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

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Summary

This report shows increasing number of patents being filed and granted on applications of New GE (so-called ‘gene-scissors’, of site directed nucleases) on plants in Europe. The patent landscape is dominated by ‘the Corteva group’ (resulting from a merger of Dow and DuPont/Pioneer) which, beyond their own patents, controls access to the most relevant patents needed by breeders which want to use the technology. In this context, ‘the Corteva group’ established a patent pool which, in 2018, already encompassed around 50 patents. Other breeders which want to have access to this pool have to sign contracts which serves Corteva with extremely strong market position which may be a regarded as a ‘hidden cartel’.

Further, there is evidence that companies are filing patents which are extremely broad in the scope of their claims and thereby extent to plant and breeding characteristics in the area of conventional breeding. Conventional breeding is not trying to directly intervene at specific sites of the genome, is based on a high level of genetic diversity, combined with crossing and selection. Very often in produces highly valuable traits, despite not being so well defined on their molecular level. Nevertheless, many patents as filed, are intentionally blurring the fundamental biological and technical differences between genetic engineering and conventional breeding with the intention to expand patent monopolies to the non-technical area of traditional breeding.

The same strategy of diffusing the differences between conventional breeding and genetic engineering can be observed in the political discussions around EU GMO regulation: The same stakeholders being in involved in the filing of patents also try to blur these differences in regard to GMO legislation. Its is an alarming signal that the EU Commission recently introduced new

terminology such as ‘conventional GMO’ which could be understood to define transgenic plants as being conventional.

In conclusion, due to the monopolistic claims that go along with the introduction of a New GE, disruptive processes in plant breeding, agriculture and food production are highly likely consequence. The interest in the proprietary technology is also impacting political decision making and trust in science. Thereby, the precautionary principle is put at risk and the pressure on ecosystems is increased which may, within a short period of time, become burdened with an increasing number of organisms which are not derived from evolutionary processes and mechanisms. This development also is likely to impact food safety.

It is recommended that the EU should

- no longer allow patents with absolute product protection to be granted in field of plant and animal biotechnology;
- start investigations on potential rise of cartels which are based on the control of access to patented technology in the area of New GE;
- harness its political decision making processes to fully integrate the perspective of the protection goals (health and the environment) and to avoid undue influence by companies and experts with interest in patents on the technology and marketing of products derived from New GE.

In addition, the EU should re-organize 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 a matter of controversial debates. 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). Apparently, the goal of the Commission is to promote New GE applications in agriculture in order to foster international trade, technology and product development. At the same time, many experts warn that the precautionary principle has to be respected and the risks of New GE organisms must not be ignored.

Patents constitute a powerful tool to control markets by proprietary technology and monopolistic ownership. Profits are expected from trade with patented products or by selling licenses for access to the technology. In the context of plant breeding, patents are known for their potentially disruptive effects because they can be used to block, hamper or control access to biological material needed by all breeders.

Some of these problems are also addressed by the report of the EU Commission, 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 report of Testbiotech is digging into this issue in more detail, providing recent data on patent applications and involved companies. It reveals effects which are systemic and go beyond what is

discussed by the EU Commission. The observed or prospected impacts are affecting conventional breeding, scientific advise, the protection of biodiversity and sustainable food production. In the light of these findings, the EU-Commission should carefully design its approach on new genomic techniques used in agriculture to avoid negative impacts on the EU's 'Green Deal' and its 'Farm to Fork' strategy.

2. The patent landscape

The following paragraphs give an overview on research institutions and companies involved in patent applications around application of nucleases (especially CRSPR/Cas). It is shown that, while there are many institutions and experts involved in the research, the commercial applications are widely controlled by handful companies with 'the Corteva group' (which resulted from a merger of Dow AgrowSciences and DuPont/Pioneer) being in a predominant position.

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 can not be used by other breeders, or in case, also gardeners or farmers without the permission of the patent holder. In result, patent holder can acquire far-reaching control over breeding and food production. The monopolistic rights of patents, for 20 years, remain valid as long as the patented genetic conditions can be found in any progeny. Thus after crossing of plants there can be an accumulation of patents in the subsequent generations. Further, patents granted on plants very often also extend to the harvest and processed food.

The European Patent Convention (EPC), which is the legal basis 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 its Article 4, "*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, in 1999, the EPO overturned its previous decision (T356/93) by a new decision of the Enlarged Board of Appeal (G1/98). As a result, opposition against patents such as Monsanto's patent on RoundupReady soybeans (EP 0546090) were rejected.[1]

Since 1999, when patents on transgenic plants were allowed, till the end of 2020, nearly 4000 European patents have been granted on plants, most of them concerning genetically engineered crops. In parallel, the international seed market has experienced an ongoing process of concentration and restructuring. Big seed companies, such as Pioneer, DeKalb and Seminis, have been taken over, whilst many smaller companies have disappeared. Today, the international seed market is dominated by a handful of big players (which originally were mainly agrochemical companies) such as Bayer (Monsanto), Corteva (former DowDuPont), BASF and Syngenta (ChemChina) (see figure 1). In result, only four companies control more than 60 percent of the global commercial seed market.[2]

