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The importance of IP protection and SPCs for biologics and biosimilar products

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Research and development necessitates important financial investments, particularly in the pharmaceutical field, where clinical studies costs easily hundreds of millions of Euros. Patents are important business tools to maintain exclusivity for the products provided in R&D and secure rights on the results of the underlying work. Pharmaceutical product development from lead compounds to the authorized drug easily takes more than 10 years. It is important to maintain product exclusivity in order to guarantee a satisfying return on investment. Biological products are used at increasing frequency in the pharmaceutical field, e.g., as therapeutics in the treatment of cancer and inflammatory diseases, as hormones, vaccines, etc. These products may also be subject to patent protection. It is of utmost importance for pharmaceutical companies to maintain exclusivity for a maximum period as the development and clinical testing up to market entry may be even longer than for small molecule drugs. Supplementary Protection Certificates (SPCs) provide legal means to extend protection for market authorized drugs. Recent decisions of the highest European Courts may provide guidance on the extent of protection conferred by such SPCs in the biopharmaceutical field. These decisions could provide guidance on how to protect biologicals and may influence the market entry of biosimilar products.

Biography

Lüder Behrens studied biology at the University Bremen (Germany) and University of Glasgow (UK). For his diploma in virology and his PhD in field of immunology, he worked at Max-Planck-Institute for Biochemistry/Neurobiology in Martinsried/Munich. Subsequently, he was Post-doctoral researcher in the field of neurovirology at the Institut Pasteur in Paris (F). In 2001, he started his training and legal studies to become a patent attorney. Since 2005, he is fully qualified patent attorney and later became a European patent attorney. He joined the renowned IP law firm Boehmert & Boehmert in 2015 and works in the offices in Berlin and Munich.

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