

New GE patents 2022: ‘Second-hand GE’ plants claimed as inventions

How CRISPR/Cas & Co are used to create new seed monopolies

Table of Contents

Summary.....	1
1. Introduction.....	3
2. Overview: Patents on New GE plants in 2021 and 2022.....	3
2.1 Methodology.....	3
2.2 Findings.....	4
2.3 Further analysis.....	5
3. Case study: The US company Inari.....	6
3.1 Who is behind Inari?.....	6
3.2 Which products is Inari working on?.....	8
3.3 Which patent applications has Inari filed?.....	8
3.4 What is the strategy behind these patents?.....	9
3.5 Is the Inari approach likely to benefit agriculture?.....	9
3.6 The effects of ‘second hand’ GE patents.....	10
4. A broader view of New GE patents and plant breeding.....	11
5. Conclusions.....	12
References.....	13

Summary

This report shows that an increasing number of patents are being filed for New GE (New Genetic Engineering or new genomic techniques, NGT) and plant breeding. This review updates previous research and is focused on patent applications with relevance to Europe.

Corteva (previously DowDuPont) and Bayer (together with Monsanto) own the overall highest number of patents granted for New GE and have also filed the highest number of patent applications: Corteva had filed nearly 100 patent applications and Bayer more than 60 by the end of 2022. At that time, the European Patent Office had already granted around 30 of these patents to Corteva. This US company is assumed to have had a predominant market position in the field of New GE and plant breeding for several years.

There were some surprising developments in 2021 and 2022, with two ‘newcomers’ from the US, Pairwise (also cooperating with Monsanto) and Inari. They are among the companies that filed the highest number of patent applications in those two years. The high number of patent applications being filed by Pairwise appear to be the result of a strategy to systematically file several international patents for the same invention.

We took a closer look at the patent applications filed by Inari and found that most of the patents were for ‘second hand’ GE plants: CRISPR/Cas technology was used to target the transgenes that had been inserted using ‘Old GE’, and thus either remove, modify or combine them with new traits. The scope of these patent applications is not confined to the technical processes but extends to all plants obtained from these processes. Even if the transgenes are removed from the plants, or slightly modified, or combined with new traits, resulting plants are claimed as Inari inventions.

It is interesting to see that a patent attorney who previously worked for Syngenta is named as the ‘inventor’ in many of these patents. In fact, the filed patent applications seem to follow a specific strategy to create patents even without inventing something substantially new. Thus, it may be assumed that these patents are not primarily driven by technological progress, but rather by a strategy to misappropriate seeds.

Inari has publicly stated that it wants to challenge the monopolies of the larger companies. The company, nevertheless, appears to be using the CRISPR/Cas technology to create new monopolies on existing plant material, and thereby also prolonging the usage of transgenic plants obtained from ‘Old GE’. It is surprising that even scientists such as Jennifer Doudna and George Church seem to somehow support this approach, as they are members of the Inari Scientific Strategy Board (SSB). It is also worth noting that many leading positions at Inari are held by experts who previously worked for Syngenta or Bayer. It remains an open question to which extent Inari is cooperating with the companies that originally created the transgenic plants (such as BASF, Bayer, Corteva and Syngenta).

There are other examples of patent applications and also granted patents that may severely impact traditional breeders. Indeed, there are at least ‘two faces’ to the use of tools such as CRISPR/Cas: on the one side, there are the new genomic techniques (NGT) being applied in plants, going along with risks and potential benefits (Testbiotech 2023). But in the context of patents, the technology is firstly often used simply as a ‘technical topping’ to claim patent monopolies on randomly and naturally-occurring genetic variants. In this context, the companies seem to aim to control access to the biological resources needed for future breeding, even if no genetic engineering is applied.

As a result, the effects of patents being granted on New GE plants may impact plant breeding much more extensively than patents previously granted on ‘Old GE’. If this development is not stopped, all kinds of plant breeding may be severely restricted; it will turn plant genomes into a ‘minefield’ of patent monopolies.

Since this development is likely to run counter to the goals of the EU in regard to sustainable agriculture goals, a technology assessment should be performed to identify potential negative impacts and make sure that at least traditional, non-targeted conventional processes in plant breeding are not affected.

Technology assessment will also be necessary to distinguish between real solutions to problems and applications of proprietary technologies that are primarily driven by expectations of making a profit.

