



Biotechnology: Safeguarding patentability is essential

The EU is currently working on a legal framework for new genomic techniques (NGTs). A step that is long overdue. However, over the course of the legislative process, there have been recurring calls to deny basic patent protection to plants and plant material bred using NGTs, thereby weakening the established Biopatent Directive. This is not appropriate and threatens legal certainty far beyond the plant sector.

Why are biopatents essential?

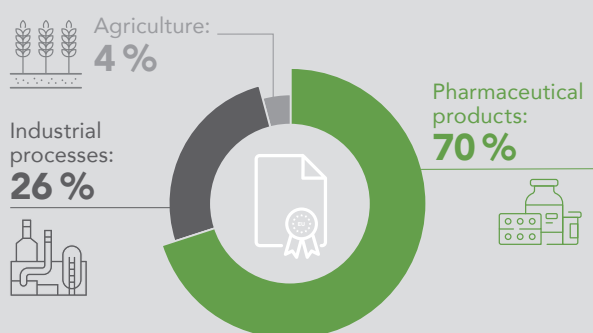
NGTs hold enormous potential for more climate protection, enhanced food security and innovative medicines. Science, politics and industry agree on this. Research-oriented companies - who use these technologies and seek to develop new products with them - are ready to invest many millions of Euros in Europe's technology of the future. Patents have always had this elementary function. Without them, companies would have no way of recouping their research and development costs.

A second, often overlooked function of patents is technology transfer. Biotech start-ups and SMEs often develop innovations which they make available to other companies and breeders for use in return for license fees. Cooperation and alliances of this kind between all sizes of companies and sectors are only enabled by patents.

Biopatent Directive at risk overall

In addition, those who insist on exceptional provisions for patenting NGTs are threatening the established Biopatent Directive. It represents an arduously negotiated compromise and has been the basis for Europe's biotech scene for over two decades. The Biopatent Directive enables groundbreaking inventions in medical, industrial and agricultural biotechnology. Anyone calling for exceptional regulations is likely to provoke a renewed debate on fundamental issues. The result would be years of legal uncertainty surrounding biopatent rights, including a halt to innovation in all areas of biotechnology.

European biopatent applications by fields of use in 2021:



Source: European Patent Office (EPO)



Allow sufficient time for market analysis

What impact do biopatents on NGT plants have on breeding innovations and the market?

To clarify this, the EU Commission plans to launch a broad-based analysis and present a corresponding report in 2026. DIB explicitly supports this approach. However: The legislation on NGTs must be enacted before the European elections in June 2024. If the legislative process is delayed, at least two years should pass between the date of adoption and the report - otherwise there is simply not enough time to gain sufficient experience and analyze the findings.



Plant variety protection + patent law = innovative strength in plant breeding

In plant breeding, intellectual property is protected by two complementary systems. Firstly, plant variety protection: for example, if a company breeds a particularly high-yielding wheat variety in the conventional way, plant variety protection gives the company an exclusive right to use it. Secondly, patent protection: for example, a biotech company develops a solution to enable wheat to thrive even in persistent drought. Because such properties can be added to many wheat varieties and not just one wheat variety, it is not plant variety protection that applies here, but exclusively patent law.

