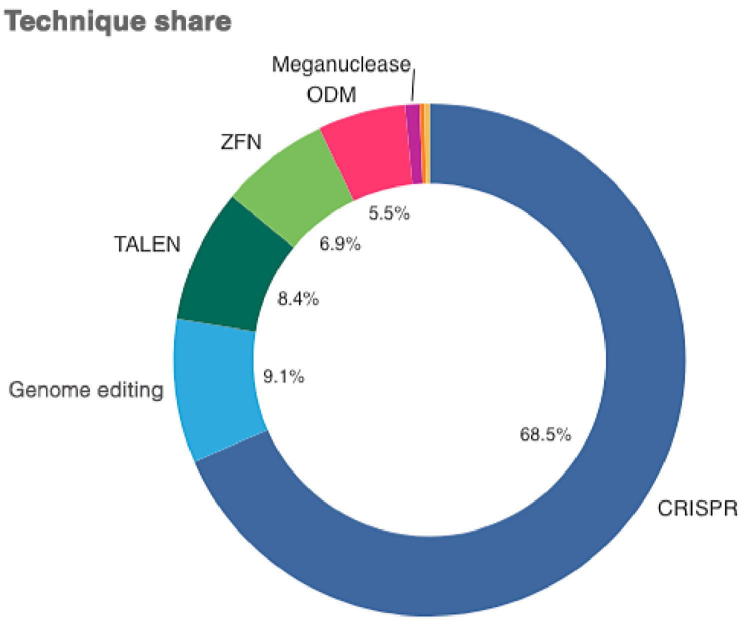


Figure 2: Percentages of CRISPR/Cas and other technologies used in New GE (Genome Editing) in plants (source: https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/index.html).

3 oligo directed mutagenesis, ODM, is not based on usage of nucleases

4 https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/index.html

Researchers around Feng Zhang and Jennifer Doudna have filed several hundred patents on the CRISPR technology, many of them also extending to Europe. In 2015, the first CRISPR/Cas patent was granted to the Feng Zhang group (EP2771468) and came under fire from several oppositions.[5] Soon after, in 2016, the EPO granted a patent to the group around Jennifer Doudna (EP2569425).

By the end of 2020, the EPO had issued more than 30 patents on CRISPR technology to the Feng Zhang group, and around 15 patents to the group around Jennifer Doudna and Emanuelle Charpentier. Other patents were granted, for example, to George Church and Virginijus Šikšnys. In addition, the EPO granted other patents on gene scissors technology, e.g. TALENs, zinc finger and meganucleases.

Access to many of these patents seems to be given via non-exclusive licences. This means that several companies, after signing contracts and paying fees, are allowed to use the technology. However, not all of these licences are non-exclusive: for example, Virginijus Šikšnys is reported to have agreed an exclusive contract with DuPont (now Corteva).[6] [7] An overview of contracts was published 2017 in the Science journal (Horn, 2017; Conteras & Sherkow 2017), mentioning companies such as Monsanto, Bayer and DuPont as well as one of the biggest livestock breeding companies, Genus.

2.3 The race between companies

A rapidly increasing number of European patent applications are being filed, in addition to the patents already granted in Europe on New GE in food plants and animals[8]. Testbiotech has in recent years published several overviews of patent applications filed by biotech companies active in the field of New GE applications in plants (Testbiotech 2016, Testbiotech 2018 and Then 2019). Figure 3 summarises some data from these reports and, in addition, includes patent applications filed on nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) up until the end of 2020.

It is evident that especially one company, Corteva (resulting from a merger of Dow AgroSciences and DuPont/Pioneer), is leading the number of filed patent applications. By the end of 2020, more than 70 patent applications covering technology, processes and in many cases also plants and seeds, had been filed by just this one company.

Table 1 gives an overview of patent applications filed by the 'Corteva group' in 2019 and 2020 at the WIPO - as also shown in Figure 3.

5 https://www.sciencemag.org/news/2017/02/how-battle-lines-over-crispr-were-drawn
6 www.prweb.com/releases/dupont-pioneer-seed/vilnius-university-cas9/prweb12804075.htm
7 https://www.nature.com/articles/nbt0116-13.pdf
8 for more information on patent applications in animal breeding see: Testbiotech (2018)

Table 1: Patent applications on site directed nucleases in the sector of plant biotechnology filed by companies of the Corteva group (Dow AgroSciences, DuPont, Pioneer) with relevance for Europe

Appli-cant	Patent Number	Technology	Year of publi-cation	Purpose
Pioneer	WO2019023590	CRISPR/Cas	2019	minimizing off-target effects
Pioneer	WO2019074841	CRISPR/Cas	2019	type I-E Crispr/Cas systems
Pioneer	WO2019075295	several kind of nucleases	2019	doubled haploid plants (rice, maize, wheat)
Pioneer	WO2019118342	several kind of nucleases	2019	male sterility
Pioneer	WO2019165168	CRISPR/Cas	2019	novel Cas 9 orthologs
Pioneer	WO2019173125	CRISPR/Cas	2019	modification of fatty acids in soybean
Pioneer	WO2019177978	CRISPR/Cas	2019	many traits, not specific
Pioneer	WO2019182884	several kind of nucleases	2019	disease resistant plants
Pioneer	WO2019204256	CRISPR/Cas	2019	modifying transcription factors
Pioneer	WO2019204373	CRISPR/Cas	2019	modifying transcription factors
Pioneer	WO2019204266	CRISPR/Cas	2019	modifying transcription factors
Pioneer	WO2019226553	CRISPR/Cas	2019	enhanced N-assimilation
Pioneer	WO2019232136	CRISPR/Cas	2019	changes of oil composition in brassica
Pioneer	WO2019232182	CRISPR/Cas	2019	increase protein content in soybean
Pioneer	WO2019236257	several kind of nucleases	2019	southern corn rust resistant crops
Pioneer	WO2020005667	CRISPR/Cas	2020	many traits, not specific
Pioneer	WO2020023449	CRISPR/Cas	2020	resistance to Downey Mildew in maize
Pioneer	WO2020041079	several kind of nucleases	2020	altered stature and naturity in rice
Pioneer	WO2020081173	several kind of nucleases	2020	many traits, not specific, also transgene
Pioneer	WO2020092491	several kind of nucleases	2020	increased protein content in soybeans
Pioneer	WO2020185751	several kind of nucleases	2020	clonal plant production
Dow	WO2020198408	several kind of nucleases	2020	many traits, not specific, also transgene
Pioneer	WO2020214986	CRISPR/Cas	2020	doubled haploid plants
Pioneer	WO2020232661	several kind of nucleases	2020	abiotic stress tolerance
Pioneer	WO2020232660	several kind of nucleases	2020	abiotic stress tolerance
Pioneer	WO2020237524	several kind of nucleases	2020	abiotic stress tolerance
Pioneer	WO2020257273	several kind of nucleases	2020	altered pod shatter in brassica plants

