SpringerBriefs in Biotech Patents

Series Editor
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Preface to the Series

Biotech patents are a different world, even for patent practitioners who have obtained their expertise in neighbouring disciplines, like chemistry. One reason for this phenomenon is that, until about 20 years ago, novel biological embodiments were generally excluded from patentability. Classical breeding methods used for their creation relied on the random distribution of genetic matter, and thus lacked reproducibility and, hence, technicity—a criterion which is, in most patent jurisdictions, considered as a conditio sine qua non to qualify for patent protection.

With the rise in biotechnological methods, such as restriction enzymes, PCR, transfection methods and the like, a molecular toolbox is now available for the artisan which guarantees reproducibility with a sufficiently high percentage. Patent applications related to these methods therefore comprise a clear technical teaching. For current methods in biotechnology, technicity is thus no longer denied.

Biotech inventions are, however, facing headwind from another direction, too. Many biotech inventions are under public scrutiny for moral issues, or because they are considered as mere discoveries rather than inventions. Some countries have already established exclusions from patentability with respect to particular fields of biotechnology, or are about to do so. Argentinia has, for example, excluded genetically engineered plants, while in the member states of the European Union, human embryonic stem cells are excluded from patent protection in the future. A recent decision by the U.S. Court of Appeals for the Federal Circuit has dispelled fears that gene sequences used for diagnostic purposes or therapeutic proteins isolated from nature would no longer be patentable.

At the same time, biotech inventions often require large investments in R&D, and can develop tremendous commercial potential, thus making patent protection a

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1 Arts. 6 + 7 of the Argentine Patent Act and Argentine Guidelines for Examination of Patent application, Part C, Chapter IV, 2.1.7.
2 Decision of the European Court of Justice, case C-34/10, published on the website of the European Court of Justice (http://curia.europa.eu).
must to recover the invested resources. It is thus not surprising that the world of Biotech patents is a quickly developing one, which is sometimes hard to keep pace with.

Although plenty of literature related to Biotech patents is available, like Hans-Rainer Jaenichen’s formidable book “From Clones to Claims”,” a comprehensive treatise addressing the different Biopatent issues from all perspectives does not yet exist.

The present series “SpringerBriefs in Biotech Patents” tries to meet this goal. Each volume comprises three chapters devoted to three related topics, which are written by genuine experts of their discipline.

It is our hope that this series will help to create a better understanding of Biopatent issues, and support patent professionals to navigate the shallow waters of Biotech patents.

Duesseldorf, Germany

Ulrich Storz

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About the Series Editor

Dr. Ulrich Storz was born in 1969 in Muenster. He graduated in Biology form the University of Muenster in 1998, where he received his Ph.D. in 2002. He is author and co-author of several scientific publications in the field of biology and biophysics as well as of several juridical publications in the field of intellectual property.

He passed the German Patent Bar Examination in 2005. Since 2005, he has been admitted to practice as European Trademark Attorney at the European Trademark Office (OHIM). In 2006, he was registered in the list of representatives before the European Patent Office.

This main practice areas in the field of Intellectual Property Law include Patent Prosecution, FTO and Patent Infringement, as well as Patent strategies; especially in the Life Science field (i.e. Biotechnology, Biophysics, Biochemistry, microbiology). One of his major fields of interest is Antibody IP.

Ulrich Storz is active as a speaker for the congress management company "Forum Institut für Management GmbH”, and he organizes the annual Rhineland Biopatent Forum.
Preface to the Volume

Patents protecting biotechnological invention are becoming ever more important. Because biotechnology has many differences with respect to other technologies, lessons learned in other fields of technology cannot simply be transferred to adopt a suitable strategy for dealing with biotechnology inventions.

In this issue, general aspects of biopatent law will be discussed. This involves questions of patentability, including ethical issues and issues of technicity, as well as questions of patent exhaustion in cases where reproducible subject matter, like cells or seeds, is protected.

Another topic is active and passive patent strategies. Companies should not only develop an own patent portfolio, but should also monitor their competitor’s activities, in order to be able to counteract should the need arise.

Further, insight will be given into patent lifetime management and additional protective measures, like supplementary protection certificates and data exclusivity. Here, strategies are discussed as to how market exclusivity can be extended as long as possible, which is particularly important for biopharmaceutical drugs, which create high R&D costs.

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