In light of the commercial interests behind New GE, the institutions of the EU are obliged to defend the interests of the broader public and not leave the field to ‘Big Biotech’.

1. Introduction

The biotech industry in the EU is currently following its own particular interests, including campaigning to end the mandatory approval processes as well as traceability and labelling requirements for plants obtained from new genomic techniques (NGT, or new genetic engineering, New GE). Biotech companies are, in addition, filing more and more patent applications for New GE plants, as well as trying to extend the scope of patents to conventionally-bred plants.

If the industry is successful in their strategy, the EU may end up with patents on the seeds of New GE plants and on conventional breeding, but without any mandatory approval processes for the genetically engineered plants. Extending the scope of the patents and deregulating New GE plants would have severe consequences for breeders, farmers, food producers and for consumers’ freedom of choice. Against this backdrop, our research aims to provide specific information on recent patent applications to assist the political decision-makers and the interested public.

2. Overview: Patents on New GE plants in 2021 and 2022

Testbiotech has followed the development of patent applications covering the usage of New GE on food plants for several years (see, for example, Testbiotech, 2021). This current paper aims to provide a focused insight allowing reliable assumptions in regard to current trends and actors. It does not include a comprehensive overview of all patents filed in this field.

2.1 Methodology

Patents granted in 2021 and 2022 have been added to this backgrounder to update some of the information contained in previous reports, it also includes patent applications filed in both years. While globally thousands of patent applications may have already been filed in this context, Testbiotech has specifically reviewed PCT¹ applications filed via the World Intellectual Property Organization (WIPO). This allows the avoidance of duplications in the numbers of regional applications that may be for the same ‘inventions’ and of patents that are not relevant to Europe - thus making the numbers of patents being filed by different actors more comparable.

For the interpretation of the findings, it has to be taken into account that New GE technologies can be combined with other approaches such as ‘Old GE’, so that it is not possible in all cases to make distinctions between New GE patent applications and other fields of plant-related inventions, or even conventional breeding processes.

The data we selected is focused on companies that filed the most patent applications in this sector. We did not consider patent applications filed by universities, even though these are known to have already filed hundreds of patent applications, especially in relation to CRISPR/Cas technology, with

¹ PCT (Patent Cooperation Treaty): International patent law treaty, concluded in 1970. It provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. A patent application filed under the PCT is called an international application, or PCT application.

major patent battles still ongoing, e. g. between University of California and MIT (see, for example, Testbiotech, 2021).

In addition, several Chinese institutions continue to file large numbers of patent applications. However, Testbiotech is not able to analyse these patents in detail as they often are published in Chinese language. Testbiotech is also not in a position to judge whether these patents from various institutions should be counted as just one ‘Chinese block’ or not. Chinese state authorities might be considered to be relevant cooperation partners for institutions such as Chinese universities. However, much more research would have been necessary to review all these cooperations and these questions were, therefore, set aside. Similarly, we also did not try to analyse cooperations between US universities and companies (for more information see, for example, Jefferson, et al., 2021; Testbiotech 2021).

2.2 Findings

As in previous years, companies such as Corteva, Bayer, BASF and Syngenta, were particularly active in this field. In comparison to other years (Testbiotech 2021), Calyxt and Keygene, seem to have undergone some changes and were, therefore, not thought to be significant for this report.

There are also some new players in the field that are specialised in New GE, such as Pairwise and Inari. These two companies filed a surprisingly high number of patent applications in 2021 and 2022. In the case of Pairwise, it appears that several PCT applications are for broadly the same inventions; therefore, these numbers need to be approached with caution. In the case of Inari, many patent applications are for ‘second-hand GE’ plants, which are discussed in more detail in a case study (Section 3).

In regard to patent applications published in 2021 and 2022, Pairwise (with several of its ‘inventions’ being covered by more than one patent) filed 30 patent applications followed by Corteva with around 25 applications and Inari with 21 applications (see Figure 1).