1 For more details also see: www.no-patents-on-seeds.org/index.php/de/hintergrund/publikationen
2 https://philhoward.net/2018/12/31/global-seed-industry-changes-since-2013/

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

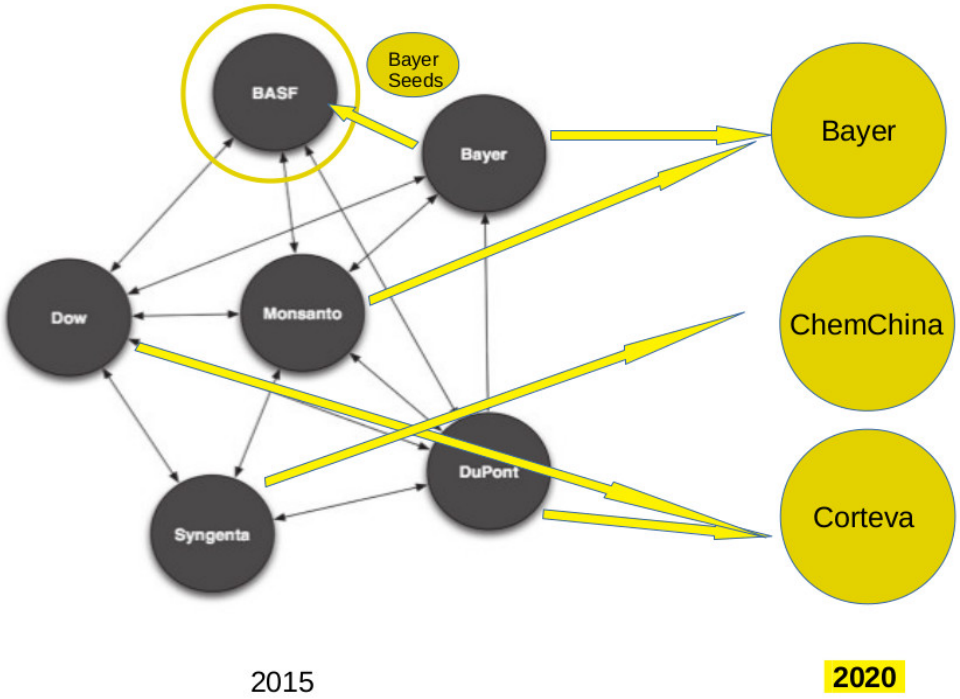


Figure 1: Seed market concentration: Development between 2015 (Howard, 2015) till 2020 (see also https://philhoward.net/2018/12/31/global-seed-industry-changes-since-2013/). Yellow: Development between 2015 and 2015. Bayer acquired Monsanto, but was obliged to sell its seed sector to BASF. ChemChina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

2.2 The 'inventors' of CRISPR/Cas

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

In most cases, Nobel price 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. Furthermore, Virginijus Šikšnys (Vilnius University) and George Church (Harvard University) also contributed to the technological development at an early stage.

Around 2012, these researchers managed to develop the CRISPR/Cas system beyond the mechanisms as detected in bacteria: By combining the Cas protein with a guide RNA, it became possible to apply the CRISPR/Cas machinery on eucaryotic cells of plants and animals.

The technology is complex and its technical potential is impressive. CRISPR/Cas enables the user to alter a specific target region in the genome. DNA-cutting enzymes are generally called nucleases. Enzymes like CRISPR/Cas are summarized as 'site directed nucleases' (SDN), since they can target specific sites in the genome. CRISPR/Cas is not the only SDN, there are others called meganucleases, zinc finger and TALENs. However, CRISPR/Cas is so far the most relevant nuclease in terms of publications, applications and patents. Thereby, CRISPR/Cas, by far, became the most important technology in the context of New GE in crops, followed by TALENs and ODM (oligo directed mutagenesis, ODM, is not based on usage of nucleases) (see figure 2).[3] In comparison to previous methods of genetic engineering in plants, CRISPR/Cas not only is more flexible and precise but also makes the genome available for changes to much larger extent (Kawall 2019). At the same time, it goes along with new challenges for risk assessment due to the specific generic intended and unintended effects of the technology (Agapito-Tenfen et al., 2018; Eckerstorfer et al., 2019; Kawall et al., 2020).