Figure 3 shows the number of patent applications per company[9]: Corteva (with more than 70 applications) is followed by Bayer with around 50, while KWS applied for around 30 patent applications. Cellectis / Calyxt was found to account for 20 to 30 patent applications.[10] In addition, Dan Voytas, who is chair of the Scientific Advisory Board of Calyxt, is involved in around a dozen further patents (filed at WIPO), covering nucleases, very often in cooperation with University of Minnesota (data not shown in Figure 3). The number of patent applications for BASF, Keygene and Syngenta is between 10 and 20.

Some other companies have also filed patents in this context (such as Rijk Zwaan, Bejeo Zaden or Sakata) likewise some Chinese institutions[11], but with lower numbers. To summarise, just a few companies are driving developments in Europe, with one company, Corteva, dominating the patent landscape.

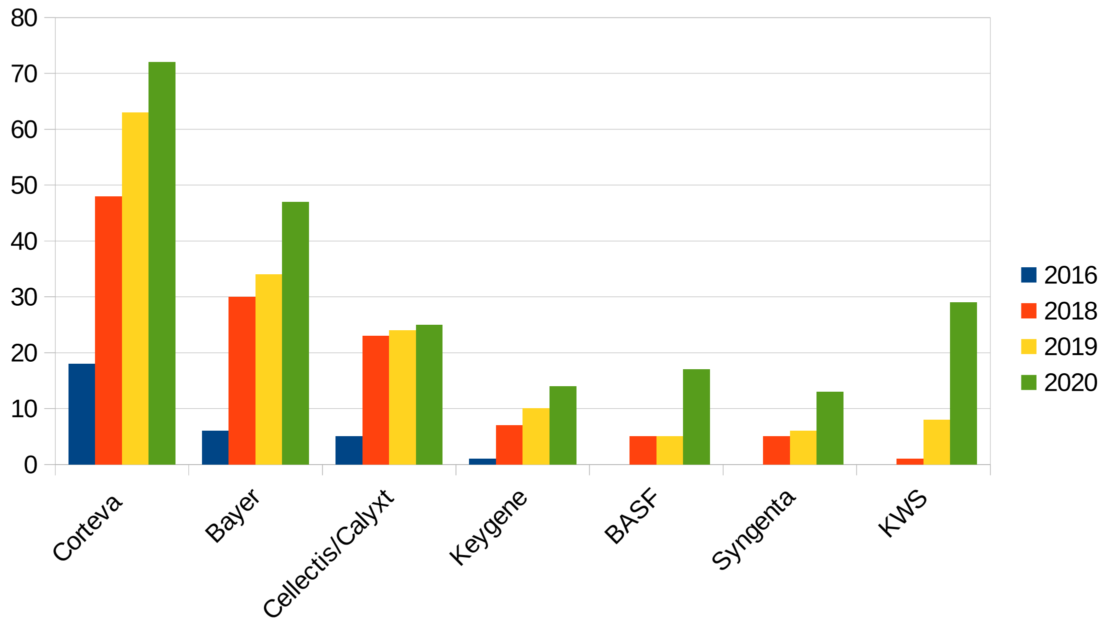


Figure 3: Number of international patent applications (WIPO /WO) on nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) in the food plant sector up until the end of 2020[12] (number of patent applications accumulated[13]).

The dominant position of Corteva is also mirrored by an increasing number of European patents that have been granted on site-directed nucleases (not only CRISPR/Cas) in crop plants (Figure 4). While Corteva already owns nearly 30 granted European patents, most other companies have below ten.

9 Number of international patent applications (WIPO /WO) on nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) involving food plants

10 Many patent applications of Calyxt/Cellectis are concerning TALENs technology

11 Some 'Corteva group' patents were filed with Chinese partners, these were integrated in the figures.

12 Figures for Corteva include relevant patents from Dow AgroSciences, DuPont and Pioneer. Figures on Calyxt do not include other patents filed by Calyxt experts, for example, together with the University of Minnesota.