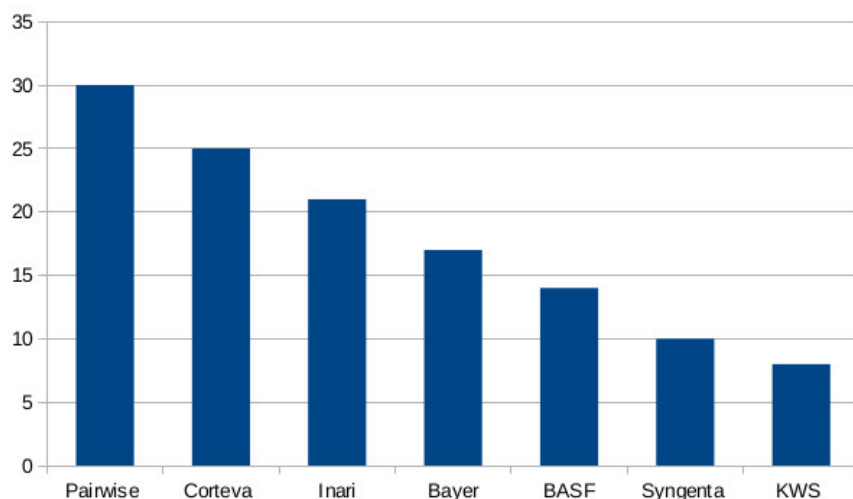


Figure 1: Number of filed international patent applications (WIPO/WO) covering usage of nucleases (especially CRISPR/Cas) in the food plant sector, published in 2021 and 2022.

Our research shows that Corteva and Bayer are still the overall leaders in the race to file patent applications for New GE (see Figure 2). By the end of 2022, Corteva (previously DowDuPont) had filed nearly 100 international patent applications relevant to Europe, covering the usage of New GE in plants, mostly under the name of Pioneer. At that time, the European Patent Office had already granted Corteva around 30 of these patents. The company is thus assumed to hold a dominant market position (see, for example, Testbiotech, 2021), and is as such making it necessary for European breeders (such as Vilmorin or Bejo Zaden) to sign contracts with their US competitor in order to gain access to the patented technology.²

Bayer (Monsanto) is in second place with more than 60 patent applications, most of them filed by Monsanto. Bayer/Monsanto also has a cooperation with Pairwise³ which has filed a high number of patent applications in recent few years. KWS, BASF, Syngenta as well as the ‘newcomers’ Pairwise and Inari all seem to be on a similar level with ca. 40 and 30 filed patent applications, respectively. We were not aware of any other companies filing similarly high numbers of patent applications.

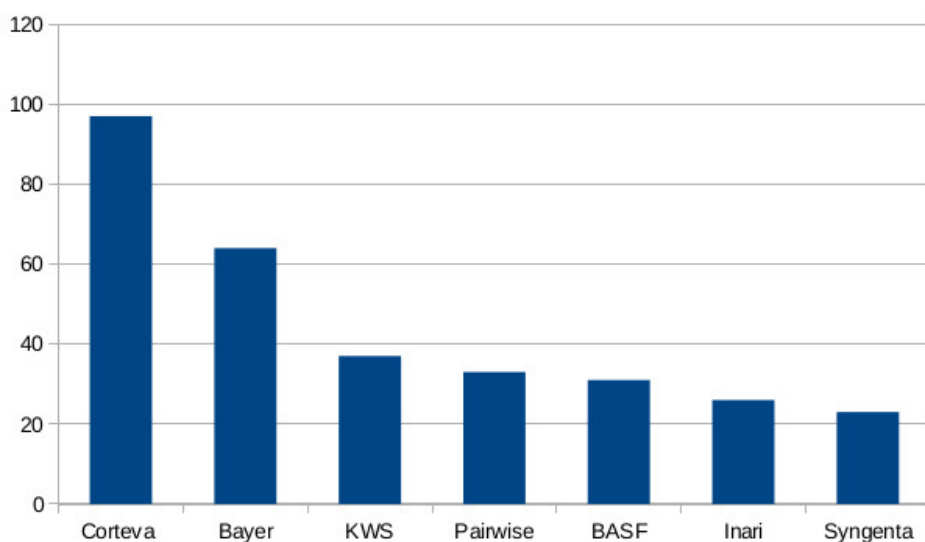


Figure 2: Overall number of filed international patent applications (WIPO/WO) covering the usage of nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) in the food plant sector, up until the end of 2022.

2.3 Further analysis

One specific observation in regard to patent applications filed by Syngenta is that many of applications are for naturally-occurring gene variants in wild relatives of soybeans with major importance for conventional breeding.

