

Life Under Patent

THE RAISE OF PATENTS
THROUGH NEW GMOS
THREATENS FOOD BIODIVERSITY
AND FARMERS' RIGHTS

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Introduction

The European Commission, with Italy's consent, may deregulate the cultivation and trade of food obtained through new genetic manipulation technologies, known as New Genomic Techniques (NGTs), labelled in Italy as Assisted Evolution Techniques (AETs, in Italian Tecniche di Evoluzione Assistita or TEA).¹

Presented as innovative biotechnologies capable of precisely and selectively modifying the genome of plants and animals, NGTs actually reintroduce risks and illusions that have accompanied first-generation genetically modified organisms (GMOs) over the past thirty years.

The attempt at deregulation aims to exclude NGTs from the scope of the EU Directive 2001/18, thereby avoiding the risk assessment, traceability, and labeling processes that are legally required for GMOs. At the same time, the Italian government is attempting to legalize open-field experimentation, which is currently limited to the United Kingdom, Spain, Sweden, and Belgium.²

Taking this path poses a danger to farmers and peasant seeds, as well as to the environment. Covered by industrial patents, NGTs and their derived products could accelerate the already concerning concentration of the seed market and contaminate uncultivated fields with biotech varieties, leading to a veritable misappropriation of peasant biodiversity and undermining the very survival of organic farming.

The world's largest agrochemical and seed companies, such as Bayer-Monsanto, BASF, Syngenta, and Corteva, have already formed a European cartel to control the supply of NGT processes and products in an oligopoly regime. One of the rhetorical pillars supporting these biotechnologies, namely accessibility for small businesses, appears to be devoid of foundation. The Centro Internazionale Crocevia has examined all the patents issued in the last 20 years on genome editing techniques and can assert that NGTs constitute a profitable business for a few entities, at the expense of agricultural biodiversity and the rights of farmers to conserve, reuse, exchange, and sell their own seeds.

This report tracks the movements of large agribusiness groups and provides numbers and information that cast doubt on the optimism of national and EU institutions regarding the sustainability and benefits of new biotechnologies. Based on our analysis, the liberalization of NGTs will colonize local food networks with proprietary technologies and production strategies based on the standardization of crops and further reduction of agricultural biodiversity. As a result, the quality of the product, food sovereignty, and security will be compromised.

Who Owns the New GMOs

The term “New Genomic Techniques” refers to a set of biotechnologies that have emerged in the past twenty years. Unlike the genetic modification practices of the mid-1990s, these techniques do not introduce genes from another species into the target organism. They can be divided into two branches: cisgenesis and genome editing. Cisgenesis functions similarly to the genetic engineering of the '90s, with the difference that the genes inserted into the host organism come from sexually compatible plants (unlike transgenic organisms, which can receive genes from different kingdoms). In the case of genome editing, on the other hand, genetic sequences are cut without the subsequent insertion of an entire exogenous gene. Sometimes, DNA sequences are inserted. The goal is to

eliminate undesirable traits of the plant or to express desired ones by leveraging the DNA's natural repair mechanisms.

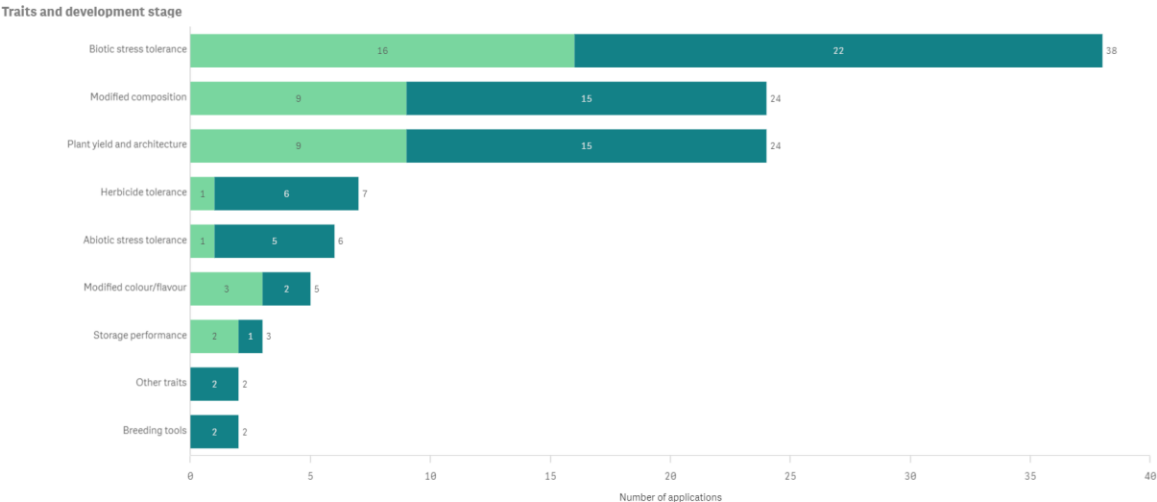
With this “cut and paste” approach, biotechnologists promise to produce more nutritious fruits and develop plants resistant to drought, insects, and pathogenic fungi. All of this would be achieved by simply speeding up a process in the laboratory that they claim is “entirely analogous” to mutations that occur in nature.³

