

Position of BIO Deutschland

Topic: Intellectual Property

Position on the Early Certainty in Examination Initiative

BIO Deutschland welcomes the intention of the European Patent Office (EPO) to enhance the efficiency of the patent application process and to achieve more legal certainty for third parties. In the past, the EPO already launched a number of measures that aim to speed up the patent application process. Currently *Early Certainty in Examination* is being discussed; meaning that grant of a patent will be concluded on average within 12 months after the start of the examination procedure.

Currently the average duration of the patent application process is 29 months¹. Reducing the application process to 12 months implies that much faster work is expected from patent examiners to maintain the same quality of patent examination. In complex sectors such as biotechnology, the abbreviation of the patent application process also leads to higher costs in an early stage, because of the extensive examination procedure. Especially small and medium sized enterprises (SME) in the research and development sector usually have a high need of capital to assure the cashflow. Therefore these companies will be additionally affected by a cost burden early on. To attract investors and partners SME as well as academic institutions often cooperate to advance their research and development and share sensitive information in the process. In order to maintain the possibility of pursuing specific aspects of the patent application at a later time more divisional applications would be necessary and cause significantly higher costs. Therefore the proposed abbreviation of the patent application process leads to a disadvantage for SME.

In research-intensive sectors, such as biotechnology, a patent application for companies in early stage is needed to assure that they are able to assert themselves in international competition. Research and development of a new biopharmaceutical product takes more than ten years in general. At the early stage of patent application, it is often not clear which main aspect should exactly be covered by the application. Applicants therefore intend to defer decision and costs to a later stage, when e. g. first clinical data are available and a candidate for development is determined.

BIO Deutschland demands an effective and non-discriminatory patent examination:

- Instead of shortening the duration of the application process an abbreviation of the patent process should only be given upon request either by a third party or by the applicant itself.

If the EPO decided to implement the *Early Certainty Initiative in Examination* BIO Deutschland calls for:

- The possibility to apply for exemptions to carry out the patent examination outside of the *Early Certainty in Examination* ("De-PACE") in order to meet the specific requirements of high-tech SME. It should be possible to defer the proceedings pending at the request of an applicant.

¹ Vgl. [http://documents.epo.org/projects/babylon/eponet.nsf/0/4C30F69F33211B6EC1257F6A0049308F/\\$File/quality_indicators_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/4C30F69F33211B6EC1257F6A0049308F/$File/quality_indicators_en.pdf)

As the sector association of the biotechnology industry, BIO Deutschland with its more than 300 member companies has set itself the objective of supporting and promoting the development of an innovative economic sector based on modern biosciences. Dr. Peter Heinrich is head of the board of BIO Deutschland,

Die Biotechnologie-Industrie-Organisation Deutschland e. V. (BIO Deutschland) hat sich mit ihren mehr als 300 Mitgliedsfirmen zum Ziel gesetzt, in Deutschland die Entwicklung eines innovativen Wirtschaftszweiges auf Basis der modernen Biowissenschaften zu unterstützen und zu fördern. Dr. Peter Heinrich ist Vorstandsvorsitzender der BIO Deutschland.

Supporting members of BIO Deutschland and branch-members are Abbvie, Avia, Bayer Pharma, Boehringer Ingelheim Pharma, Clariant Produkte (Deutschland), CMS Hasche Sigle, Deutsche Bank, EBD Group, EY, evotec AG, Isenbruck | Bösl | Hörschler, Janssen, KPMG, Merck, MiltenyiBiotec, MorphoSys, PricewaterhouseCoopers, Qiagen, Roche Diagnostics, Sanofi-Aventis Deutschland, SAP, Thermo Fischer, Vertex and VWR.



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