For example, Syngenta/ChemChina filed a patent application for soy plants with resistance to Asian soybean rust, WO2022173659. The patent describes how the gene variants were detected in populations of wild relatives of soybeans (*Glycine tomentella*), i. e. by screening for natural resistance. Despite showing that crossing and selection are sufficient to generate new varieties with

² <https://www.euractiv.com/section/agriculture-food/news/corteva-signs-first-major-gene-editing-deal-with-european-company/>, <https://www.corteva.com/resources/media-center/corteva-agriculture-and-bejo-sign-agreement-on-genome-editing.html>

³ <https://www.pairwise.com/news/monsanto-and-pairwise-announce-rd-collaboration-to-accelerate-innovation-in-agriculture-with-gene-editing>

improved resistance to Asian soy rust, the claims cover gene variants and plants inheriting the genes, regardless of whether these are obtained from genetic engineering processes or from conventional breeding. It seems that plants are inheriting any of the listed ca. 45.000 gene variants (SNPs) are claimed as inventions. Furthermore, the patent also covers soybean plant production methods, including selecting plants using the marker genes. CRISPR/Cas is mentioned as a relevant method in the patent application. However, according to the wording of the patent, it is not applied and not necessary to achieve the desired plants (see No Patents on Seeds!, 2023).

Such patent applications were only partially taken into account for this report; in these cases, it appears that NGTs were simply used ‘on top’ to give the impression of a technical invention. However, they are a good example of how CRISPR/Cas technology is being used to misappropriate biological resources needed by all breeders. These patents are, in particular, likely to block or hamper traditional breeding activities in this field (see No Patents on Seeds!, 2023; Testbiotech 2023). We are aware that this problem is also relevant for patents filed by other companies, e. g. KWS and Corteva (Pioneer, DowDuPont).

In regard to the patents that were granted, a KWS patent on maize (EP3560330) provides evidence that the current legal practice at the European Patent Office (EPO) is indeed insufficient to prevent patents from being granted on conventional breeding. The KWS patent claims maize plants, regardless of whether they are derived from random mutations or genetic engineering. In addition, it claims the usage of naturally-occurring gene variations for the screening and selection of plants within the process of conventional plant breeding. As indicated in the patent description, the respective gene variants were originally detected in existing maize plants obtained from conventional breeding. However, with this patent, KWS can now control the future production of plants derived from randomly mutated genes, and prevent other breeders from using the naturally-occurring genes in selection processes in conventional plant breeding (see No Patents on Seeds!, 2023).

3. Case study: The US company Inari

We were surprised that a relatively small, US-startup company, Inari, was leading in terms of the numbers of relevant filed patent applications, with more than 20 PCT applications in 2022. A closer look at Inari revealed that it has a number of well-known scientists such as Jennifer Doudna and George Church on its so-called Scientific Strategy Board (SSB). Furthermore, many experts in leading positions at Inari previously worked for companies such as Syngenta and Bayer.⁴ What also caught our attention were public communications showing that they were attempting to combine New GE and artificial intelligence (AI) (Waltz, 2019). For these reasons, we decided to focus our attention on this company in a case study.

3.1 Who is behind Inari?

The US company, Inari, is based in Cambridge, Mass., with additional sites in Ghent, Belgium. It was founded in 2018, and is funded by the investor Flagship Pioneering that is also represented on the Inari Board.

⁴ www.inari.com

In its public communications (see, for example, Waltz, 2019), the combination of artificial intelligence and CRISPR/Cas technology is highlighted as a core competence. It was, for instance, reported that Inari was able to increase the size of tomatoes by more than 140 percent just by interfering with the gene regulation of the plants.⁵ However, there are no indications that these tomatoes underwent further development for placement on the market.

Inari is trying to create the impression of a small company challenging the big corporates by using the most recent technologies. According to Waltz (2019), the CEO of Inari, Ponsi Trivisvavet, is quoted as saying: “All the genetics [for those crops] are owned by just a couple of multinational companies and we want to challenge that.” However, the Inari⁶ website shows that most of the key positions are held by experts who previously worked for ‘seed giants’ such as Syngenta and Bayer (see Tables).