The objective of this report is not to delve into why these claims are at least optimistic, if not misleading, and essentially unscientific.⁴ Instead, we will focus on explaining why NGTs, beyond their hypothetical effectiveness, represent a potential goldmine for a small group of economic entities at the expense of small and medium-scale producers, consumers, and ecosystems.

Currently, NGT experimentation on plants in the EU is minimal compared to the United States and China. Data from the Joint Research Center of the European Commission indicates 90 applications out of 426 globally.⁵ In Italy, there are only 9 applications. The most commonly used biotechnology is CRISPR, accounting for 86% of cases. Biotechnologists primarily work on cereals, oilseeds (such as rapeseed and sunflower), textile crops (such as hemp and cotton), vegetable crops, tubers, and roots. For now, only a small portion of the research is focused on fruits, legumes, and forage.

Despite the promoters' public discourse focusing on the beneficial effects of NGTs in combating climate change, only 6 applications aim to develop drought-resistant plants. The vast majority of research continues to revolve around traits unrelated to sustainability, as efforts are primarily focused on enhancing resistance to insects and other pathogens, modifying the internal composition of plants and fruits, increasing yields, and obtaining herbicide resistance.

FIGURE 1 Application of NGTs by type of genetic traits in the EU and development stage. Light green: advanced research and development stage. Dark green: preliminary stage. Source: European Commission.

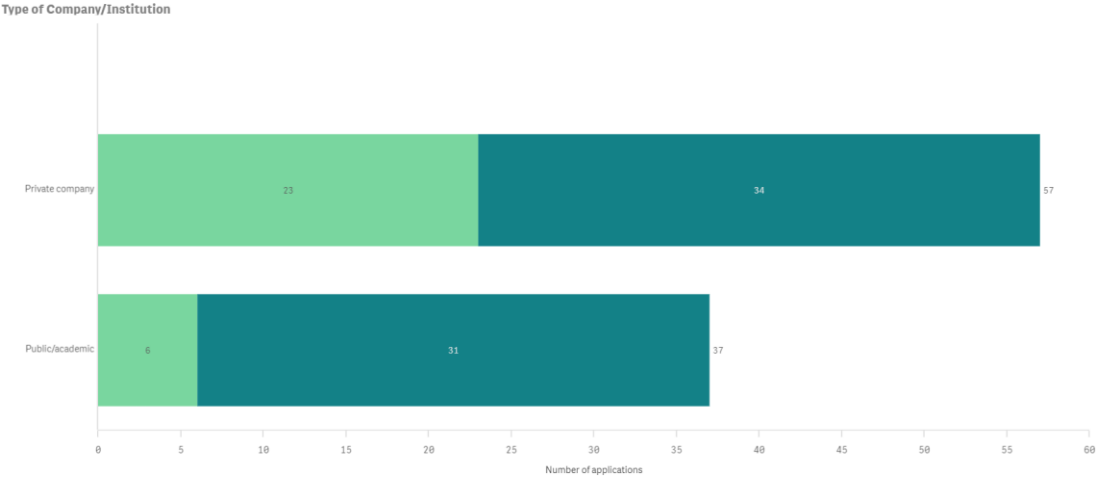


Only a third of the applications have reached an advanced stage of research and development, while the rest are still in the preliminary phase. However, most of the applications closest to commercialization are in the hands of the private sector. The division of labor in the field of research has long relegated the public sector to handle upstream activities in the value chain, while the

industry firmly occupies the final phase. This approach does not arise primarily to serve the general interest but rather to entrust market actors with the direction of innovation.

