

Intellectual Property Issues

Therapeutics, Vaccines and Molecular Diagnostics

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Preface

This is the second volume of SpringerBriefs on Biotech Patents. Other than the first volume, which addressed some fundamental issues of Biotech Patents, this volume will deal with three commercially important technical disciplines within the Biotech arena, namely therapeutic antibodies, molecular diagnostics and peptide vaccines and peptide therapeutics.

Therapeutic antibodies are the fastest growing group of protein therapeutics. Antibody patents are subject to similar principles as patents related to small molecular drugs, although some differences apply, particularly with respect to inventive step. The basic principles for protecting antibody compounds will be discussed. Further, additional ways to create follow-up protection for antibody therapeutics will be discussed.

Another important market relates to Molecular Diagnostics. According to the latest figures the molecular diagnostic market in the US alone is worth about \$2.9 billion, with a predicted annual growth of 15% until 2015, resulting in a volume of \$6.2 billion. This alone justifies a closer look at the relevant patent issues accompanying these developments. An overview of the patent landscape in molecular diagnostics is thus provided, and issues of patentability with respect to the different technologies and compounds used therein are discussed.

Peptide Vaccines and Peptide Therapeutics are increasingly entering into the focus of pharmaceutical companies. However, peptide patents pose particular problems which are quite uncommon even for skilled biopatent experts. The peptide section is intended to give a broad overview of areas of law that are particularly relevant to the patenting of peptide vaccines and therapeutic peptides as products and in compositions. The scope of patentable subject matter will be discussed, as it has been the focus of much wrangling and debate in the courts. Further, a comparative look is provided at how American and Chinese authorities treat peptide-based inventions.

We hope that this volume will be helpful for patent practitioners to be able to anticipate, or appropriately respond to, problems coming up in the patent prosecution process, and to develop a suitable patent strategy with respect to these capital intensive technologies.

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