

Statement of BIO Deutschland

Waiving intellectual property rights does not create access to COVID-19 vaccines

In the debate about waiving patent protection for COVID-19 vaccines, the Biotechnology Industry Organization Germany e.V. (BIO Deutschland) emphasizes that waiving patent protection for COVID-19 vaccines should be rejected because

- **a waiver of patents on COVID-19 vaccines does not automatically help to speed up vaccine production.** Production of the novel vaccines requires considerable expertise and appropriate production facilities, which often requires months if not years of preparation. In addition, production figures show that there will be sufficient vaccine capacity in the near future.
- **this would have prevented necessary innovations for BioNTech Pfizer's now globally successful vaccine.** A waiver of patent protection would lead to a de facto expropriation of biopharmaceutical companies whose business basis is their intellectual property.
- **in the future, the development of 2nd generation vaccines by innovative biotech companies for new Covid-19 variants is almost prevented or at least severely delayed.** This raises the question for innovative companies of why to invest in the future if, in effect, control and ownership of the results is lost.
- **drugs and vaccines are protected not only by one patent, but by a whole bundle of patents, whereby individual patents of this bundle in turn often protect other drugs and vaccines as well.** Thus, release of patents would also threaten the development of active ingredients with regard to other areas of research.
- **the problem of national export restrictions is not solved by a waiver of patents.** India and the U.S. have imposed export bans on key intermediates and/or finished products in COVID-19 vaccine production, which is significantly disrupting supply chains worldwide. At the same time, both countries are calling for a waiver of patents to protect their own populations, which seems counterproductive.
- **the dependency on long-standing know-how, qualified personnel with experience in GMP production and highly complex technology transfer for production is not solved.**
- **the safety of patients could be endangered.** Only the transfer of GMP-compliant and licensable production of a safe biological (e.g. RNA-based) vaccine, incorporating the necessary know-how of the original company, can enable the ramp-up of global vaccine production in the short term.
- **the international competitiveness of the biotech industry would be threatened, as it is not only about the COVID-19 vaccine, but about broad and complex technology platforms as the basis of the vaccine.** This is also about innovations in oncology, for example.
- **Intellectual property is not something that can be turned on and off.** A temporary waiver would be a dangerous example that shows that intellectual property is no longer valid in times of crisis. This would send a devastating signal to research-based industries and prevents innovation.

Thus, the key to improving access to vaccines is not a patent waiver, but to increase vaccine production. The following measures can be considered to achieve this goal:

- accelerated approval and better regulatory support for biotechnology processes, products and plants, as well as
- more financial support for vaccine manufacturers to stockpile vaccines, so that production does not come to a standstill and the risks for companies are cushioned.

This statement was drafted by the working group on protection rights and technical contracts of BIO Deutschland.

The working group on protection rights and technical contracts, **BIO Deutschland e.V.: Dr. Martin Pöhlchen**, Sinfonie Life Sciences Management GmbH, is **head of the working group on protection rights and technical contracts with representatives of the following companies** AbbVie Deutschland GmbH & Co. KG, Ascenion GmbH, AVIA GmbH, Axolabs GmbH, Baker & Mc Kenzie, Bayer Intellectual Property GmbH, bbCell GmbH, Boehmert & Boehmert Anwaltspartnerschaft mbB, Clariant Produkte (Deutschland) GmbH, CMS Hasche Sigle Partnerschaft von Rechtsanwälten und Steuerberatern mbB, Deutsches Krebsforschungszentrum (dkfz), Patentanwälte Isenbruck Bösl Hörschler PartG mbB, KPMG Law Rechtsanwaltsgesellschaft mbH, NEUWERK Rechtsanwälte, Osborne Clarke, Provendis GmbH, QIAGEN GmbH, Sinfonie Life Science Management GmbH, Zimmermann & Partner mbB, ZSP Patentanwälte PartG mbB

As the sector association of the biotechnology industry, BIO Deutschland with its more than 340 member companies has set itself the objective of supporting and promoting the development of an innovative economic sector based on modern biosciences. Oliver Schacht, PhD is head of the board of BIO Deutschland,

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