There are cases where the public sector promotes NGTs. In Italy, the Council for Agricultural Research and Analysis of Agricultural Economics (CREA) as well as other institutes, are doing so. However, the close cooperation with major players in the private sector within the National Agrifood Cluster (CLAN) indicates substantial alignment between the agenda of a part of public research and that of biotechnology and agro-industrial lobbies.⁶ For some time now, companies have tended to influence the direction of basic research in order to appropriate the most promising results and use them in applications that can guarantee short-term profit. In this case, the key is the ability to obtain industrial patents for NGT processes and products, which guarantee exclusive ownership of the "invention" for twenty years. This is not possible for commercial varieties obtained without genetic manipulation, which can, at most, be covered by plant breeders' rights—a form of intellectual property protection that allows third parties access to the genetic material for further research to develop new varieties.

FIGURE 2 Application of NGTs in the EU by type of institution and development stage. Light green: advanced research and development stage. Dark green: preliminary stage. Source: European Commission



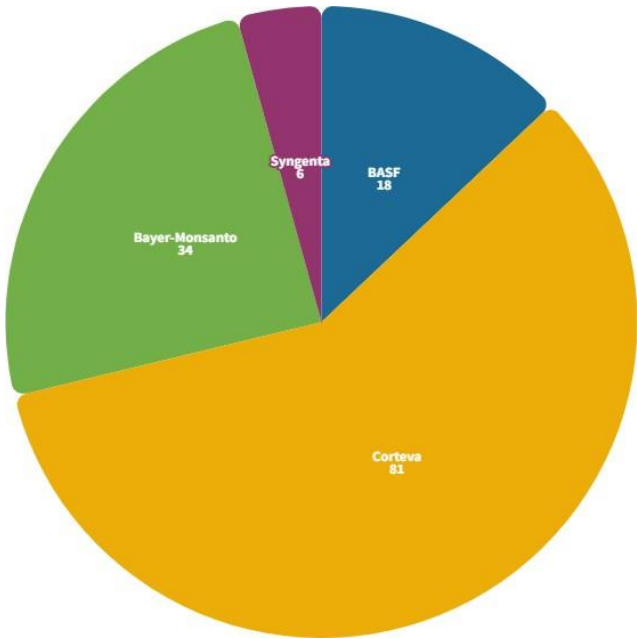
A Business for the Few

This trend is also evident from the examination of patents granted so far on New Genomic Techniques by the European Patent Office (EPO). Analysis conducted by Crocevia on a ad-hoc built dataset (see Appendix A for the methodology) reveals that in the past twenty years, 970 European patents have been filed for new genome manipulation biotechnologies. Of these, 510 are active, and 460 are pending. The majority of applications have been filed in the last 5 years and cover “inventions” by researchers working for internationally connected research centers such as the Broad Institute, Harvard University, and the Massachusetts Institute of Technology (MIT). No patents have been filed by Italian institutions or companies.

Among the major multinational companies in the agribusiness sector (the so-called Big 4), BASF has filed 18 patents with the EPO, Bayer-Monsanto 34, Corteva (which incorporated Dow-DuPont) 81, and Syngenta 6. These agribusiness multinationals have largely delegated basic research to biotechnology

companies and research centers. Then, they just buy the most promising discoveries with the intention of bringing them to commercial application. Therefore, for these big companies, controlling the last mile, from the laboratory to physical seeds, is enough to control the market of new plant varieties derived from NGTs. However, currently, the patents filed mostly cover the process rather than the product. Globally, the only NGT varieties in production are a tomato with higher gamma-aminobutyric acid (GABA) content developed by Sanatech Seed in Japan⁷ and a high oleic soybean variety by Calyxt. There is also a rapeseed variety from Cibus, likely obtained through NGTs. However, following a study promoted by Greenpeace that traced its modifications,⁸ Cibus declared that it did not use new biotechnologies but that the modification occurred accidentally.⁹ Despite the industry's lack of transparency, several countries are relaxing their regulations to allow for the commercial production of new GMOs, particularly for animal feed.¹⁰ In 2023, Canada,¹¹ China,¹² and the United Kingdom¹³ have done so. A European liberalization of NGTs could lead to the release of these genetically modified organisms on the continent's soil and their commercialization without labeling, resulting in unlabeled GMO foods and beverages on our tables, in supermarkets, restaurants, or school cafeterias.

FIGURE 3 European patents filed on NGTs by the top 4 agrochemical multinational companies in the world. Source: Elaboration by Centro Internazionale Crocevia.