13 See also Testbiotech (2016 & 2018) as well as Then (2019).

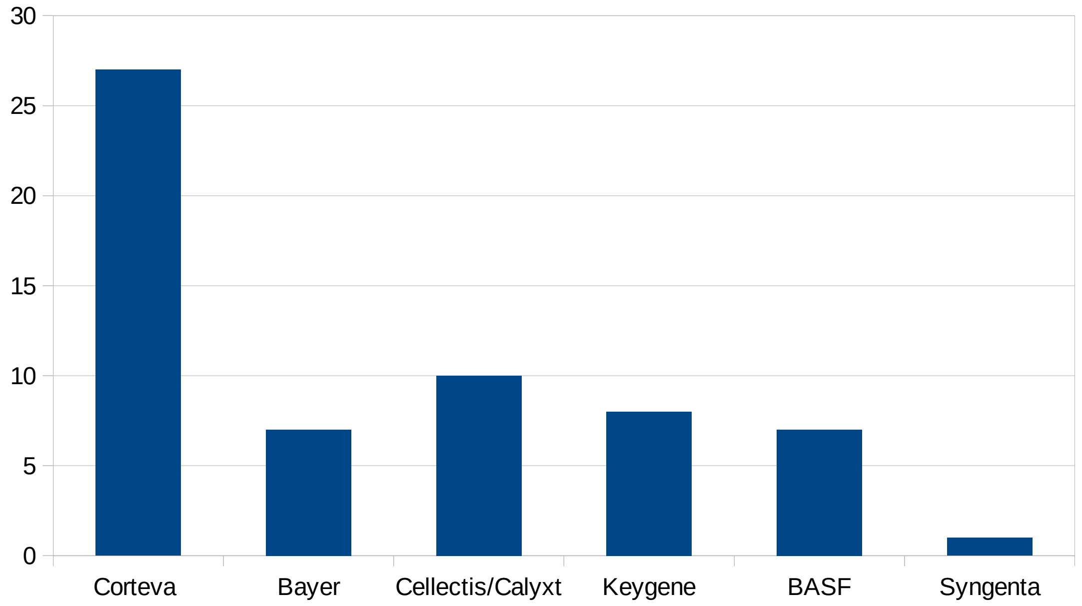


Figure 4: Number of granted European patents on site directed nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) and applications in crops up until the end of 2020.[14]

The history of developing nucleases is also reflected in the patents filed over the years, e.g. patents applied for and granted to 'the Corteva group' in earlier years, often concern zinc finger nucleases (see Table 2). This can be compared to patent applications 2019/2020 filed by the 'Corteva group', which are mostly on CRIPSR/Cas technology (see Table 1).

14 See above

Table 2: European patents granted on site-directed nucleases owned by companies in the 'Corteva group' (Dow AgroSciences, DuPont, Pioneer) with relevance for plant biotechnology

Appli-cant	Patent Number	Technology	Year of grant	Purpose
Dow	EP2092068	zinc finger	2014	making phosphorous more available in seed
Dow	EP2415873	zinc finger	2015	making phosphorous more available in seed
Dow	EP2049663	zinc finger	2015	insertion of transgenes, all kind of traits
Dow	EP2412812	zinc finger	2015	making phosphorous more available in seed
Dow	EP2417262	zinc finger	2015	introducing site directed nuclease via nanoparticles
Dow	EP2415872	zinc finger	2016	making phosphorous more available in seed
Dow	EP2205749	zinc finger	2016	glyphosate resistance
Dow	EP2525650	zinc finger (landing pad)	2017	insertion of transgenes, all kind of traits
Dow	EP2491127	zinc finger	2017	oil composition in brassica (transgenic)
Dow	EP2722392	zinc finger	2017	oil composition in brassica (transgenic)
Dow	EP2370575	zinc finger	2017	insertion of transgenes, all kind of traits
Dow	EP 3072973	zinc finger	2018	glyphosate resistance
Dow	EP 2892321	nucleases (incl. CRISPR/Cas)	2018	changes in oil composition in soybean
Dow	EP 2844754	zinc finger	2018	changes in malate dehydrogenase
Dow	EP 2847338	nucleases (incl. CRISPR/Cas)	2018	insertion of transgenes, all kind of traits
Dow	EP 3047726	landing pad for nucleases	2018	insertion of transgenes, all kind of traits
Dow	EP 2893023	nucleases (incl. CRISPR/Cas)	2018	changes in oil composition
Dow	EP 3070169	zinc finger	2018	making phosphorous more available in seed
Pioneer	EP 3191595	CRISPR/Cas	2019	all kind of traits
Pioneer	EP 3036327	CRISPR/Cas	2019	all kind of traits
Dow	EP 2885412	landing pad for nucleases	2019	insertion of transgenes in maize, all kind of traits
Dow	EP 3066192	landing pad for nucleases	2019	insertion of transgenes in maize, all kind of traits
Dow	EP 2981166	nucleases (incl. CRISPR/Cas)	2020	all kind of traits, herbicide resistance mentioned
Pioneer	EP 3036332	CRISPR/Cas	2020	all kind of traits
Dow	EP 2525649	zinc finger	2020	excision of transgenic elements

The patents listed above not only claim the technology, but also a wide range of plants and their traits: this includes transgenic and non-transgenic plants; plants producing insecticides; herbicide-resistant plants; plants with changes in nutritional quality; plants with changed responses to environmental stress; plants with alterations in growth habit and yield; plants with changed characteristics in regard to storage and processing. The plant species range from cereal and oilseed crops (such as maize, soybean, oilseed rape, wheat and rice) to legumes and, in some cases, also trees.

As a recent Joint Research Center (JRC) of the EU report shows[15], many potential applications, such as stress tolerance, modified composition and yield (plant architecture), might be developed within the coming decades. However, when it comes to applications under development that are close to the commercial stage, herbicide resistance is (still) in the lead.