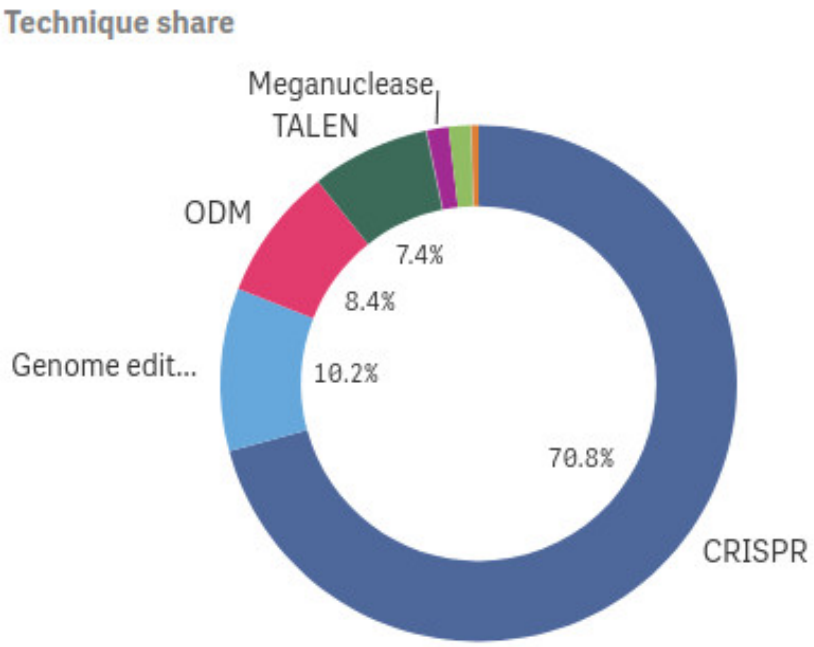


Figure 2: Proportion between CRISPR/Cas and other technologies used in New GE (Genome Editing) in plants (source: https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/index.html).

Researchers around Feng Zhang and Jennifer Doudna have been filing several hundred patents on the CRISPR techology, many of them also extending to Europe. In 2015, a first CRISPR/Cas patent was granted for the Feng Zhang group (EP2771468) and came under fire by several oppositions.[4] Soon after, in 2016, EPO granted a patent to the group around Jennifer Doudna (EP2569425).

3 https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/index.html
4 https://www.sciencemag.org/news/2017/02/how-battle-lines-over-crispr-were-drawn

Till end of 2020, the EPO issued more than 30 patents on CRISPR technology to the Feng Zhang group and around 15 patents for the group around Jennifer Doudna and Emanuelle Charpentier. Further patents were granted, for example, to George Church and Virginijus Šikšnys. In addition, also patents on other gene scissors such as TALENs, zinc finger and meganucleases were issued by the EPO.

In many of these patents, also applications on human cells and animals are claimed, adding a specific ethical dimension: For example, Jennifer Doudna and Emmanuelle Charpentier are named as the inventors of patent EP3401400 which was opposed because of ethical concerns by Testbiotech. According to the opponent (Testbiotech), potential interventions in human germ line and commercial uses of human embryos are not fully excluded, as would be required by European law.[5] In additon, the patent also claims the application of CRISPR/Cas on cells of plants and animals.

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

2.3 The race between companies

There is a soaring number of European patent applications as well as granted patents in Europe which concern New GE in food plants and also in livestock[8]. Within the last years, Testbiotech published several overviews on 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 summarizes some data from these reports and in addition includes patent applications on nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) till end of 2020.

It is evident that especially one company, Corteva (previously known as DowDupont), is leading in the number of patent applications in the field. By end of 2020, more than 70 patent applications covering technology, processes and in many cases also plants and seeds, were registered just by this one company.

Table 1 gives an overview on patent applications filed by the ‘Corteva group’ in 2019 and 2020 at WIPO[9] as also integrated in Figure 3. It has to be assumed that most of these patent applications will also be transferred to and examined by the EPO.

5 www.testbiotech.org/node/2554
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)
9 World Intellectual Property Organisation

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

Applicant	Patent Number	Technology	Year of publication	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 halpoid 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

The number of patent applications per company[10] are shown in Figure 3: 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. In addition, Dan Voytas which 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). BASF, Keygene and Syngenta are between 10 and 20 in number of patent applications.

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

There are also some other companies filing patents in this context (such as Rijk Zwaan, Bejeo Zaden or Sakata) as well as some Chinese institutions[11], however with lower numbers. Therefore, we conclude that in Europe just a few companies are heading the development with one company, Corteva, dominating the patent landscape.

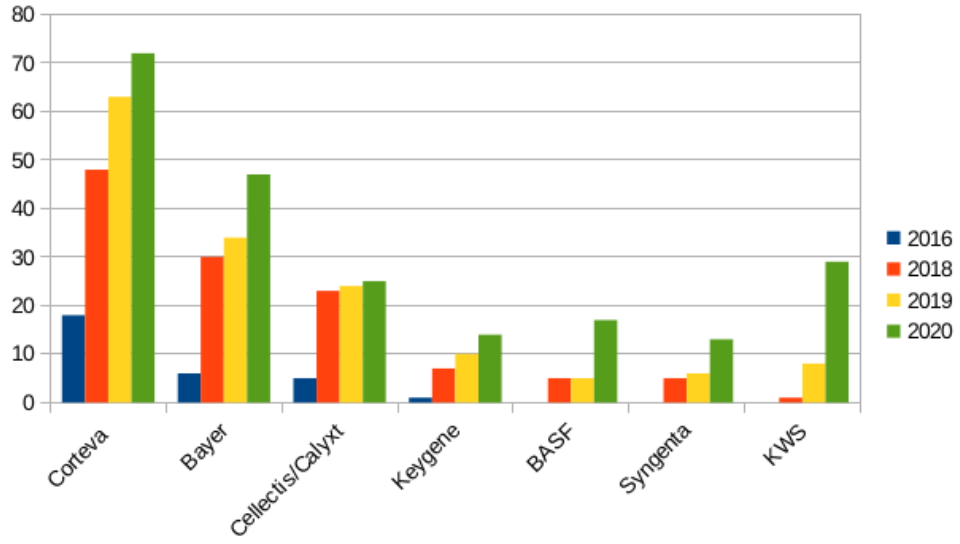


Figure 3: Number of international patent applications (WIPO /WO) on nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) in the food plant sector till end of 2020[12] (number of patent applications accumulated[13]).