Science at the Service of Agribusiness

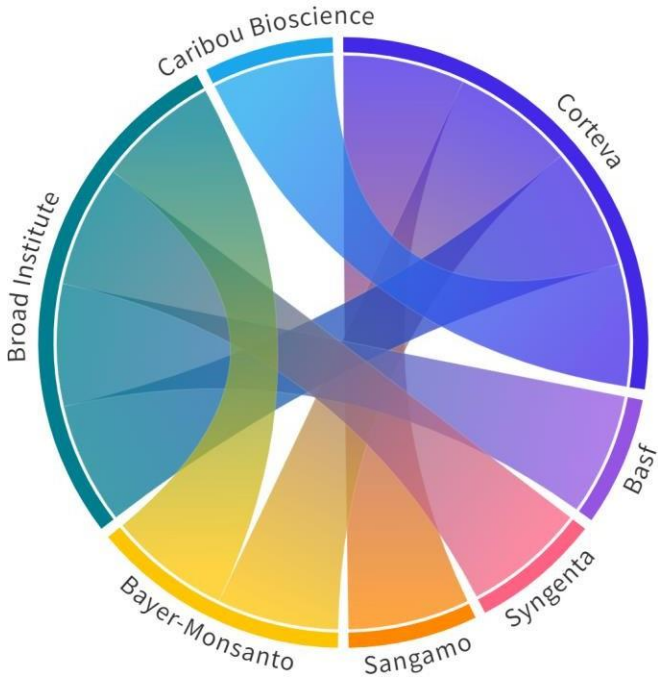
While awaiting this wave of deregulation, large agrochemical and seed companies have entered into agreements with the most active biotechnology companies in the field. This is demonstrated by the licensing contracts between Dow (now Corteva) and the California-based biotechnology company Sangamo in 2005,¹⁴ Monsanto (Bayer) and Dow (Corteva) in 2016,¹⁵ and the Broad Institute (which brings together scientists from Harvard and MIT) and DuPont (Corteva Group).¹⁶ The Broad Institute, which is home to one of the inventors of CRISPR, Feng Zhang, has also entered into agreements with BASF (2017),¹⁷ Monsanto (2016),¹⁸ and Syngenta (2017).¹⁹ Furthermore, Corteva has signed an agreement in 2015 with Caribou Biosciences,²⁰ a start-up founded by the other two inventors of CRISPR, the Nobel Prize laureates in chemistry Jennifer Doudna and Emmanuelle Charpentier.

Essentially, all the big names have signed contracts to utilize the technology developed by these researchers.

In this way, multinationals have secured access to NGTs, which were previously used for basic research, and now intend to use them for applied research. They will soon be ready to sell the results to farmers, thereby strengthening their position as input providers for agriculture.

However, these multimillion-dollar agreements with the agribusiness sector create economic dependence on academia that is underfunded by governments. Consequently, researchers tend to become the biggest supporters of genomic editing, as the continuity of funding from the private sector relies on persuading policymakers.

FIGURE 4 License agreements between major research institutions and the top 4 agrochemical multinational companies globally. Source: Elaboration by Centro Internazionale Crocevia.



Farmers' Rights Under Attack

Unlike the provisions of the plant variety protection system based on plant breeders' rights, patented genetic material is not freely available without the patent holder's authorization and cannot be used, for example, to select new varieties (see Box 1). The growing use of this form of intellectual property protection through NGTs and the new Unitary Patent System (see Box 2) would represent a significant change for the European Union, where the plant breeders' rights mechanism has prevailed thus far. The result could be further consolidation of control over agricultural biodiversity by a few entities. Such a scenario would pave the way for the crystallization of unsustainable agricultural practices, reinforcing the current system that favors industrial and intensive agriculture. The Big 4 already control 62% of the global seed market and 51% of the pesticide market.²¹ Through patents on NGTs, this share could further increase, making farmers increasingly dependent on a handful of companies.

Even the European Commission recognizes this market concentration risk in its 2021 study²² but still subscribes to the rhetoric that patents and other forms of intellectual property promote innovation.

BOX 1

PATENTS AND CPVRs, THE INTELLECTUAL PROPERTY OF BIODIVERSITY

The rules for granting intellectual property rights to breeders have a long history. The first patent was issued in the United States in 1930, after lengthy legal issues, for a climbing rose. Since then, the patenting of living things has spread widely.