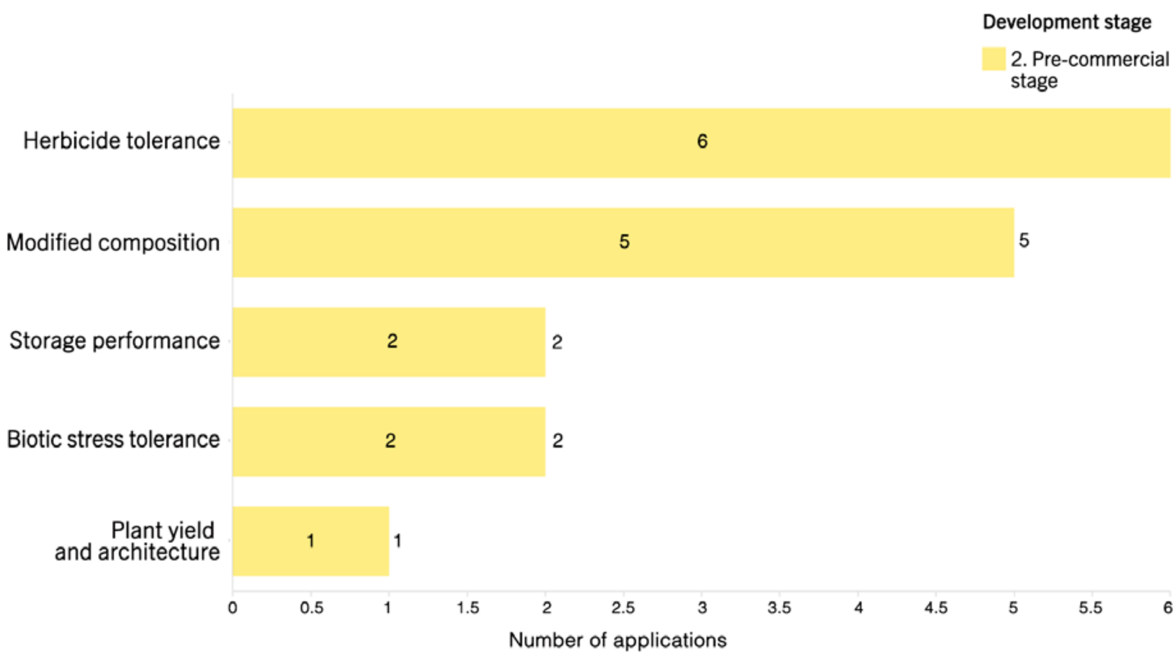


Figure 5: Traits in plants derived from New GE that are close to the commercial stage (as of May 2021) (source: https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/index.html).

Nevertheless, the filed patent applications cannot actually be used to predict which products will finally enter the market; there are only four CRISPR/Cas plants are known to be close to marketing or already being cultivated:

- Soybeans developed by Calyxt, based on TALENs, cultivated in the US (on a relatively small scale) with a change in oil composition;
- 'Waxy' maize plant developed by Corteva (formerly DowDuPont), derived from CRISPR/Cas with a change in starch composition (announced for the US);

15 https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/index.html

- Transgenic CRISPR/Cas maize developed by Corteva (former DowDuPont) with herbicide resistance (glufosinate) and insect toxicity (applied for import into the EU);
- CRISPR/Cas tomato with enhanced GABA-concentration foreseen for deregulation in Japan.
- These products also have a history in patents, with Calyxt and Corteva having applied for the relevant patents themselves. However, the marketing of the tomatoes appears to be hampered by patents: it was reported that in Japan, the plants can only be distributed for non-commercial cultivation in private gardens because patent rights prevented the marketing of seeds and fruits.[16]

3. Negative impacts on innovation, food production and the environment

New GE technology in combination with patents on plants (and animals) can endanger food production due to disruptive impacts on breeders, farmers and the environment, e.g.

- Monopoly on biological resources needed for further breeding;
- Hampering conventional plant breeding innovation;
- Disrupting established ways of traditional food production;
- Fuelling risks to health and the environment due to short term profit maximisation for investors and companies.

3.1 A disruptive technology in a closely knit network

The potential impacts on breeders, farmers and food producers are complex. They are faced with a technology that has disruptive potential in more than one sense. For example, in its presentation to investors in 2018, Calyxt framed gene editing as a *"disruptive technology"* meant to accelerate product development.[17] The same language is used in a later Calyxt report to investors in December 2020, stating that the strategic mission is to *"identify disruptive plant-based solutions"*. Furthermore, at the same conference with investors, they explained that *"this is an exciting time for Calyxt and a rapidly developing disruptive plant-based technology story. (…) We are a leader in gene editing with exclusive access to proprietary TALEN technology for use in plants, which we use to successfully commercialize the first gene editing food product in the U.S."*[18]

Needless to say, Calyxt is not the only company following a strategy of introducing disruptive technologies into plant breeding and food production. However, compared to other companies, Calyxt is being more explicit about it. The key message in these statements is clear: traditional plant breeding should be replaced by a new technology owned by Calyxt (or by Cellectis, which filed the most of the patent applications used by Calyxt and also is its largest shareholder). In combination with exclusive proprietary rights, the new technology is meant to not just replace breeding processes and technologies, but also disrupt the systems and markets of current food production. This is the unique selling point that Calyxt offers to its investors.

16 www.testbiotech.org/en/news/crispr-tomatoes-approved-japan
17 www.calyxt.com/wp-content/uploads/2018/06/Calyxt-Investor-Presentation_May-2018.pdf
18 https://seekingalpha.com/article/4411607-calyxt-inc-clxt-q4-2020-results-earnings-call-transcript

The strategy to introduce new technologies in order to disrupt existing production processes and traditional markets is not unique to genetic engineering. Similar disruptive strategies were used by BASF in the 19th century: BASF replaced the production of certain colours extracted from natural resources with chemical synthesis in about 1860. It filed patents on its technology and processes at the same time. As a result, the traditional markets for these colours suffered a complete breakdown and were replaced by the products, productions systems and markets centered on the new technology owned by BASF (Zimmermann, 1965).

One may argue that disrupting existing production systems and markets is simply the way that innovation works. Indeed, new technologies have had disruptive effects in many areas in the past, often with positive outcomes: electric lights replaced candles, cars replaced horses, computers replaced mechanical typewriters. However, the question arises as to which extent such a development would be desirable today in plant breeding, agriculture and food production.

More precisely, what consequences might a disruptive technology have in the context of food production which is embedded in a network of seed diversity, biodiversity, natural resources and ecosystems? These closely knit networks also include small and medium sized breeders, traditional farmers and regional markets typical of European food production systems. Can we, should we promote developments to disrupt and replace these living networks by proprietary technologies and market strategies of international companies? Should we not consider the risk that we might also destroy our food sovereignty and food security if we disrupt these networks?

In addition, it should be clearly explained what disruptive effects could mean for ecosystems and health safety: patents are valid for a term of 20 years, and therefore it is in the interest of investors and companies to make as much profit as possible from their patented seeds within this period of time. Companies are inevitably driven by this incentive to market as many of their seeds and related products as fast as possible.