Tables: Key positions at Inari (source: inari.com)

INARI: TEAM

NAME	POSITION	FORMER/OTHER AFFILIATIONS (INARI website)
Ponsi Trivisvavet	CEO & Director	President of Syngenta Seeds North America
Pierre-Etienne Boin	Chief Legal Officer	Syngenta, General Counsel for Seeds and Biotechnology globally
Dr. Catherine Feuillet	Chief Scientific Officer	Bayer CropScience, head of trait research
Claudia Nari	Chief Product Officer	Bayer Crop Science, Head of Regulatory Science Strategy and Operations
Dr. Michael Kock	SVP, Innovation Catalyst	Syngenta, head of intellectual property

INARI: BOARD

NAME	POSITION	FORMER/OTHER AFFILIATIONS (INARI website)
Mike Mack	Executive chair	Syngenta, CEO, executive director of the board from 2008 to 2015
Robert Berendes	Director	Flagship Pioneering Syngenta, global head of business development, member executive committee
Howard W. Buffett	Director	Executive director of the Howard G. Buffett Foundation
Ignacio Martinez	Co-Founder and director	Flagship Pioneering Managing director of Syngenta Ventures

INARI: SCIENTIFIC STRATEGY BOARD (SSB)

NAME	POSITION	FORMER/OTHER AFFILIATIONS (INARI website)
George Church	Scientific Co-Founder	Harvard University
Jennifer Doudna	Nobel Prize Winner 2020	University of California
Dirk Inze	Plant molecular genetics	Flemish Institute of Biotechnology (VIB)

⁵ <https://www.farmprogress.com/corn/inari-brings-8-corn-hybrids-to-market>

⁶ www.inari.com

It is interesting to see that Inari also has established a Scientific Strategy Board (SSB) with very well-known researchers, e. g. George Church (who is named as one of the co-founders of Inari) and Jennifer Doudna (one of the inventors of CRISPR/Cas). There are also some European experts, such as Dirk Inze from the Flemish Institute for Biotechnology (VIB), who in the past also filed patents with CropDesign/BASF.

3.2 Which products is Inari working on?

Inari is primarily working on maize, soybeans, wheat, tomatoes and others. In 2019, it was announced that the company will bring eight corn hybrids to the market.⁷ In 2022, after two US patents were granted, Inari announced that soy and maize hybrids would be brought to market within the next three to four growing seasons.⁸

According to Inari, New GE will be used to introduce further genetic changes to varieties already cultivated in the US that inherit transgenic elements, such as herbicide resistance and insect toxicity.⁹

Inari has also filed an application to carry out field trials in 2023 in Europe (Belgium), using maize derived from New GE that is shorter than normal due to altered gene expression (B/BE/23/V1).¹⁰

3.3 Which patent applications has Inari filed?

Inari has filed more than 100 patent applications for plants manipulated using New GE. At least 26 of them may be relevant to Europe (up until the end of May 2023) since they were filed via the PCT treaty and the World Intellectual Property Organization (WIPO). 18 of these applications were published in 2022. Some of them are already being examined at the European Patent Office (EPO).

At least 16 out of the 26 PCT applications are for existing transgenic plants and traits held by other companies, such as Bayer/Monsanto, Corteva (previously DowDuPont), BASF and Chemchina/Syngenta. For example, patent application WO2022026379 claims the application of New GE on the following events: Bt11, DAS-59122-7, DP-4114, GA21, MON810, MON87411, MON87427, MON88017, MON89034, MIR162, MTR604, NK603, SYN-E3272-5, 5307, DAS-40278, DP-32138, DP-33121, HCEM485, LY038, MON863, MON87403, MON87403, MON87419, MON87460, MZHGOJG, MZIR098, VCO-01981-5, 98140, TC1507, A5547-127, DAS44406-6, DAS68416-4, DAS81419-2, GTS 40-3-2, MON87701, MON87708, MON89788, MST-FG072-3, SYHT0H2, DAS-21023-5, DAS-24236-5, COT102, LLCotton25, MON15985, MON88701, MON88913, GT73, HCN28, MON88302 and MS8.

According to the text of these patent applications as well as according public communications¹¹, New GE is applied to genetically engineer these events to either improve, modify or delete the transgenes and, as required, add further traits to the plants. One approach to achieving access to high yielding plant material for further breeding is to simply remove the transgenes from the plants

⁷ <https://www.farmprogress.com/corn/inari-brings-8-corn-hybrids-to-market>

⁸ <https://www.forbes.com/sites/annhinch/2022/02/22/patents-aim-to-boost-corn-and-soy-performance-by-editing-gmo-traits/>

⁹ <https://www.prnewswire.com/news-releases/inari-to-bring-growers-proprietary-gm-traits-in-tandem-with-novel-gene-edits-301478065.html>

¹⁰ <https://www.biosafety.be/content/bbe23v1>

¹¹ <https://www.prnewswire.com/news-releases/inari-to-bring-growers-proprietary-gm-traits-in-tandem-with-novel-gene-edits-301478065.html>

by using New GE and excising the DNA constructs. For example, patents WO2022026379 (EP4172344) and WO2022026390 (EP4172341) both claim plants derived from transgenic plants from which the patented gene constructs were removed.