The US IPR approach that has set the standard equates a plant, seed or genetic trait with any industrial invention. To get a patent, one must prove that his idea meets the requirements of novelty, originality and the possibility to be developed on industrial scale.

Once obtained, a patent guarantees exclusive ownership of the invention for 20 years.

While this patenting approach has taken hold in the US, a slightly softer one has been adopted in Europe: the Community Plant Variety Right (CPVR), created on the basis of the international UPOV Convention in 1961 (amended in '78 and then in 1991). The granting of CVPRs is administered by the Community Plant Variety Office (CPVO), located in Angers, France. This EU agency examines and grants CVPRs covering all EU member states. The criteria for protection are Distinctness, Uniformity and Stability (DUS).

A variety under CVPR is protected for 25 years, rising to 30 years in the case of vine varieties or tree species. The difference between patent and CVPR is that in the latter case, other plant breeders can access the protected variety for research and development activities. Even small farmers, under certain conditions and for a limited number of species (see EU Regulation No 2100/94), can re-use the seed of protected varieties without paying royalties to the CVPR holder again. In the case of a patent they couldn't do so: they must get consent of the patent holder to buy the patented plant, or get a licence (exclusive or non-exclusive) from him. The patent is therefore even more stringent than the CVPR and guarantees the exclusive monopoly.

The difference is that CVPRs cover new varieties developed by seed companies through cross-breeding and selection methods, while patents are granted for products of biotechnologies. Deregulation of new GMOs would thus open the door to US-style patenting in Europe as well.

One particularly concerning aspect of deregulating NGTs is the impact on biodiversity, with the potential reduction of genetic diversity in agriculture. Many crops rely on wind or insects for pollination. The close proximity of fields is likely to result in the contamination of non-NGT fields with patented genetic material from crops obtained through genomic editing and cisgenesis. The next generation of non-modified plants may then express traits covered by patents. This is a significant problem: in addition to posing a potential risk to food security, biocontamination gives the companies that own the patented germplasm the right to sue farmers who find it in their fields without having purchased it. According to the law, the judiciary can order the destruction of the crop or allow the patent holder to requisition it entirely. Furthermore, Article 125 of the Italian Industrial Property Code²³ allows the judge to determine a sum to be paid as compensation for damages. It is evident, therefore, how NGTs can harm organic and biodynamic agriculture, which prohibit the use of GMOs. After incurring the costs of conversion and product certification, farmers could lose their market advantages. Currently, this market is worth €120 billion worldwide, €45 billion in Europe, and €4 billion in Italy.²⁴ Moreover, biocontamination would make it impossible to achieve the goal of the

Farm to Fork strategy, which is the agricultural pillar of the European Green Deal, wherein at least 25% of EU agricultural land should be under organic cultivation by 2030.²⁵

BOX 2

THE NEW EU UNITARY PATENT SYSTEM AMERICANIZES INTELLECTUAL PROPERTY

Since June 1, 2023, the Unitary Patent System (UPS) has been in effect, resulting from the reform of the existing European patent system. Seventeen countries, including Italy, have joined the unitary European patent. Companies applying for the new unitary patent have an advantage: they no longer need separate approvals from the national patent offices of the 27 member countries. Once their rights are approved by the European Patent Office (EPO), they will be covered in all 17 participating countries under the UPS.

Furthermore, the registration costs will be significantly lower: 5,000 euros compared to the corresponding 20,000 euros to cover the same 17 countries (32,000 euros if they were seeking protection in all 27). Additionally, any appeals can be made to a single European court, bypassing the various national courts that could previously lead to different cases. The only risk is that if a patent is revoked, under the UPS system, it loses its coverage in all 17 countries simultaneously. However, this scenario seems unlikely, as the reform was designed to increase patenting in Europe to compete with the United States, China, and Japan.

Rather than simplifying matters, however, the reform complicates the landscape. In fact, the other two legal pathways to obtain a patent will remain active. It will be virtually possible for a company to apply for the unitary European patent for one invention, choose the "classic" European patent for another, and seek national patent protection in a country with particularly favorable legislation for a third. The expected increase in patent registrations raises concerns about a corresponding rise in lawsuits against farmers for intellectual property infringement.

However, there will be a slight difference with the US-style patent: the new UPS, in fact, provides the possibility for breeders to access the patented material for research purposes. However, unlike the CVPR standard, there are no exceptions for small-scale farmers. Different rules are therefore piling up that will make the issue even more complex, with this new mechanism that it could look like a sort of "UPOV+" system, increasing the power of the private sector over the supply chain and reducing the perimeter of farmers' rights.