It is therefore not at all surprising that stakeholders aim for fast-track environmental releases, large-scale cultivation of their plants and open markets for trading the commodities. From this perspective, deregulation of New GE is crucial: it allows fast access to markets in Europe. Whereas a lack of sufficient control poses a significant threat to ecosystems, agriculture and food production, investors and companies are simply aiming to make the highest amount of profit they can from a patented and disruptive technology.

3.2 A 'patent cartel' to control research and development

Corteva is following a different strategy in its public relations in comparison to Calyxt: for example, in an interview published in Brussels based media Euractiv in June 2018[19], Corteva claims to help farmers to survive, whereas 'Mother Nature' is putting them under pressure. Regardless of whether the problem is caused by climate change, or loss of biodiversity, or an increasing burden of chemicals, New GE (and Corteva) will provide the necessary technology to fix the problem: *"Corteva boss: 'Mother Nature' changes the game quickly and demands new agricultural tools".*

According to this kind of marketing, it is nature which is disruptive, and it is the company that is delivering the technology to survive. It creates the impression that climate change and losses in biodiversity are a problem caused by nature which can only be fixed with new technologies.

Corteva is a new name for an old player: after the merger of Dow AgroSciences (DAS) and DuPont (Pioneer) to DowDuPont, which was finalised in 2017, the agriculture division of the merged companies was

19 https://www.euractiv.com/section/agriculture-food/interview/corteva-boss-mother-nature-changes-the-game-quickly-and-demands-new-agricultural-tools/

renamed Corteva Agriscience. In 2019, three separate new companies DuPont, Dow and Corteva Agriscience were announced.[20] However, if growers sign contracts with Corteva, the text of the contracts still defines the name of the company as: "*'Corteva' and 'Corteva Agriscience' means, collectively, DAS, Pioneer, DuPont, and their affiliated companies.*"[21]

As shown in Figures 1 and 2, 'the Corteva group' dominates the patent landscape in regard to patent applications and European patents granted for New GE. To consolidate its dominant position, the company created mechanisms to control access to CRISPR/Cas technology. In 2018, the company explained its strategy (Then, 2019) at a meeting with the EU Commission, EU Member States, stakeholders and civil society organisations: in addition to its own patent applications, it negotiated several licences with the 'inventors' of the CRISPR/Cas technology, including the University of California, the Broad Institute/MIT and the Vilnius University[22]. They established a patent pool comprising the 48 most important patents needed for plant breeding: 35 patents granted to Broad Institute/MIT, 4 patents granted to the University of California, 2 patents granted to the Vilnius University and 7 granted to DowDuPont. According to the DowDuPont presentation, even then (!) plant breeders needed access to this large number of patents if they wanted to fully utilise CRISPR/Cas technology. Breeders interested in accessing the patent pool not only have to pay licence fees, but also have to sign contracts on stewardship and confidentiality.

Controlling access to the patent pool means that the company is in an extremely strong market position. Announced as a way of making patent law more 'democratic' by organising access to the patented technology[23], this is, in actual fact, a strategy to control competitors and to perpetuate a predominant market position. While it is still possible for other big companies, such as Bayer (Monsanto), to directly obtain licences independently of 'the Corteva group', this is hardly possible for most of the smaller breeders.

As a result, most of the European breeders will not be able to gain access to the technology without signing contracts with Corteva. Increasing market concentration in the breeding sector seems to be an unavoidable result of the introduction of CRISPR/Cas technology, with inevitable downstream consequences for farmers and food producers. Even now, farmers who want to grow transgenic crops produced by Corteva (brand name *Enlist*) have to sign contracts with requirements not to use seeds from the harvest and to apply specific pesticides.[24]

Besides companies such as Simplot,[25] Vilmorin[26] or Yield10 Bioscience, the gene banks International Rice Research Institute (IRRI) and the International Maize and Wheat Improvement Center (CIMMYT) have also signed contracts with Corteva.[27] Cooperation with gene banks furnishes Corteva with an influential position

20 https://www.corteva.de/ueber-uns/unsere-geschichte.html
21 https://www.corteva.ca/content/dam/dpagco/corteva/na/ca/en/files/trait-stewardship/Corteva-Agriscience-TUA-Canada-Form-English.pdf
22 See also https://www.broadinstitute.org/news/dupont-pioneer-and-broad-institute-join-forces-enable-democratic-crispr-licensing-agriculture
23 See above
24 https://www.corteva.ca/content/dam/dpagco/corteva/na/ca/en/files/trait-stewardship/Corteva-Agriscience-TUA-Canada-Form-English.pdf
25 https://markets.businessinsider.com/news/stocks/j-r-simplot-company-secures-agricultural-research-and-commercial-license-from-corteva-agriscience-and-broad-institute-of-mit-and-harvard-1027434426
26 https://www.euractiv.com/section/agriculture-food/news/corteva-signs-first-major-gene-editing-deal-with-european-company/
27 https://crispr.corteva.com/our-promise-crispr-cas-corteva-agriscience/

in regard to the use of the global genetic resources needed for future plant breeding. Moreover, these contracts might encourage Corteva to market genome edited plants developed by the gene banks[28]. The wording of these contracts appears to be confidential, but should be made public.

Current ongoing developments may also cause the Corteva market strategy to be influenced by even higher profit expectations: in 2021, Corteva was targeted by a group of investors known as Starboard-Value.[29] This is a group of investors, also known as 'investor activists', who enforce their interests not only by acquiring shares, but also by requesting to be represented on the boards of the companies.[30] As a result, the introduction of New GE organisms to the market is likely to be pushed by increasing pressure from investors, thus potentially multiplying disruptive effects on ecosystems, seed markets, agriculture and food production.

3.3 Hampering innovation in conventional breeding

Innovation strategies in the conventional plant breeding sector are very different to those in New GE. First of all, conventional breeding starts with a broad range of genetic diversity, which is needed for further crossings and selection to derive a desired trait (breeding characteristics). Conventional breeding (including 'random' mutagenesis) can generate desired traits which are complex, distinct and heritable, and often based on so-called Quantitative Trait Loci (QTLs). This means that the combination of diverse genetic information contributes to a specific trait, such as yield or stress resistance. In many cases, these traits are not well-defined at the genomic level.