3.4 What is the strategy behind these patents?

The concept of Inari seems to make use of varieties that are already on the market and considered to be so-called elite varieties. These varieties are meant to represent the highest degree in market performance, such as that achieved with conventional breeding methods. Access to these varieties cultivated in the US, is blocked by patents on the transgenes that make them resistant to herbicides and toxic to insects. It means that other breeders cannot use the plants to produce new varieties as long as the patent protection is still valid for the inserted transgenes and for the plants or seeds inheriting them.

Apparently, Inari is primarily using transgenic plants for which patent protection has expired (after 20 years). Indeed, the first patents granted to Inari in 2022 in the US on INIR6 (see application WO2022026954 / PCT/US2021/044198) and INHT31 (see application WO2022026563 / PCT/US2021/043479) are for transgenic events developed by Corteva (previously Pioneer/DowDuPont) known as maize event DP4114 (insect toxicity) and a Monsanto (Bayer) soybean event MON89788 (resistance to glyphosate). These events were originally developed more than 20 years ago and have since then been introduced into many plant varieties in the US. Inari claims that it will, within a short period of time, produce new varieties from these existing varieties with and without the original transgene, and thus save around 2 years of development.¹²

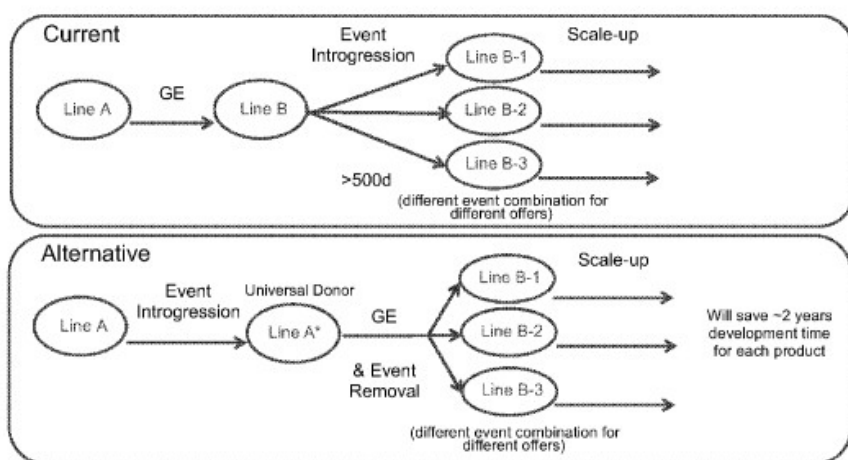


Figure 3: Graphics from patent application WO2022026379

3.5 Is the Inari approach likely to benefit agriculture?

As shown in Figure 3 (above), Inari has several ways in which it can proceed: if the transgenes are not removed, but modified or combined with other traits, this would prolong patent protection for herbicide resistant and insecticidal plants. As Inari says “We are proud to be the first company

¹² <https://www.prnewswire.com/news-releases/inari-to-bring-growers-proprietary-gm-traits-in-tandem-with-novel-gene-edits-301478065.html>

granted patents for gene editing GM traits.”¹³ Other companies, such as Bayer, Corteva, BASF and ChemChina, may follow the same New GE strategy to increase their own profits. It remains an open question to which extent Inari is also cooperating with the companies that originally created the transgenic plants. It seems that New GE may contribute not only to continuing patent protection, but also to agricultural practices that have already caused an increase in pesticide use in many regions. Numerous observers would regard such a development as unsustainable and not beneficial to agriculture (see Testbiotech, 2023).

Furthermore, the use of ‘second hand GE’ plants may cause an accumulation of risks in the breeding populations due to unintended genetic changes or interactions of genetic alterations. It is well known that ‘Old GE’ as well as ‘New GE’ can cause unintended genetic changes that are unlikely to occur with processes used in conventional breeding, and that these may remain undetected (for overview see, Koller et al., 2023). These alterations may accumulate either by further crossings or repeated GE applications, thus also increasing the risks to health and the environment.