With the deregulation of NGTs, even more concerning is the possibility of patenting native characteristics of plants, ie traits that already exist in nature. Currently, the only legal instrument that limits this misappropriation of native or traditionally crossbred plants is European Regulation No. 1829/2003,²⁶ which requires the publication of methods for distinguishing a GMO from any other plant. This explains why other proponents of separate and weaker regulation for NGTs are pushing to modify European legislation: they want to eliminate the obligation to publish this information.

The spread of NGTs can therefore permanently compromise farmers' rights to conserve, exchange, reproduce, and sell their own seeds. These collective rights arise from Article 9 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA),²⁷ which was achieved in 2001 by peasant movements for food sovereignty after years of negotiations within the FAO. Farmers'

rights have also been incorporated into Italian seed legislation, and with the deregulation of new GMOs, they are at risk of being systematically violated.

Beyond Patents: Licensing Platforms

The patenting of living organisms, however, is not well-received in Europe. There is strong resistance from civil society and farmers towards this particularly rigid model of germplasm privatization, which increases costs for cultivators and those intending to use it for selecting new varieties. Therefore, big agrochemical and seed companies are consolidating new management systems for their “inventions”: licensing platforms.

These platforms work similarly to software in the field of computer science. Those who wish to use them enter into a contract with the rights holder, pay a fee, and, upon accepting certain rules, gain access to the program. Something similar is happening in the field of seeds, traits, and genomic editing technologies.

New Strategies, Old Knowledge

In this spirit, the Agricultural Crop Licensing Platform (ACLP)²⁸ was established in March 2023, initiated by the Big 4 companies along with KWS (holding 40 patents on NGTs), Limagrain (holding 3 patents), BNA, HZPC, and Elsoms Ackermann Barley.

Collectively, these companies control at least 180 patents on New Genomic Techniques in the EU, according to Crocevia’s analysis. If deregulation were to occur for products derived from these techniques, anyone wishing to participate in the game would have few alternatives to entering into agreements with the ACLP.

Under this system, third-party access to patented traits and breeding technologies can be defined by platform members based on private law. In practice, a “one-stop shop” has been created, parallel to the public one, for farmers and breeders who will pay a fee to access the varieties and traits owned by platform members. The promise is that this mechanism will lower costs compared to acquiring each individual patent.

Civil society organizations have noted²⁹ that this solution has several side effects: the practice stipulates that license fees must be renewed. Therefore, customers will not only have to purchase licenses once but, depending on the agreement, may have to pay repeatedly to maintain their right to use the germplasm. Additionally, seed-producing companies can also require royalties that customers must pay when selling products containing the licensed germplasm.

The market power of the companies that created the ACLP raises some questions: is a private mechanism about to emerge, parallel to the intellectual property protection systems codified by European law, that is less transparent and potentially even more restrictive?

The Shadows behind the Paywall

Mechanisms like the ACLP could also facilitate the sale of non-patented biological material that companies may choose to include in their offerings to licensees. Behind the paywall, once established, much more than a collection of patents can be placed, including plant varieties and

technologies that may not meet the requirements for patentability. The extreme case would be the sale of germplasm obtained freely from local varieties selected by farmers over the centuries. This would be a true act of biopiracy, based on the appropriation of genetic material that is then resold through licensing agreements.

These agreements can indeed bypass the patent office, which involves the public registration of the invention and the disclosure of various information, often including the genetic sequence for which the patent is sought. All this transparency is not an advantage because it exposes the creators of new GMOs to legal disputes regarding the actual novelty or usefulness of their inventions. It might be more convenient to base everything on licenses protected by trade secrets and distributed through large platforms like the ACLP. If licensing agreements were to begin to supplant traditional patenting, much less information would be available about the GMOs circulating in the market.

In addition to the wave of patents that the new biotechnologies have already raised, therefore, we must take into account the emergence of this new phenomenon. Alongside platforms like the ACLP, various forms of agreements between seed companies and farmers are gaining ground. One example is the establishment of club varieties and buy-back contracts, mechanisms that supplement the more traditional industrial patent but are more free from public control.