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

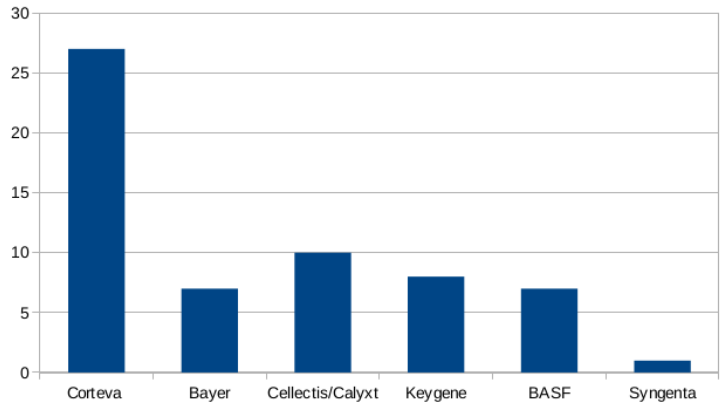


Figure 4: Number of granted European patents on site directed nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) and applications in crops till end of 2020.[14]

11 Some patents of 'the Corteva group' were filed with Chinese partners, these were integrated in the figures.
12 Figures on Corteva include relevant patents from Dow AgroSciences, DuPont and Pioneer. Figures on Calyxt do not include other patents filed by experts of Calyxt filed for example together with University on Minnesota.
13 See also Testbiotech (2016 & 2018) as well as Then (2019).
14 See above

The history in the developing nucleases is also represented in the patents as filed over the years. For example, patents applied and granted for ‘the Corteva group’ in earlier years, often concern zinc finger nucleases (see table 2). This can be compared to the patent applications 2019/2020 of ‘the Corteva group’ which are mostly concerning CRIPSR/Cas technology (see Table 1).

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

Applicant	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 as listed in tables and figures above do not only claim the technology, but also a wide range of plants and their characteristics: Included are transgenic and non-transgenic plants, plants producing insecticides, herbicide resistant plants, plants with changes in nutritional quality, with changed reactions to environmental stress, with alterations in growth habit and yield as well as with changed characteristics in regard to storage and processing. The range of plant species are cereal and oilseed crops (such as maize, soybean, oilseed rape, wheat and rice) as well as legumes and, in some case, also trees.

As a recent report from Joint Research Center (JRC) of the EU shows[15], many potential applications such as stress tolerance, modified composition and yield (plant architecture) might be developed withing next decades, however, when it comes to applications developed near to commercial stage, herbicide resistance is (still) the leading application.

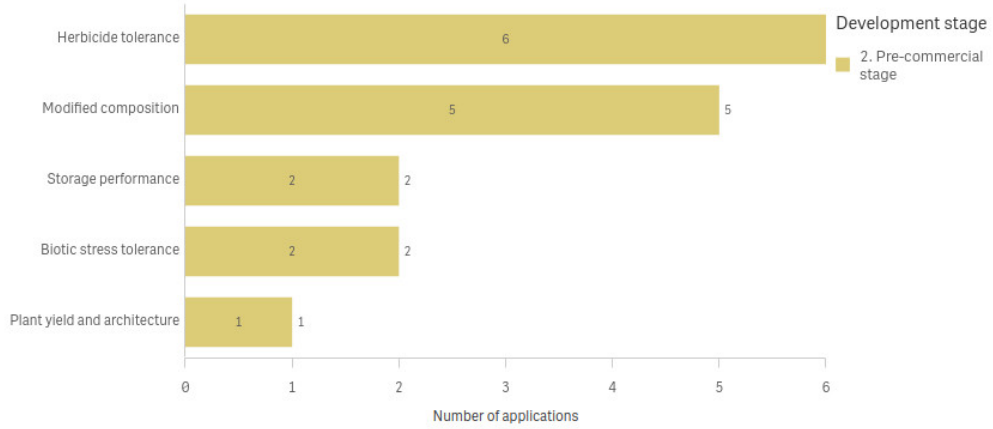


Figure 5: Traits in plants derived from New GE being close to the commercial stage (as of May 2021) (source: https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/index.html).