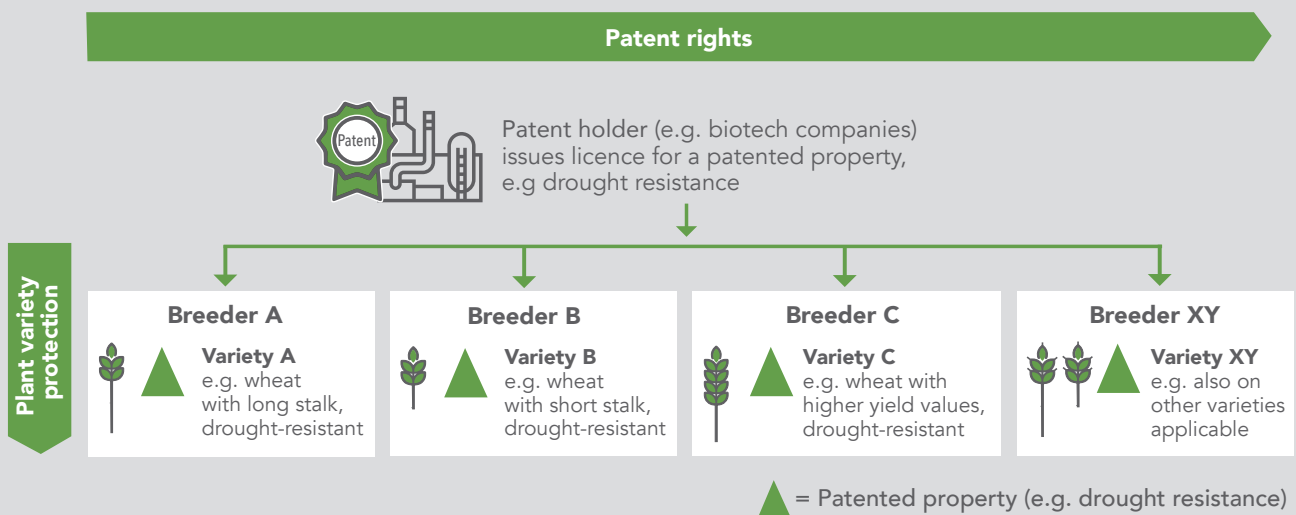
The interaction between plant variety protection and patent law is balanced and protects the interests of all parties involved:

- **Breeder's exemption:** Traditional breeders can freely use patented biotech traits to develop new plant varieties. The consent of the patent holder is not required. It is only when the new variety is brought to market that the patent holder must be remunerated for his invention.
- **Distinct patenting requirements:** Biopatents are only granted if they are based on a new invention and on

Property rights promote cooperation between breeders and biotech companies

The targeted development of plants is characterized by a particular protection and innovation system. It enables traditional breeders to use biotechnological

innovations and thus further optimize their respective varieties. A restriction of patent law threatens this well-established system.



technical processes. It is also clear that no biopatents will be granted on plant traits that are produced using essentially biological breeding methods such as crossbreeding and selection. The Biopatent Directive prohibits patenting in this area.

- **Disclaimer solution:** It is ensured that patents on NGT processes do not extend to plants with identical

properties that occur in nature or are produced by conventional breeding. This is ensured by the disclaimer solution of the European Patent Office.

- **Right of prior use:** Breeders who have developed certain plant characteristics may, of course, market these permanently. Subsequently granted biopatents have no influence in this regard.

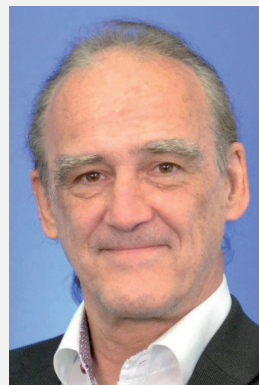
Innovation ecosystem of immeasurable value

„Germany's biotech scene is characterized by intensive cooperation. On a daily basis, experts from research and science, start-ups, SMEs and large companies work together intensively across institutional and corporate boundaries to create new innovations.“

This innovation ecosystem has proven to be an invaluable asset. Property rights - in particular plant variety and patent protection - play a vital role in this regard. They offer innovation and security of investment. They sustainably promote research and development and enable the indispensable tech transfer for further innovations.

Patents are particularly crucial for start-ups and SMEs without large capital resources so that they can obtain sufficient funding for their innovation efforts. Without the

important patent protection, Europe would no longer be an investment area for innovation and would not be competitive internationally.“



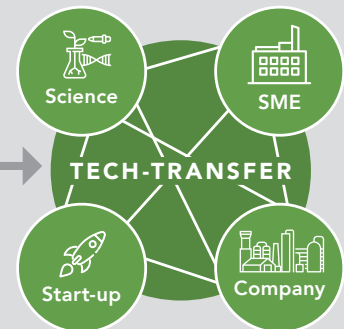
Dr. Ricardo Gent
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Note

Further information on technical transfer in biotechnology is available in the BioTech Letter 1/2023.