In the context of conventional breeding, it should be considered that some genetic alterations are more frequently observed than others: the organisation of the genome (including the distance between two genes on a chromosome, recombination hot spots, gene clusters, large genomes, linkage drag, repair mechanisms and epigenetic effects) allows some changes and gene combinations to occur more frequently than others, while some have to be considered to be unlikely or even very unlikely (for overview see Testbiotech, 2020).

On the other hand, technical methods of genetic engineering involve adding genes or the direct and targeted change of specific genes to generate a new trait in the genome of plants or animals. CRISPR/Cas also makes a much larger part of the genome available for genetic change compared to conventional breeding; it allows biological traits to be generated that were not previously achievable (Kawall 2019). However, complex traits cannot be generated with the new methods of New GE if they are not well-defined at the genomic level. Thus, in many cases, more complex traits based on QTLs are often more easily achievable using conventional breeding than with genetic engineering.

In conclusion, conventional breeding (including random mutagenesis) can be easily and clearly distinguished from targeted genetic engineering (see Testbiotech, 2020). This finding is crucial in regard to GMO regulation as well as for patent law.

These differences are also addressed in European patent law: the G2/07 and G1/08 decisions stipulate that, in order to grant a patent, the EPO must request a technical step that directly and purposefully establishes a desired trait (defined phenotype) in the genome; therefore, it is fundamentally different to conventional breeding methods (see Tippe et al., 2021)

However, industry has a strong interest in blurring the differences: the companies have an interest in in extending the boundaries of patentability beyond the technical area into conventional breeding, and thus throw out

28 See https://publications.jrc.ec.europa.eu/repository/handle/JRC123830
29 https://www.corteva.com/resources/media-center/corteva-enters-agreement-with-starboard-value.html
30 https://en.wikipedia.org/wiki/Starboard_Value

the prohibition in patent law[31] which excludes patents on *"essentially biological processes"* for breeding of plants and animals. To this end, industry is trying to argue that there are no fundamental differences between conventional breeding and New GE. As a result, according to industry, plants and animals are patentable, regardless of whether they are derived from targeted technical interventions or random processes (Tippe et al., 2021).

In short, there is a general line of argument repeatedly put forward by industry in the context of patent law and GMO regulation with one objective: genetic engineering methods should as far as possible be seen as equivalent to conventional breeding (see, for example, Leopoldina, 2019). This claim is causing confusion and controversy in the debate on GMO regulation in the EU. It also has consequences for the EPO: patents granted with 'absolute product protection' on plants or animals cover the respective genotype or phenotype independently of the process that was applied. Therefore, these patents can cover genetic engineering as well as conventional breeding. Patents filed for plants (and animals) derived from New GE can thus hamper conventional breeding. In many cases, traditional breeders may no longer have the freedom to develop and market their new conventional varieties.

A case study: patent application by BASF

A case study (see Tippe et al., 2021) can help to illustrate the problem: several companies systematically file patent applications which disguise conventional breeding as technical inventions. One example is patent application WO2020239495 filed by BASF/Nunhems, which claims 'oomycete resistance in tomato and cucumber'.

The technical description of the patent shows that New GE was not used to generate plants with desired traits. Instead, the starting point was a native trait from an Indian gene bank. To derive plants with the desired resistance to diseases, many cycles of crossing and selection were performed. This achieved homozygous alleles and breeding lines with suitable genetic backgrounds. No targeted methods of new or old GE were applied.

However, the wording of the claims is not restricted to any particular method. Rather, it claims all plants with the desired traits and characteristics. The methods listed in the claims ("chemical mutagenesis, radiation mutagenesis, tissue culture or targeted genome editing techniques such as Crispr based techniques") intentionally blur the distinction between conventional breeding (random mutations) and the techniques used in New GE.

This wording of the claims definitely make sense from the perspective of industry: if the patent is granted as set out in the application, it will cover all plants, seeds and fruits with the relevant traits, including those derived from conventional breeding, even though these are officially excluded from patent protection.

The situation can also be exploited in another way: if BASF were in future to 'replicate' the described traits with CRISPR/Cas and then file another patent, then this patent could extend to conventional breeding.

The patent application filed by BASF is certainly not the only one to be formulated in this way. Some further examples of patent applications for plant and animal breeding, with and without New GE are shown in Table 3 (Testbiotech, 2018).

31 Art 53(b) of the EPC and Article 4 of EU Directive 98/44/EC

Table 3: Some examples of patent applications covering New GE as well as conventional breeding

Patent number	Company	Content
WO 2014110552	Recombinetics	Hornless cattle for natural and synthetic genetic applications
WO2017040695	Recombinetics	Selection of genetic variants in cattle such as polled, climate adaption and fertility and related usages
WO2017044744	Monsanto	Mildew resistance in maize
WO2017106731	Monsanto	Northern leaf blight resistance
WO2018031874	Monsanto	Resistance to 'late wilt' in maize
WO2014006159	Bayer	Changed oil composition in soybean
WO2015000914	Bayer	Changes in flowering times
WO2016176476	Bayer	Changed oil composition in oilseed rape

Further research shows that the EPO has already granted similar patents, and many more similar patent applications have been filed in Europe (Tippe et al., 2021).

Consequently, innovation in conventional breeding can be significantly hampered, disrupted or even blocked. In many cases, it is very difficult for traditional breeders to consider all the legal uncertainties in regard to the technical content and legal consequences of patents. All these aspects act as a deterrent and contribute to discouraging conventional breeders from working on traits which might fall under the scope of patents filed by the large companies. Thus, the blurring of the differences in relation to New GE techniques means that traditional breeders are hampered in their endeavours by monopolistic patent claims and associated legal uncertainties.

