BioTech Letter

Biopatents

1 | 2023

Deutsche Industrievereinigung Biotechnologie

Biopatents: Maintaining the basis of Germany's innovation ecosystem

Germany's biotech sector is based on a unique innovation ecosystem where scientists, start-ups, small and medium-sized enterprises (SMEs) and large businesses cooperate intensively to develop innovations. The various actors share their knowledge and drive forward new solutions that are urgently needed to achieve key political goals – ranging from protecting the climate and preserving biodiversity to securing global healthcare and food supply. This open innovation ecosystem relies on research actors being able to patent their innovations.

Three central properties make biopatents indispensable:

- **Technology transfer:** In the biotech sector in particular, specialized start-ups and SMEs develop groundbreaking technologies which they usually allow other companies to use in return for licensing fees. Patent protection turns ideas into tradable goods. Without it, a reliable, structured and fair transfer of technologies would not be possible. And patents are not a black box, quite the contrary: After a waiting period, the patent office publishes a written presentation of the invention. Thus, knowledge is shared and benefits all actors in the innovation ecosystem.

- **Copy protection:** Patents offer a high level of protection against theft of ideas. This is essential for the survival of SMEs in particular. With this protection and the prospect of return on investment, patents open up the willingness of companies to invest: In their efforts to develop biotechnological innovations, they may have to engage in many years of research. This often involves huge investments that must pay off at a later point in time. Otherwise, companies will reduce or abandon innovative research altogether.

- **Support for start-ups and SMEs:** In most cases, patents are the only way for start-ups and SMEs without a substantial capital base to gain the necessary access to sufficient financial resources. Thus, patents form the foundation for later sales and for the longevity and economic success of these companies.

R&D spending of German biotech companies in 2022:

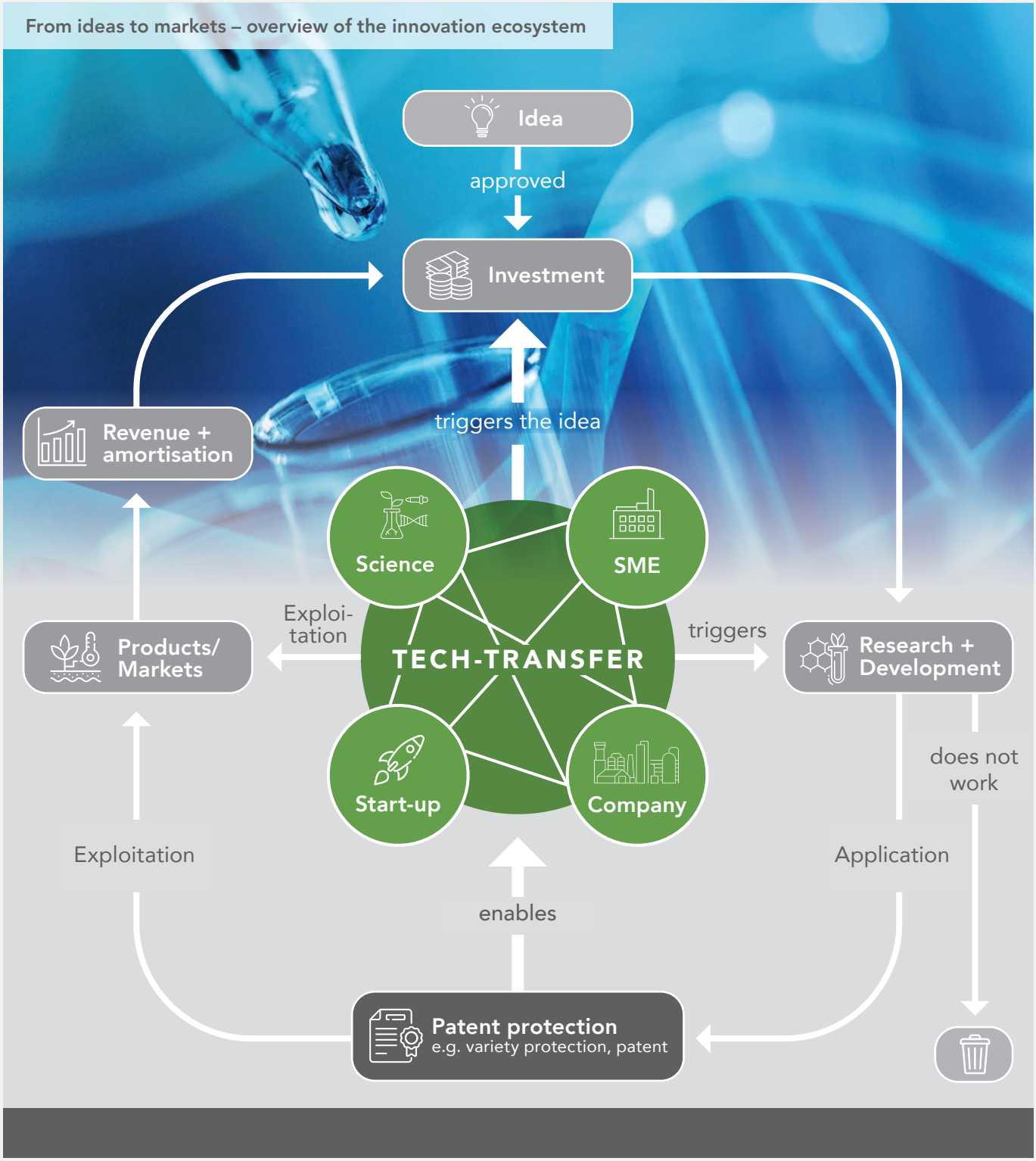
3.8

billion euros

Source: EY, figure largely comprises pharma

Preserve diversity in the innovation ecosystem
Patent protection serves as a guarantee for diversity and the ability to cooperate in the German and European innovation ecosystem. Without this protection, biotechnology could become increasingly concentrated in a few companies: Only those who advance biotechnological research and development on their own, keep the results secret and transfer them into their own products would be in a position to bring innovations to the market without patent protection – albeit under more difficult conditions than with patent protection. SMEs and start-ups would lose out, with a massive drop in Germany's innovation momentum. Therefore, the Biopatent Directive must be left in its existing form.