Patent protection
e.g. variety protection,
patent

enables



Farmers are not affected by patent law

Do biopatents have a negative impact on farmers? The answer is: no.

Farmers are not directly affected by patents because, there are generally no direct relationships between the farmers and the holders of patents on plant traits. Farmers acquire seeds from breeding companies and with the seeds the

right to use them for the purpose of agricultural cultivation. This includes any patents contained in a variety.

Under plant variety protection and patent law, farmers may also reseed part of their harvest for the purpose of agricultural cultivation after acquiring the seeds - against payment of the so-called reseeding fee to the breeder.

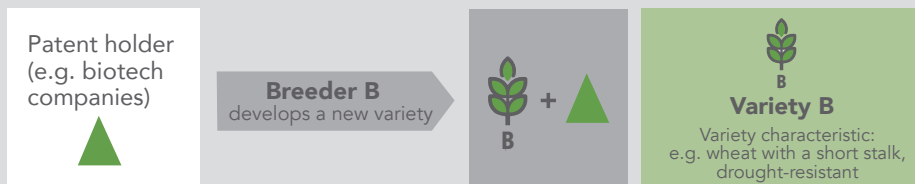
This also applies to any existing patents. In practice, therefore, the farmer usually only pays financial compensation to the holder of the plant variety right, which covers any patents contained in the respective variety.

The concern sometimes expressed that this may reduce the diversity of varieties is also unfounded. Whether a breeder uses a patented plant trait is his decision alone. Market demand - and not the existence of patents - will be the guiding factor.

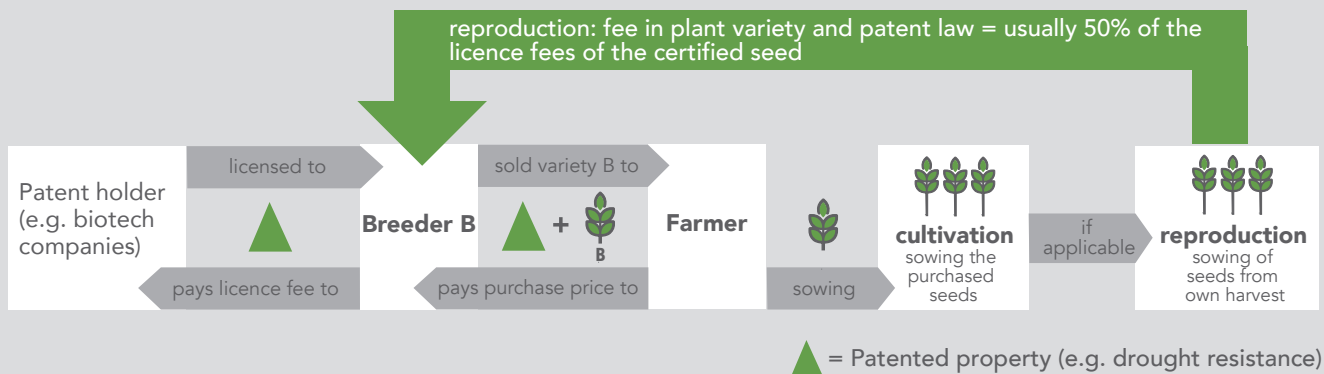
Overview of the value chain

1. Breeding line until the market launch of the variety

No licence fees are due until the variety is launched on the market (breeder's privilege):



2. From the market launch of the variety



Patent holders promote easy access to patents

Some actors in the value chain complain about the lack of transparency regarding existing property rights. In addition, the transaction costs for licensing patents are too high in terms of personnel and finances. Plant biotechnology companies take these challenges very seriously.

Licensing platforms such as the Agricultural Crop Licensing Platform (ACLP) offer solutions: They ensure transparency, low transaction costs for license agreements and therefore simple, reliable, and legally secure

technology transfer. In this way, the platforms also provide actors without patent law expertise with easy access to biotechnological innovations in the plant sector.

DIB is convinced that in this way, reliable, structured, and fair access to patents and thus effective participation in the „innovation ecosystem“ in plant biotechnology can be realized for breeding companies of all sizes and to the benefit of the entire value chain - without any patent bans!

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