This is also a problem for the goals of the so-called EU 'Green Deal' and 'Farm to Fork Strategy'. These projects aim to make agricultural systems more resilient, better able to cope with climate change as well as reduce pesticide use and promote access to innovation in plant breeding. At the same time, they are intended to promote innovation in plant breeding. However, extending patent protection from the field of technical inventions into conventional breeding, risks significantly hindering plant breeding in its role of bringing innovation to farmers and food production.

4. Impact on public debate and political decision-making

At the same time as the first patent applications on CRISPR/Cas technology for genetic engineering of plants and animals were being filed, companies and research institutions 'coincidentally' became increasingly active in publicly demanding the deregulation of most organisms derived from New GE.

The arguments brought forward in this respect also aim to blur the fundamental differences between conventional breeding and genetic engineering in order to:

- Avoid labelling to take away future choice from farmers, food producers and consumers
- Avoid mandatory risk assessment to accelerate marketing.

'New Breeding Techniques' (NBTs) is a term that interested stakeholders used very early on to describe New GE, and thus present it as a simple variation of conventional breeding. A new network called the 'New Breeding Techniques Platform' was created in 2012 to coordinate efforts to deregulate New GE. This was an attempt to bring companies and academic institutions together in an effort to exempt as many New GE organisms as possible from GMO legislation. The activities of the platform were exposed by the Corporate Europe Observatory (CEO, 2016). In the meantime, although their activities were stopped, they are now being continued under the umbrella of EU SAGE (European Sustainable Agriculture Through Genome Editing)[32] (for further information also see CEO, 2021).

It is not only the biotech industry attempting to disguise New GE as simply a new traditional breeding method. Rather, reports from acknowledged academic institutions, such as Leopoldina and ALLEA, reveal that they are also trying to create the impression that, for example, CRISR/Cas applications are of the same 'nature' as processes used in conventional plant breeding.

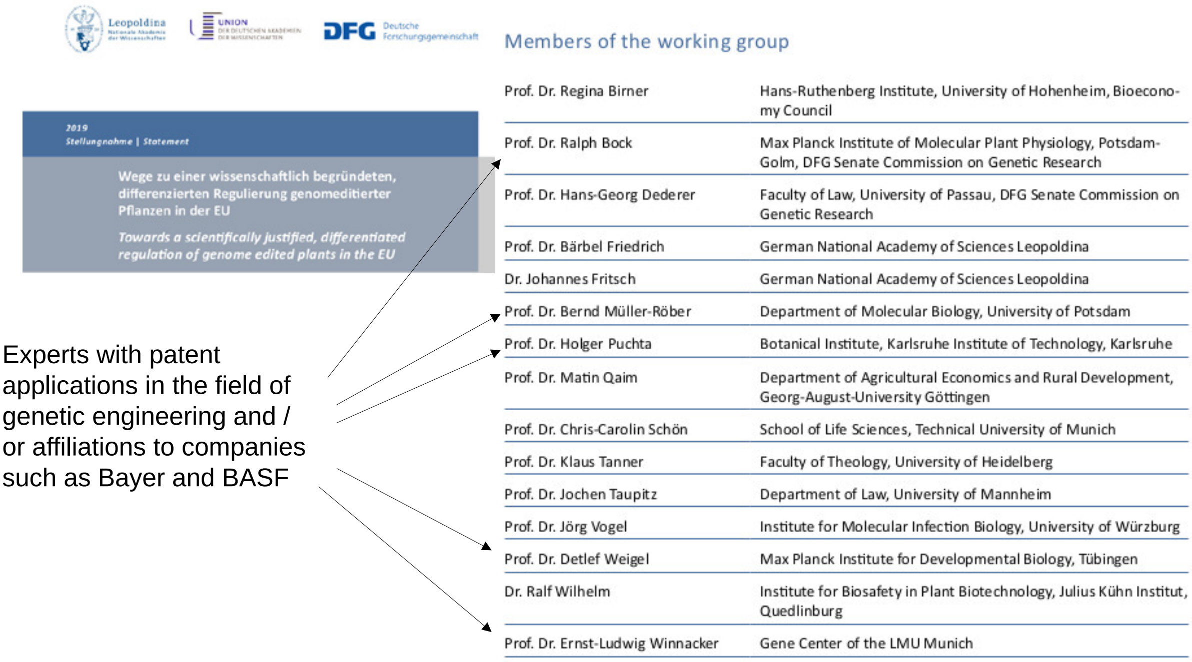
A 2020 ALLEA (All European Academies) report and a 2019 Leopoldina report are prominent examples of such publications trying to promote the impression that the genotypes derived from New GE (genome editing) are of the same quality as changes in the genome which occur 'at random' (Testbiotech 2020). In 2021, incorrect Leopoldina findings were exposed in a report compiled by the European Network of Scientists for Social and Environmental Responsibility (ENSSER).

It is striking how similar the arguments brought forward in favour of New GE deregulation are to those being used to expand the scope of patents into conventional breeding. The coincidence might be explained by the fact that experts involved in filing patent applications also played a key role as authors of the ALLEA (2020) and Leopoldina (2019) reports.

The ALLEA (2020) report was coordinated by VIB (Vlaams Instituut voor Biotechnologie), which "in partnership with companies such as Bayer and CropDesign (BASF)" is testing "new crops with improved yield and increased stress resistance".[33] Cellectis (Calyxt), Bayer and BASF are all research partners of VIB. Representatives of Bayer and BASF are also members of the General Assembly of VIB[34], and Bayer is also represented in the Board.[35] Two members of VIB are named as authors of the ALLEA report. One of them is Dirk Inzé, who was a founder of CropDesign (part of BASF until 2021, now part of VIB again)[36] and is also involved in several patent applications for VIB, CropDesign and BASF. It should also be mentioned that VIB plays a leading role in the EU SAGE lobbying platform, which again is promoted in the ALLEA report.