BOX 3

CLUB VARIETIES AND BUY-BACK CONTRACTS: PRIVATIZING A SUPPLY CHAIN

Variety clubs are agreements between private parties through which the developers of a variety can “lease” it to others. The variety is licensed to selected farmers who grow the plants according to the seed company’s provisions. The cultivator must pay licensing fees to obtain the variety “under management,” usually in the form of royalties based on trees, agricultural land area, or the weight of the marketable produce. Often, the fruits of club variety are sold with a registered trademark, and the accompanying marketing efforts often contribute to their commercial success. By joining a club, therefore, economic benefits are obtained in exchange for freedom and rights. Moreover, by definition, the club functions when it consists of a minority capable of outperforming the competition without a recognizable brand.

Buy-back contracts are agreements between a seed company and farmers in which the company provides the varieties to be cultivated and subsequently acquires the entire harvest, taking charge of the direct marketing. While this approach partially addresses the main problem farmers face every year, namely the sale of their products, it also increases the power of the contractor and promotes product standardization and the industrialization of cultivation methods. In the medium term, this leads to increased risks of failure due to the impacts of climate change and the spread of pathogens, which propagate more rapidly where genetic diversity is reduced.

Conclusion

This analysis highlights the dangers to biodiversity and farmers' rights that would result from the deregulation of new GMOs. It is clear that NGTs primarily increase corporate concentration in the seed and agrochemical industries and intensify the monopoly of intellectual property. On the contrary, it is not at all clear how they serve the public interest and address the sustainability challenges of agriculture.

The discussion goes beyond technology and closely concerns the type of society and agriculture we want to create in the European Union and Italy. The vision outlined by the proponents of deregulation is one in which the precautionary principle is abolished, market power is further concentrated, and farmers become producers of a food that belongs to others. The only sovereignty they have left is over the risks, both climatic and economic, that no one will share with them.

The Italian government and the European Commission cannot deny the contradictions between the liberalisation of the new patented GMOs and the development of organic farming, while they seem to be disinterested in agroecology and food sovereignty, which has been repeatedly flaunted in recent times.

According to Crocevia, immediate measures need to be taken to contain the problem while there is still time. At the Italian level, this means blocking the deregulation of field experimentation, while at the European level, it means withdrawing the proposal to deregulate NGTs and continuing to regulate them under the EU Directive 2001/18, as established by the ruling of the Court of Justice of the European Union in 2018.³⁰ This way, products of genomic editing and cisgenesis would remain subject to a risk assessment process, traceability, and labeling. Additionally, the ability of member states to prohibit their cultivation and commercialization on their territory (opt-out option which Italy is still exercising for transgenic GMOs) would be preserved.

Solutions to make agriculture more resilient to the impacts of the climate crisis must be sought elsewhere. Multiple genes are involved in drought resistance,³¹ through interactions that can only be discovered through the patient work of crossing and selection carried out by farmers and for farmers. The ability of farmers to dynamically evolve biodiversity through sustainable conservation, reproduction, and exchange of seeds has ensured genetic diversity that has made it possible to cultivate even in extreme climates. A single genome modification in the laboratory is unlikely to yield similar results, especially considering that the effectiveness is still to be verified.

It is therefore a priority to abandon false solutions and support the development of farmer seed systems through supportive policies. In this regard, public research should be adequately funded and oriented towards the public interest, working together with small-scale producers to support the transition to agroecological food systems. Placing the benefit of the community ahead of private profit should be the primary mission of institutions, with the ultimate goal of countering the patenting of life and any form of intellectual property protection that limits farmers' rights to conserve, reuse, exchange, and sell their own seeds, as enshrined in international law. These recommendations indicate a challenging but necessary path to move in the right direction.

Annex A- Methodology

For the patent research, we utilized the publicly accessible database The Lens, a project curated by the social enterprise Cambia. The search query adopted was as follows:

- "plant genome editing"~5 OR "plant gene editing"~5 OR "plant genome modification"~5 OR (plant AND ("genome editing"~5 OR "genome modification" OR "gene editing"))

The search was limited to European Union (EU) patents and focused on the last twenty years, specifically between January 1, 2003, and April 30, 2023.

The research yielded 1,884 patent applications belonging to 1,271 families (a family being a group of patent documents derived from the same initial document, known as the priority document). Among these, 885 patents were found to be active, 698 were pending, and 301 were classified as either interrupted (236), inactive (42), expired (22), or with unknown status (1).