In any case, the patents as filed can hardly be used for predictions which products will finally enter the market. However, at least four CRISPR/Cas plants are known to be close to marketing or already under cultivation:

- a soybean of company Calyxt, based on TALENs, cultivated in the US (at relatively small scale) with a change in oil composition;
- a ‘waxy’ maize plant of Corteva (former DowDuPont), derived from CRISPR/Cas with a change in its starch composition (announced for the US);
- a transgenic CRISPR/Cas maize from Corteva (former DowDuPont) with herbicide resistance (glufosinate) and insect toxicity (applied for import into the EU);
- a 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 tomato seems to be hampered by patents: It is reported that in Japan, because of patents rights, only plants for private non-commercial cultivation in home gardens can be distributed, while marketing of seeds and fruits is not allowed.[16]

15 https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/index.html
16 www.testbiotech.org/en/news/crispr-tomatoes-approved-japan

3. Negative impacts on innovation and food production

The New GE technology in combination with patents on plants (and animals) can endanger food production by disruptive impacts on breeders, farmers and the environment because of

- monopolistic control of biological resources needed for further breeding;
- hampering conventional plant breeding innovation;
- disrupting established ways of traditional food production;
- fueling risks for health and environment by high expectations for profits of investors and companies.

3.1 A disruptive technology in a closely-knit network

The potential impacts for breeders, farmers and food producers are complex. They are faced with a technology that has disruptive potential in more than one meaning. For example, Calyxt, in its presentation for investors in 2018, framed gene editing as a "*disruptive technology*" which is meant to accelerate product development.[17] The same framing is used in a later Calyxt report to investors in December 2020 stating the strategic mission to "*identify disruptive plant-based solutions*". Furthermore, in the same conference with investors it was explained "*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]

Of course, Calyxt is not the only company following this strategy of introducing disruptive technologies into plant breeding and food production. But compared to other companies, Calyxt is being more explicit about it. The key message of these statements is clear: Traditional plant breeding should be replaced by a new technology owned by Calyxt (or by Cellectis which applied for most the patents and is the largest shareholder of Calyxt). Thereby, the new technology, in combination with exclusive proprietary rights, is supposed not only to replace processes and technologies in breeding but also to disrupt the systems and markets of current food production. This is the unique selling point that Calyxt offers to its investors.

The strategy to introduce new technologies to disrupt existing production processes and traditional markets is not unique for genetic engineering. Similar disruptive strategies were executed by BASF already in the 19th century: At that time, around 1860, BASF replaced the production of certain colors which were extracted from natural resources by its chemical synthesis. In parallel, BASF filed patents on its technology and processes. In consequence, the traditional markets for these colors suffered a complete breakdown and, step by step, were replaced by the products, productions systems and markets centered around the new technology owned by BASF (Zimmermann, 1965).

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

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

More precisely, what consequences may 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 marktes which are typical for 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? Shouldn't we consider the risk that, by disrupting these networks, we also might destroy our food sovereignty and food security?

In addition, disruptive effects also have to be spelled out in regard to the ecosystems and health safety: Since the duration of a patent is limited to 20 years, it is in the interest of investors and companies, to push for profit of their a patented seeds within this period of time. Therefore, the companies are driven by the incentive to market as many of their seeds and related products as fast as possible.

Therefore, these stakeholders aim for fast track environmental releases, large scale cultivation of their plants and open markets for trade of the commodities. From this perspective, deregulation is crucial: It allows market access and environmental release for large numbers of various genetically engineered organisms within short period of time. While such a dynamic, without sufficient control, will pose a significant threat to ecosystems, agriculture and food production, it is in the short term interest of investors and companies which are aiming to profit from a patented and disruptive technology.

3.2 A 'patent cartel' to control research and development

Corteva, in its public communications, follows another strategy compared to Calyxt: For example, in an interview published in Brussels based media Euractiv in June 2018[19], Corteva claims to help farmers to survive while it is 'mother nature' which is putting them under pressure. No matter whether the problem is caused by climate change or loss of biodiversity or increasing burden of chemicals, New GE (and the company 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 propaganda, it is nature which is disruptive, and it is the company which is delivering the technology to survive. Thereby, the impression is raised that climate change and losses in biodiversity are a problem caused by nature that can only be fixed by new technologies.

Corteva is a new name for an old player: Starting with a merger between Dow AgroSciences (DAS) and DuPont (Pioneer) to DowDuPont which was finalised in 2017, the agriculture division of the merged companies was named Corteva Agriscience. In 2019, three separate companies DuPont, Dow and Corteva Agriscience were announced.[20] However, if growers are signing 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 figure 1 and 2, 'the Corteva group' dominates the patent landscape in regard to patent applications and granted European patents in the field of New GE. To foster its dominant position,

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

the company managed to create mechanisms to control access to the CRISPR/Cas technology. In 2018, at a meeting with the EU Commission, EU Member States, stakeholders and civil society organisations, the company explained its strategy (Then, 2019): In addition to its own patent applications, several licenses were negotiated with the 'inventors' of the CRISPR/Cas technology, including the University of California, the Broad Institute/MIT and Vilnius University[22]. Thereby, a patent pool of the 48 most important patents needed for plant breeding was established: 35 patents of Broad Institute/MIT, 4 patents of University of California, 2 patents of Vilnius University and 7 patents of DowDuPont. According to the presentation of DowDuPont, already at that time (!) access to this high number of patents was needed for those plant breeders which want to fully apply the CRISPR technology. Breeders interested in accessing the patent pool, are not only requested to pay license fees, but also to sign contracts on stewardship and confidentiality.