It also remains doubtful whether the Inari approach will be faster than conventional breeding processes. However, this also presumes that the Inari approach will not have any negative ‘trade-offs’. As seen in many cases, this cannot be generally expected, as the application of NGTs in plants is likely to lead to trade-off effects (Testbiotech 2023).

3.6 The effects of ‘second hand’ GE patents

There are several known ways of using CRISPR/Cas to delete smaller or larger parts of a plant genome. It seems that Inari was able to develop variants of the gene-scissors to target the transgenes inserted via Old GE. Under some circumstances, these new variants of the gene-scissors may be considered to be technical inventions.

However, the scope of the patents is not confined to the technical processes but extends to all plants obtained from these processes. This includes plants which still inherit the old traits, but which are also slightly modified, as well as plants with additional traits inserted into their genome. Furthermore, even if the transgenes are removed from the plant genome and no new trait is inserted, the claims still cover the resulting plants as inventions, e. g. in WO2022026375, WO2022026379 (EP4172344) and WO2022026390 (EP4172341). These patents could be seen as an ‘invention of non-GE plants’ and have the capacity to substantially disrupt the interests of conventional plant breeders.

It is interesting to see that a patent attorney who previously worked for Syngenta (Michael Kock) is named as ‘inventor’ on many of these patents. In fact, the filed patent applications seem to follow a specific strategy to create patents even without inventing something substantially new. Thus, it may be assumed that these patents are not primarily driven by technological progress, but by a strategy that uses the patent system to create new monopolies covering existing biological material.

Indeed, these patents could be used to control and block access to biological resources which might otherwise be freely used by other breeders after patent protection has expired: if the excision or modification of the gene construct is regarded as an invention, the resulting plant material (including without the transgenes) can be covered by a new patent. This means that, even if no new

¹³ <https://www.prnewswire.com/news-releases/inari-to-bring-growers-proprietary-gm-traits-in-tandem-with-novel-gene-edits-301478065.html>

characteristics are being introduced, the resulting plants can no longer be accessed without the consent of the patent holder. As a result, granting these patents would in all likelihood undermine the breeder's exemption and hamper further breeding.

Consequently, a company that was ostensibly started to challenge the monopolies of the bigger companies and to develop traits with the help of New GE and Artificial Intelligence, appears (at least at this stage) to be primarily interested in introducing new monopolies on plant material and prolonging the usage of 'Old GE'. Any such patents on New GE plants may, in fact, have a much broader impact on plant breeding than the patents granted on 'Old GE'. It is worrying that scientists, such as Jennifer Doudna and George Church, seem to support this approach by holding positions on the Inari Scientific Strategy Board (SSB).

4. A broader view of New GE patents and plant breeding

There is increasing concern about the ever greater numbers of patent applications being filed and granted in Europe on New GE, especially in regard to ways in which this may impact breeders, farmers, food production and agrobiodiversity.

Many of these patents claim naturally- or randomly occurring gene variants as used in traditional breeding. This includes the plants inheriting the gene variants, regardless of whether they are derived from techniques of genetic engineering or not. In this context, New GE is often used to simply 'dress up' the patent claims as technical inventions, while in reality no such technical processes are necessary to obtain plants with the desired traits (see No Patents on Seeds!, 2023).

These developments will increase costs, legal uncertainties and also create new dependencies, especially for traditional breeders. Restricted access to biological diversity endangers the ability to develop climate resilient crops. Furthermore, it is damaging to the viability of Europe's plant breeding industry, which is largely made up of small and medium sized companies. These patents hinder or block innovation especially in regard to traditional breeders: as yet, the breeders' exemption in the plant variety protection system (PVP) in Europe still guarantees that plant varieties obtained from conventional breeding can be used for the production of new varieties without restriction.¹⁴ This freedom to operate (to use conventionally-bred varieties for further breeding) could end. Consequently, these patents pose a serious threats to farmers, breeders, food security and agrobiodiversity.

The biotech industry is trying to dispel the concerns about the patents by proposing their own 'solutions'. For example, the seed industry has introduced licensing platforms, such as the Agricultural Crop Licensing Platform (ACLP).¹⁵ Clearly, such private initiatives cannot be a substitute for the rights of breeders to use the naturally existing and randomly occurring biological material for further breeding. The PVP law gives all breeders the freedom to operate using conventionally-bred varieties already on the market to breed improved varieties, and sell them independently.¹⁶ However, within patent law and under the ACLP platform, the breeder is not allowed to market new varieties without a license contract, which would put an end to freedom to operate. If no political initiative is taken to protect the legally guaranteed access to biological diversity for European breeders, plant breeding will in future become dependent on private contracts with conditions that may be changed at any time.