To view the results online, you can follow the link: <https://link.lens.org/zC59AuZid0e>

A qualitative analysis was conducted on this dataset with the intention of distinguishing patents related to inventions in the medical or industrial fields from those specifically related to agriculture and the food sector. This analysis is not a simple task, as biotechnology companies and researchers working primarily in the medical or pharmaceutical fields often patent genome editing techniques encompassing various possible applications, including plant biotechnology. In doing so, they aim to maximize the potential of their “inventions.”

Nevertheless, this examination allowed for a good approximation in eliminating false positives and isolating 510 active patents and 460 pending patents related, in full or in part, to agriculture and the food sector. Over 90% of these patents were granted in the last five years. The majority of these patents are held by research centers and universities such as the Broad Institute, Harvard University, and the Massachusetts Institute of Technology (MIT), while 180 are directly controlled by the Big 4 agribusiness companies and, to a lesser extent, by other members of the ACLP licensing platform. Among these, 88 have already been granted, and 92 are pending. Noteworthy is the fact that the Big 4 have entered into numerous licensing agreements in recent years for the use of genome editing techniques developed by the aforementioned research centers. This enables them to access and utilize the editing technology to develop genetic material and plant varieties for subsequent patenting.

Notes

- ¹ Centro Internazionale Crocevia (2023). LEAK – La proposta UE sui nuovi OGM è peggio del previsto. <https://www.croceviaterra.it/ogm/leak-la-proposta-ue-sui-nuovi-ogm-e-peggio-del-previsto/>
- ² Testbiotech (2023). Field trials on plants derived from new genetic engineering – development in Europe. <https://www.testbiotech.org/en/field-trials-new-ge-plants>
- ³ CREA, Federchimica, Assobiotech (2023). Position Paper - Nuove tecniche genomiche “Genome Editing e Cisgenesi”. <https://www.crea.gov.it/documents/20126/0/Position+Paper+-+Gene+editing+240123.pdf/69dd2a09-c599-105e-177f-cdee388a1465?t=1678806057923>
- ⁴ Kawall K (2021). The generic risks and the potential of SDN-1 applications in crop plants. *Plants* 10(11): 2259. <https://www.mdpi.com/2223-7747/10/11/2259>; Kawall K et al (2020). Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. *Environmental Sciences Europe* 32(1):106. <https://doi.org/10.1186/s12302-020-00361-2>; Eckerstorfer MF (2019). An EU perspective on biosafety considerations for plants developed by genome editing and other new genetic modification techniques (nGMs). *Frontiers in Bioengineering and Biotechnology* 7(2019). <https://www.frontiersin.org/articles/10.3389/fbioe.2019.00031/full>; Ormandy EH et al (2011). Genetic engineering of animals: Ethical issues, including welfare concerns. *Can Vet J* 52(5):544–550. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078015/>; Kim J, Kim J-S (2016). Bypassing GMO regulations with CRISPR gene editing. *Nature Biotechnology* 34:1014-1015. <https://www.nature.com/articles/nbt.3680>
- ⁵ EU JRC (2022). https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/index.html
- ⁶ <https://clusteragrifood.it>
- ⁷ Waltz E (2021). GABA-enriched tomato is first CRISPR-edited food to enter the market. *Nature Biotechnology* 40:9-11. <https://doi.org/10.1038/d41587-021-00026-2>
- ⁸ Chhalliyil P, Ilves H, Kazakov SA, Howard SJ, Johnston BH, Fagan J. A Real-Time Quantitative PCR Method Specific for Detection and Quantification of the First Commercialized Genome-Edited Plant. *Foods*. 2020; 9(9):1245. <https://doi.org/10.3390/foods9091245>
- ⁹ GMWatch (09/21/2020). Company claims first commercial gene-edited crop wasn’t gene-edited after all. <https://gmwatch.org/en/106-news/latest-news/19535-company-denies-first-commercial-gene-edited-crop-is-gene-edited>
- ¹⁰ Government of Canada. Decision Documents – Determination of Environmental and Livestock Feed Safety. <https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236> (last accessed 3 June 2023)
- ¹¹ Government of Canada. Directive 2009-09: Plants with novel traits regulated under Part V of the Seeds Regulations: Guidelines for determining when to notify the CFIA. <https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/eng/1304466419931/1304466812439> (last accessed 3 June 2023)
- ¹² Reuters (05/04/2023). China approves safety of first gene-edited crop. <https://www.reuters.com/science/china-approves-safety-first-gene-edited-crop-2023-05-04/>
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