This possibility to control access to the patent pool puts the company in an extremely strong market position. What was announced as a method to make patent law more 'democratic' by organising access to the patented technology[23] at closer sight turns out as 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 gain licenses independently from 'the Corteva group', this seems hardly possible for most smaller breeders.

In 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 inevitable result from the introduction of the CRISPR/Cas technology, going along with downstream consequences for farmers and food producers. Already now, farmers who want to grow transgenic crops produced by Corteva (brandname Enlist) have to sign contracts which request them not to re-use the harvest as seeds and also to apply specific pesticides.[24]

Not only companies like Simplot,[25] Vilmorin[26] or Yield10 Bioscience signed contracts with Corteva, but also the genebanks International Rice Research Institute (IRRI) and the International Maize and Wheat Improvement Center (CIMMYT).[27] The cooperation with gene banks serves Corteva with an influential position in regard to the use of the global genetic resources needed for future plant breeding. Also, the marketing by Corteva of genome edited plants developed by the gene banks[28], might be encouraged by these contracts.

There are developments underway which may lead to the market strategy of Corteva to be influenced by profit expectations to an even higher degree: In 2021, Corteva was targeted by a group of investors called Starboard-Value.[29] This group which also known as 'investor activists' enforcing their interests not only by acquiring shares but by requesting to be represented in the board of the companies.[30] In consequence, the market introduction of New GE organisms is likely to

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/
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

be pushed by increasing pressure from investors, potentially also multiplying their disruptive effects upon ecosystems, seed markets, agriculture and food production.

3.3 Hampering innovation in conventional breeding

The strategies for innovation in conventional plant breeding compared to New GE are largely different. Conventional breeding starts from a broad range of genetic diversity, which is needed to perform 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, often based on so-called Quantitative Trait Loci (QTLs). This means that various genetic information, in combination, contribute to a specific trait such as yield or stress resistance. Such traits are, in many cases, not well-defined at the genomic level. Due to the methods used in conventional breeding, some genetic alterations are more frequently observed than others: The organisation of the genome (including the distance between two genes 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 as unlikely or even very unlikely (for overview see Testbiotech, 2021a).

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

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

Indeed, these difference are also adressed in European patent law: In its decisions G2/07 and G1/08, the EPO, for granting a patent, requests a technical step that directly and purposefully establishes a desired trait (defined phenotype) in the genome, and makes it therefore fundamentally different to methods of conventional breeding.

However, industry has strong interests to blur these differences: The companies are interested in extending the boundaries of patentability from the technical area to conventional breeding and to abolish the prohibition in patent law[31] which are excluding patents on "*essentially biological processes"* for breeding of plants and animals. For this purpose, industry tries to argue that there are no fundamental differences between conventional breeding and New GE. In result, according to industry, plants and animals are patentable, no matter if derived from targeted technical intervention or random processes (Tippe et al., 2021).

In short, there is a general line of arguments, repeated by industry in the context of patent law as well as in regard to GMO regulation with the same goal: Random processes, induced by chemical or physical mutagens, are presented as being equivalent to genetic changes caused by New GE (see for example Leopoldina, 2019). This claim leads to confusion and controversial debates about

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

GMO regulation in the EU. It also has consequences for the practice of the EPO: If patents are granted with ‘absolute product protection’ on plants or animals they cover the respective genotype or phenotype independently from the process that was applied. Therefore, these patents can cover genetic engineering as well as conventional breeding. By this way, patents filed for plants (and animal) derived from New GE can also hamper conventional breeding. Traditional breeders, in many cases, may no longer have freedom to operate 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 exemplify 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’.[32]

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

However, the wording of the claims is not restricted to any method. Instead, all plants with the desired traits and characteristics are claimed. The methods which are listed in the claims (“*chemical mutagenesis, radiation mutagenesis, tissue culture or targeted genome editing techniques such as Crispr based techniques”*) are blurring the distinction between conventional breeding (random mutations) and the techniques which are used for New GE.

Such a 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 characteristics, also those derived from conventional breeding, despite these officially are considered as non-patentable. The case of the BASF patent application is, by far, not the only one. Some further examples for patent applications that concern plant and animal breeding with and without New GE are shown in Table 3 (Testbiotech, 2018).

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

32 Oomycetes are known to cause plant diseases such as downy mildew and late blight.

As shown by further research, similar patents were already granted by the EPO and many more, similar patents, were applied in Europe (Tippe et al., 2021). In this context, there several reasons to blur the differences between conventional breeding and New GE: On the one hand, patents might be enriched by technical toppings to raise the impression they would be inventive, while in fact they are just based on methods such crossing selection. On the other hand, companies are interested to extent their monopolistic control to area of conventional breeding to hamper competition.

In consequence, innovation which is derived from conventional breeding can substantially be hampered, disrupted or even blocked. For traditional breeders, in many cases, legal uncertainties in regard to the technical content and legal consequences of patents are pervading. In result, there are deterring effects that prevent conventional breeders from working on traits which might fall under the scope of patents filed by the big companies. Thus, by blurring the differences to techniques used by New GE, monopolistic control is also affecting traditional breeders.