¹⁴ Article 14 of UPOV 1991, <https://www.sicasov.com/common/pdf/reglementation/upov1991.pdf>

¹⁵ <https://aclp.eu/>

¹⁶ Article 14 of UPOV 1991, <https://www.sicasov.com/common/pdf/reglementation/upov1991.pdf>

Therefore, together with other EU institutions, the EU Commission should take immediate action to enforce and strengthen current prohibitions in patent law to safeguard the future of traditional plant breeding in Europe.

Political initiatives should:

- reinforce the prohibitions of Article 53 (b), European Patent Convention, in regard to plant and animal varieties and conventional breeding by correcting the interpretation of European patent law;¹⁷
- establish a clear distinction between the technical inventions of genetic engineering and other breeding methods to exclude patents on native traits, randomly occurring gene variants and conventionally bred plants;¹⁸
- restrict the scope of the patents to the specific technical processes;
- introduce full transparency in regard to patents on New GE seeds by labelling seed packages with all relevant patent numbers and the name of patent holders.

5. Conclusions

This report shows that an increasing number of patents are being filed for New GE and plant breeding. It is likely that a large-scale introduction of New GE plants into European agriculture would be associated with increasing dependency on companies such as Corteva and Bayer, which are able to some extent control access to the technology.

In addition, many of these patents may also severely impact traditional breeders. Indeed, there are at least two aspects in regard to tools such as CRISPR/Cas: in the context of patents, the technology is firstly often simply a ‘technical topping’ devised to claim patent monopolies randomly and cover naturally-occurring genetic variants. Secondly, the technology is being used ‘to invent’ GE free plant material. Companies filing such patents are aiming to misappropriate access to biological resources needed for future breeding, regardless of whether New GE is used or not.

As a result, patents on New GE plants may impact plant breeding on a much broader scale than previous patents on ‘Old GE’. This could mean that all kinds of plant breeding would be severely restricted if the genomes of plants become a ‘minefield’ of patent monopolies.

Since this development is likely to run counter to the goals of the EU in regard to sustainable agriculture, a technology assessment should be performed to identify potential negative impacts and make sure that at least traditional, non-targeted conventional processes in plant breeding are not affected.

Technology assessment will also be necessary to distinguish between solutions to real problems and applications of proprietary technologies are primarily driven by expectations of profit. In light of the commercial interests behind New GE, the institutions of the EU are obliged to defend the interests of the broader public and not leave the field to ‘Big Biotech’.

¹⁷ See no Patents on Seeds!, 2023

¹⁸ The national patent law of Austria can be used as a model law, see <https://www.parlament.gv.at/gegenstand/XXVII/ME/229?selectedStage=100>

References

Jefferson, O.A., Lang, S., Williams, K., Koellhofer, D., Ballagh, A., Warren, B., Schellberg, B., Sharma, R., Jefferson, R. (2021) Mapping CRISPR-Cas9 public and commercial innovation using The Lens institutional toolkit. *Transgenic Res* 30: 585-599.

<https://doi.org/10.1007/s11248-021-00237-y>

Koller F., Schulz M., Juhas M., Bauer-Panskus A., Then C. (2023) The need for assessment of risks arising from interactions between NGT organisms from an EU perspective. *Environ Sci Eur*, 35(1):27. <https://doi.org/10.1186/s12302-023-00734-3>

No Patents on Seeds! (2023) The future of plant breeding is under threat in Europe. Current interpretation of patent law is insufficient to stop patents on conventional breeding, <https://www.no-patents-on-seeds.org/en/report2023>

Testbiotech (2021) New GE and food plants: The disruptive impact of patents on breeders, food production and society. <https://www.testbiotech.org/node/2772>

Testbiotech (2023) Genetic engineering in agriculture: between high flying expectations and complex risks. The use of genetic engineering in agriculture requires a comprehensive technology assessment, <https://www.testbiotech.org/node/3044>

Waltz, E. (2019) With CRISPR and machine learning, startups fast-track crops to consume less, produce more, nature biotechnology, *Nat Biotechnol*, 37: 1251-1252, <https://doi.org/10.1038/d41587-019-00027-2>