Protecting and Enforcing Life Science Inventions in Europe

under EPC and EU Law - From Antibodies to Zebrafish

von
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2nd edition, completely revised and updated

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Preface to the second edition

Eighteen years have passed since the first edition of this book was published in 1997. This period has witnessed rapid development in the life sciences. Many biotechnology companies then on the cutting edge of research and development no longer exist, while others have taken their place to push that edge yet further. The sequencing of the human genome, completed several years after the first edition of this book appeared, has ushered in a new era of therapeutics, based not only on the elucidation of the many new genes made available, but also on the genes belonging to any one particular individual. The result has been the dawn of personalized medicine. Biologics now make up a significant proportion of today's blockbuster drugs and of these, many are antibody-based therapeutics. Embryonic stem cells bear the potential to raise the standard of health in society, while simultaneously challenging that society with serious ethical questions. Advances in the genetic engineering of plants are rapidly changing our answers to one of the most ancient and fundamental questions of human survival: What do we and our children eat? Finally, transgenic animals have become indispensable tools in modeling diseases which threaten our health. Yet how do we strike an ethically defensible balance between our desire for better health and potential animal suffering?

These and other issues continue to occupy both researchers and Legislators at the beginning of the 21st century. Legislators and Boards of Appeal in the European Patent Office have invested considerable effort over the last two decades to adjust the law and practice governing life science inventions to the rapidly changing technological landscape. The number of changes in law and its interpretation during this period stands as testament to what an active field life science research continues to be. Motivated by these changes since this book's first edition, and encouraged by repeated inquiries from friends and colleagues around the world, we felt the time had come for an updated edition of our handbook on patenting in the life sciences.

Despite the many developments mentioned above, the basic nature and intended audience of our book remain unchanged. As for the first edition, the present second edition is intended as a practical handbook to assist those active in the life sciences who are interested in converting the fruits of their research into protective, enforceable rights in Europe. This book does not intend to present an exhaustive account of all legal developments and decisions within the life science field; other existing books admirably meet this call. Rather, we intend to convey a sense of the requirements for patentability as well as the issues influencing patent enforcement by presenting illustrative examples of relevant decisions and claims. In this way, we intend this book to serve as a starting point for those readers who may not have attorney training, but still require general

guidance as to the factors influencing patent protection for life science inventions, and examples of claim language used to capture them. As in the first edition, each section of the book contains both generic and specific examples of claim language to this end.

At the same time, the content of the second edition differs in several important aspects from its predecessor. In December 2007, the EPC-2000 went into force. The EPC-2000 represented the most comprehensive overhaul of the European Patent Convention since its inception in 1973, and included the incorporation of many new material provisions relevant to the life sciences. In fact, many major changes in the EPC related to the European Directive 98/44/EC on the Legal Protection of Biotechnological Inventions. This Biotech Directive was not yet in force when the first edition went to press, and was only implemented in the EPC in 1999. Such fundamental statutory changes would alone have warranted an update of any book based on the old provisions of 1973.

Where the first edition focused primarily on biotechnological subject matter, the present edition addresses the broader field of life sciences. This includes a more detailed treatment of chemistry, particularly as relevant to small molecule therapeutics not offered in the first edition.

A further important difference between this second edition and its predecessor is the choice to now omit all treatment of German national law and practice. While Germany indeed continues to lead the European pharmaceutical market, Applicants increasingly prefer obtaining patent protection in Germany via a European patent application examined and granted centrally in the European Patent Office. By virtue of the simple volume of cases handled by the EPO, this office has become the clear trendsetter in the development of new case law relating to life science inventions. Under these circumstances an exclusive focus on Europe in the present edition seemed appropriate.

Finally, this second edition adds a chapter on the enforcement of patent rights throughout Europe. It is said that the real value of a patent becomes clear only when it is enforced. True to this notion, the new chapter addresses issues of enforcement both within and – especially important in Europe where borders are so close together – between European states. It is our hope that this new chapter will provide a helpful impression of the scope in which a patent may be enforced against a putative Infringer, as well as the factors to consider so that such enforcement has the best chances of succeeding.

The further development of life science technology and law will not cease with the publication of this second edition; the field is in constant flux, and this flux is a good thing. For the purposes of preparing the present manuscript, however, we were forced to draw a line, beyond which further developments could no longer be considered. We drew this line at August 1, 2014. Legal developments and case law after this date could not be taken into account in this edition.

The present book thus represents a practical snapshot of the legal landscape surrounding the patenting and enforcement of life science inventions in Europe up to late 2014. It is our hope that this book will assist the interested reader with his or her entry into this exciting field.

Munich, September 2014

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Table of Contents