This problem also concerns the goals of the so-called ‘Green Deal’ and the ‘Farm to Fork Strategy’ of the EU. These projects aim to make agricultural systems more resilient, adapt to climate change and reduce pesticide use and also want to promote access to innovation in plant breeding. However, by expanding patent protection beyond technical inventions to conventional breeding, plant breeding risks to be negatively affected in its crucial role as bringing innovation to farmers and consumers.

4. Impact on public debate and political decision making

In timely coincidence with the first patent applications on CRISPR/Cas technology for genetic engineering of plants and animals, companies and research institutions became increasingly active in publicly demanding the deregulation of most organisms derived from New GE.

Their pattern of arguments is aiming to blur the fundamental differences between breeding and genetic engineering with the purpose to

- avoid labeling to leave farmers, food producers and consumers without choice
- avoid mandatory risk assessment to accelerate marketing.

By using the terminology ‘New Breeding Techniques’ (NBTs), interested stakeholders tried to frame New GE as a simple variation of conventional breeding. To coordinate the efforts to deregulate New GE, in 2012, a new network was created called ‘New Breeding Techniques Platform’ in which companies and academic institutions joined forces with the objection to exempt all New GE organisms, or as many techniques as possible, from GM legislation. The activities of the platform were exposed by Corporate Europe Observatory (CEO, 2016). In the meantime, the platform’ activities were discontinued, but only to be pursued under the umbrella of EU SAGE (European Sustainable Agriculture Through Genome Editing)[33] (for further information also see CEO, 2021).

It is not only the biotech industry who attempts to disguise New GE as just a new method of traditional breeding. Rather, reports from acknowledged academic institutions such as Leopoldina and ALLEA also try to raise the impression that for example CRISR/Cas applications are of the same ‘nature’ as the processes used in conventional plant breeding.

33 https://www.eu-sage.eu/

A 2020 report by ALLEA (All European Academies) as well as a 2019 report by Leopoldina are the prominent examples for relevant publications which try to give the impression that the genotypes derived from New GE (genome editing) would be of the same quality as those changes in the genome which occur ‘at random’ (Testbiotech 2020). In 2021, the incorrect findings of Leopoldina were exposed by a report by the European Network of Scientists for Social and Environmental Responsibility (ENSSER).

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

The report of ALLEA (2020) 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*”.[34] Research partners of VIB are Cellectis (Calyxt), Bayer and BASF. Representatives of Bayer and BASF are also members of the General Assembly of VIB[35], and Bayer is also represented in the Board[36]. 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)[37] and is also involved in several patent applications for VIB, CropDesign and BASF. It also should be mentioned that VIB plays a leading role in the EU SAGE lobbying platform, which again is promoted by the ALLEA report.

Similarly, the report of Leopoldina (2019) was written by experts which are known to be involved in patent applications on 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 activities of EU SAGE which are coordinated by VIB.

34 See https://web.archive.org/web/20200128060113/http://www.vib.be/en/business-opportunities/Pages/Pipeline.aspx
35 http://new.vib.be/general-assembly
36 http://new.vib.be/board-directors
37 https://www.basf.com/global/en/media/news-releases/2021/01/p-21-100.html

