SpringerBriefs in Biotech Patents

Biopatent Law: Patent Strategies and Patent Management

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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,[1] while in the member states of the European Union, human embryonic stem cells are excluded from patent protection in the future.[2] A recent decision by the U.S. Court of Appeals for the Federal Circuit[3] 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

[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).

[3] Association for Molecular Pathology, et al. v. USPTO, Myriad Genetics, et al. v. Myriad Genetics, Inc. See No. 2010-1406 (Fed. Cir. July 29, 2011).

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",[4] 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.

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[4] Jaenichen HR, McDonell L, Haley J F, Hosoda Y: From Clones to Claims: The European Patent Offices's Case Law on the Patentability of Biotechnology Inventions in Comparison to the United States and Japanese Practice, Heymanns 2006.