From ideas to markets – overview of the innovation ecosystem



Patent protection and plants: Breeders' interests are safeguarded

Intellectual property in plant breeding is protected by two complementary systems: On the one hand, classical plant breeding is protected by plant variety rights, which give breeders an exclusive right of use of their plant variety. On the other hand, only patent protection is available for plant traits generated by biotechnological processes, since these plant traits can be applied across many varieties. Patent protection provides companies with an exclusive right to their inventions for a limited period of time. Important to know: Patent protection is narrowly defined. It does not cover plants produced by an essentially biological process. Furthermore, it does not cover plants with the same properties that occur naturally. This is ensured by the so-called "disclaimer solution" of the European Patent Office, which limits the scope of the patent claim to technically generated properties.

Further improve transparency

Scientific institutions and companies of all sizes must be able to participate in the well-working innovation ecosystem. To ensure that innovations are disseminated as widely as possible, access to patented plant traits needs to be made simple. Especially from the perspective of smaller plant breeders, transparency about existing protection rights and the cost of licensing are important aspects.

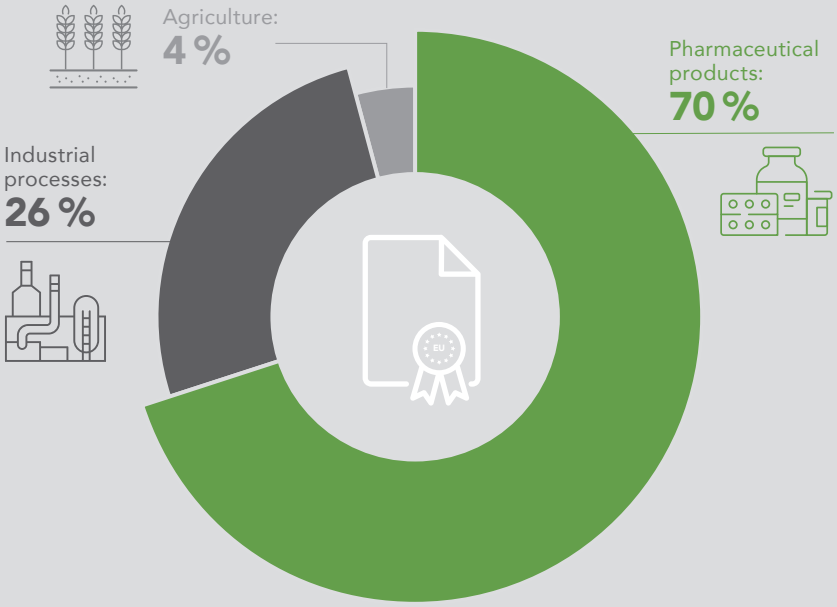
The DIB takes these challenges very seriously indeed and supports its membership in initiatives that enhance transparency and promote low-threshold certification schemes. Already today, licensing platforms (such as the Agricultural Crop Licensing Platform / ACLP) provide non-discriminatory access, in particular for SMEs. They create legal clarity and enable easy access to biotechnological innovations in the plant sector, also for actors without expertise in patent law. Changes to the existing Biopatent Directive would put the functioning of the present system at risk and reduce transparency. The directive must remain in its current form.

European Patent Office

Biopatents: Focus on pharmaceuticals

Biopatents are of vital value for innovations in all fields of biotechnology. For this reason, the legislator should keep the Biopatent Directive in its current form for all sectors accordingly. In 2021, pharmaceutical innovations and developments in industrial biotechnology accounted for 96 percent of the granted biopatents. Anyone who challenges the biopatent regulation in one of the fields of biotechnology directly endangers legal certainty in the other biotechnology areas.

European biopatent applications by fields of use in 2021



Source: European Patent Office (EPO)

The example of Ogura highlights: Patents offer massive added value

Intellectual property is worth protecting: from the perspective of society and from the viewpoint of users of future products. This is especially true for intellectual property based on biotechnological innovations in crops. Hard facts and figures prove this.

What remains the most relevant case study in this regard dates back to 2015, when a team of researchers comprehensively investigated the value of Ogura – a biotechnological method by which particularly high-yielding hybrid seeds can be produced. Ogura had been developed and patented by the French research institute INRA. The institute granted non-exclusive licenses to several seed companies. The first seed based on the Ogura technology was placed on the market in 2000.

The key messages: Firstly, biotechnological innovations are being adopted. For instance, in 2012 an impressive 83 percent of French farmers already cultivated the new hybrid oilseed rape, and annual production increased by 320,000 tons. Secondly, the total benefit over the 20-year patent term amounts to one billion euros, three quarters of which are to the advantage of farmers and consumers. This aspect cannot be appreciated highly enough. Thirdly, the research cost 56 million euros and took almost a decade to complete. Resources that could only be amortized after 15 years. The researchers clearly stated that this would not have been possible without patent protection.

The example highlights the enormous value of biopatents to all of us. We must have the legal certainty that we can continue to work with biopatents in the future.

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