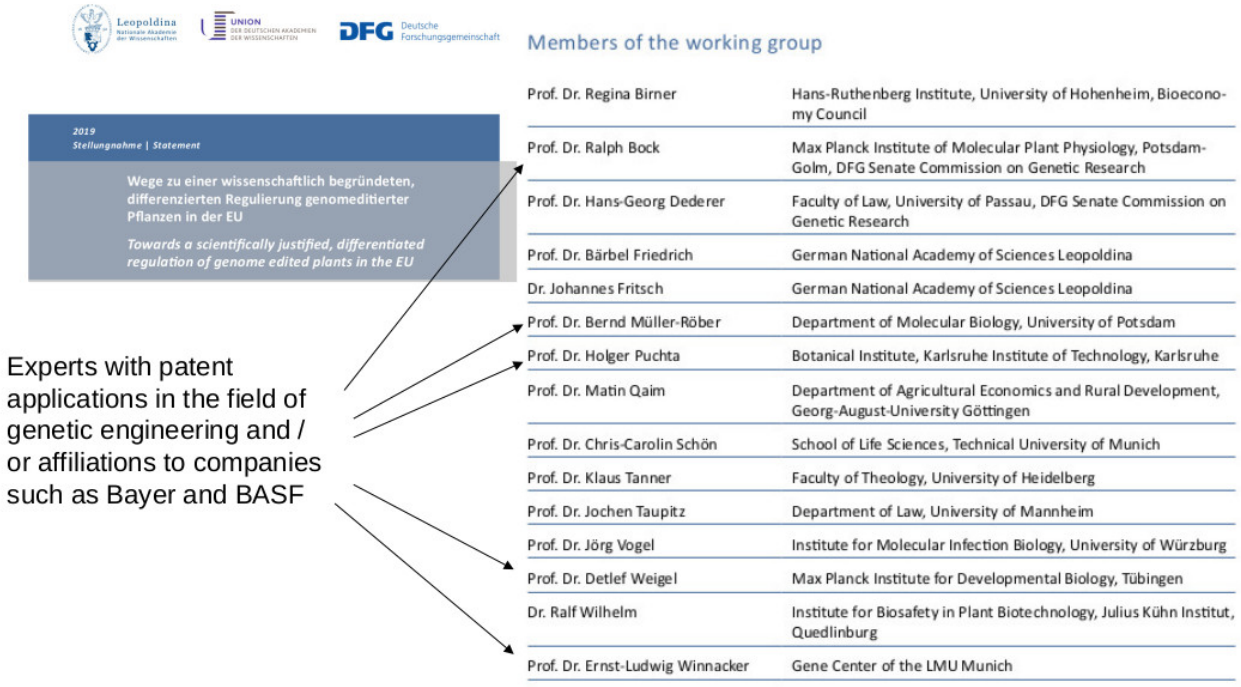


Figure 6: The list of experts named in the report of Leopoldina (2019), highlighting those which are involved in patent applications in GE plants.

Scientists and experts which are involved in developing New GE products and patent applications are in a delicate situation: For example, EFSA acknowledges that patents have an impact on independence and conflict of interests (COI) of experts.[38] Therefore, their expertise has to be considered with caution. In many cases, experts involved in patent applications (very often as inventors) also closely cooperate with companies (very often the patent holders). Also the political decision makers in the EU have to get aware of problems that go along with strong bias in academic expertise. However, so far, this seems not 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 looks like positions as promoted by Leopoldina (2019) and ALLEA (2020) were embraced by the EU Commission's report. At the same time, a large bunch of scientific findings showing generic risks associated with the processes of New GE if applied on plants, are not mentioned in the report (see Testbiotech 2021a, FGU 2021). In consequence, the EU Commission might propose to change EU legislation to deregulate many New GE applications on plants.

The influence of biased expertise is getting especially evident by the specific terminology uses in the EU Commission report: The terminology as used seems to suggest that transgenic plants, derived from 'Old GE' could be deregulated as being equivalent to conventional breeding. For the first time, in a regulatory context, the expression 'conventional GMO' was adopted and defined by EU Commission as being 'transgenic'. The history of this expression shows that the report of Leopoldina (2019) was decisive for the coining of this terminology (see Testbiotech 2021b). This terminology was embraced by the EU Commission without reference, explanation or justification and may cause severe legal problems in the near future.

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

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's report.

The corona pandemia shows which detrimental effects it can have for overall society and democracy if risks are neglected and not correctly assessed. In the case of the pandemia and also in regard to climate change, science plays a crucial role to inform the political decision making and public debate. It is worrying that in the field of New GE, even highly acknowledged scientific institutions are not able to protect themselves from being hijacked 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 published by ALLEA (2020) and Leopoldina (2019) are suited to damage the credibility, reliability and general role of science. Similarly to the way how tobacco industry previously exerted undue influence on political decision making (see for example Bero, 2005), there is a problem of science being taken hostage by industry in the context of New GE which was also evidenced by a report of CEO in 2021. Therefore, the impact of industry and vested interests on the current debate within the EU, should be investigated carefully before taking any further potential steps in regard to GMO regulation are taken.

In addition, 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, environment and nature). This risk assessment should be completely independent of any interests in developing new GE technologies, or specific applications, or marketing of the resulting products.

5. Conclusions & recommendations

This report shows increasing number of patents being filed and granted on applications of New GE (use of site directed nucleases) on plants. The patent landscape is dominated by 'the Corteva group' which, beyond their own patents, controls access to the most relevant patents needed by breeders which want to use the technology. In this context, Corteva established a patent pool which, in 2018, already encompassed around 50 patents.

Further, there is evidence that companies are filing patents which are extremely broad in the scope of their claims and thereby extent to plant and breeding characteristics in the area of conventional breeding. Many patents as filed are intentionally blurring the differences between conventional breeding and genetic engineering with the intention to expand patent monopolies claimed on the technology of genetic engineering to the non-technical area of plant breeding.

The same strategy is observed in the political discussions around EU GMO regulation: There are attempts of the same stakeholders as being in involved in the filing of patents which try to diffuse the biological and legal differences between genetic engineering and conventional breeding by new terminology such as 'conventional GMO'.

In conclusion, due to the monopolistic claims that go along with the introduction of a New GE in plant biotechnology, disruptive processes in plant breeding, agriculture and food production are highly likely consequence. The interest in the proprietary technology is also impacting political decision making and trust in science. Thereby, the precautionary principle is put at risk and the pressure on ecosystems is increased which may, within a short period of time, become burdened

with an increasing number of organisms which are were not subjected to evolutionary processes and mechanisms. This development also may impact food security as well as food safety.

Recommendations:

1. The EU should no longer allow patents with absolute product protection to be granted in field of plant and animal biotechnology. Instead the patents should strictly be limited to the technical processes.

2. The EU should start investigations on potential rise of ‘hidden cartels’ which are based on the control of access to patented technology in the area of New GE.

3. The EU should harness its political decision making processes to fully integrate the perspective of the protection goals (health environment and nature). In parallel, the EU should avoid undue influence by companies and experts with interest in profits which could be derived from patent-protected New GE-technology or by marketing of patented seeds and animals derived there off.

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