32 https://www.eu-sage.eu/
33 See https://web.archive.org/web/2020*/http://www.vib.be/en/business-opportunities/Pages/Pipeline.aspx
34 http://new.vib.be/general-assembly
35 http://new.vib.be/board-directors
36 https://www.basf.com/global/en/media/news-releases/2021/01/p-21-100.html

Similarly, the Leopoldina (2019) report was written by experts known to be involved in patent applications for GE plants, some of them together with industry (see Figure 6). In addition, the experts Ralph Bock, Holger Puchta and Detlef Weigel are also involved in of EU SAGE activities which are coordinated by VIB.



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Prof. Dr. Jochen Taupitz	Department of Law, University of Mannheim
Prof. Dr. Jörg Vogel	Institute for Molecular Infection Biology, University of Würzburg
Prof. Dr. Detlef Weigel	Max Planck Institute for Developmental Biology, Tübingen
Dr. Ralf Wilhelm	Institute for Biosafety in Plant Biotechnology, Julius Kühn Institut, Quedlinburg
Prof. Dr. Ernst-Ludwig Winnacker	Gene Center of the LMU Munich

Figure 6: The list of experts named in the Leopoldina (2019) report, highlighting those who are involved in filing patent applications on GE plants.

Scientists and experts who are involved in developing New GE products and filing patent applications are in an awkward situation: for example, EFSA acknowledges that patents have an impact on the independence and conflicts of interest (COI) of experts.[37] Therefore, their expertise has to be considered with caution. In many cases, experts involved in filing patent applications (very often as inventors) also closely cooperate with companies (very often the patent holders). Political decision-makers in the EU need to be aware of the problems associated with strong bias in academic expertise. However, this does not so far seem to be the case.

For example, at the end of April 2021, the EU Commission (2021) published a report on new genomic techniques (genome editing, New GE, NGT). It appears that positions promoted by Leopoldina (2019) and ALLEA (2020) were embraced in the EU Commission report. At the same time, the report makes no mention of numerous scientific papers describing generic risks associated with New GE applications in plants (see Testbiotech 2021a, FGU 2021). As a consequence, the EU Commission seems prepared to suggest far-reaching deregulation New GE applications in plants.

The influence of biased expertise is particularly evident in specific terminology used in the EU Commission report: the terminology it uses seems to suggest that transgenic plants, derived from 'Old GE' could be deregulated to be equivalent to conventional breeding. The term 'conventional GMO' was used for the first time

37 https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

in a regulatory context; it was adopted and defined by the EU Commission to mean 'transgenic'. The history of this term reveals that the Leopoldina (2019) report was a decisive factor in its formulation (see Testbiotech 2021b). It was subsequently embraced by the EU Commission without reference, explanation or justification, and may lead to serious legal problems in the near future.

Thus, there is evidence that the strategy of industry and their affiliated experts, to systematically blur the distinction between genetic engineering and conventional breeding, was successful in influencing the EU Commission report.

The coronavirus pandemic has highlighted the kind of detrimental effects there can be for civil society and democracy if risks are neglected or incorrectly assessed. Science has played a crucial role in informing political decision-making and the wider public debate during the pandemic – the same is true for climate change. It is worrying that in the field of New GE, even highly acknowledged scientific institutions are unable to protect themselves from hijacking by stakeholders with vested interests in the marketing of the technology and its products.

The authorship of experts with vested interests in reports, such as those published by ALLEA (2020) and Leopoldina (2019), has the potential to damage the credibility, reliability and general role of science. Similarly to the way in which the tobacco industry previously exerted undue influence on political decision-making (see for example Bero, 2005), it appears that science is being co-opted by industry in respect to New GE. This is also made clear in a CEO report published in 2021. Therefore, the impact of industry and other vested interests on the current debate within the EU, should be investigated carefully before any further potential steps in regard to GMO regulation are taken.

Moreover, there is an urgent need for systemic and long-term risk research driven by the precautionary principle and carried out from the perspective of the protection goals (health, the environment and nature). This risk research, something which is currently barely available in the EU, should be completely independent of any interests in developing New GE technologies or generating and marketing resultant products.

5. Conclusions & recommendations

This report shows that an increasing number of patents are being filed and granted on New GE applications (use of site-directed nucleases) in plants. The patent landscape is dominated by 'the Corteva group' which, apart from their own patents, controls access to the most relevant patents needed by breeders who want to use CRISPR/Cas technology. In this context, Corteva established a patent pool in 2018, which already at that time comprised around 50 patents.

Further, there is evidence that companies are filing patents which are extremely broad in the scope of their claims, and thus extending to plant and breeding traits derived from conventional breeding. Many of the filed patents intentionally blur the differences between conventional breeding and genetic engineering, with the aim of expanding patent monopolies, claimed on the basis of genetic engineering technology, into the non-technical area of plant breeding.

A comparable strategy can be observed in the political discussions around EU GMO regulation: the same stakeholders involved in the filing of patents are attempting to blur the biological and legal differences between genetic engineering and conventional breeding by using new terminology, such as 'conventional GMO'.

Monopolistic claims on patented technology and possible implications for competition associated with the introduction of New GE in plant biotechnology, make disruptive processes in plant breeding, agriculture and food production highly likely. This development is in strong contradiction to repeatedly voiced arguments stating that CRISPR/Cas technology would be cheap, and therefore more accessible for smaller and medium sized breeding companies.

These new proprietary technology claims affect both political decision-making and trust in science, and therefore call the precautionary principle into question and increase pressure on ecosystems. Ecosystems may well be impacted within a short period of time by an increasing number of organism which have not undergone the biological complexity of evolution. This is also in part due to the duration of patent protection. The pressure ensuing from short term profit maximisation has the capacity to impact world food security and our food safety.

Recommendations for the EU therefore include:

- Strict limitations on patent protection and, in particular, no longer allowing patents on conventional plant or animal breeding;
- Starting investigations into the potential rise of anti-competitive and cartel behaviour based on the control of access to patented technology in the field of New GE, and investigation into the extension of patent protection to conventional breeding;
- Strengthening political decision-making processes to fully integrate the perspective of the protection goals (health and the environment); avoiding inappropriate influence from companies and experts with a vested interest in patents on the technology, and pushing back against products derived from New GE.

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