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Preface

Patents are a focal point in the development, manufacture, and marketing of pharmaceutical and biotechnological products. The scope of patent protection for these products has profound effects upon pharmaceutical and biotech research, and the development of new therapeutic products.

For over twenty-five years, we and our colleagues have advised pharmaceutical and biotechnology companies on patent issues and represented them in patent litigations involving major drugs, diagnostic products, and medical devices. From our work with these companies, we saw the need for a practical guide to help both lawyers and non-lawyers navigate through these complex issues. To this end, our group has produced *Pharmaceutical and Biotech Patent Law*.

Traditional patent law treatises cover patent law as a general topic without focusing on the law's impact on specific areas of technology. Over the past several decades, however, the courts and the U.S. Congress have made many significant changes to U.S. patent law that uniquely affect the pharmaceutical and biotech industries. Both political and technological forces have driven these changes. Specific provisions of the Patent Statute, such as the Hatch-Waxman Act, have been enacted to adjust the balance between pioneering and generic drug companies. An entire chapter of the book has been devoted to this topic, which is often overlooked in other patent treatises and relegated to non-patent books on FDA regulation. Congress also amended the U.S. Patent Statute to harmonize United States law with foreign patent law. The book discusses these changes in the context of pharmaceutical and biotech issues. There has also been a tremendous growth in patent litigation involving the pharmaceutical sciences. New and developing areas of technology, such as molecular biology, have generated an ever-growing body of case law specific to these areas. This body of pharmaceutical and biotech law, we believe, deserves separate treatment apart from the general discussion of patent law.

We organized the book to present patent law issues that arise from the earliest stages of drug discovery through final regulatory approval, marketing, and enforcement, and arranged the chapters in that order. To make this book accessible to the non-lawyer, we have kept lengthy discussions of case law to a minimum. Instead, we emphasize fundamental holdings and principles organized by substantive topics, rather than by individual cases. Where necessary, we provide a more

expansive treatment for the most important decisions. However, to provide rapid access to relevant cases for practitioners, we have made an effort to provide citations to significant decisions in footnotes.

One particularly unique feature of the book is a chapter on different types of pharmaceutical patents. Rather than limiting the book's organization to general topics such as anticipation and obviousness, we created individual sections organized based on the types of pharmaceutical and biotech patents, much as the industry informally categorizes its patents. Thus we have sections that focus on the case law and issues surrounding chemical compound patents, pharmaceutical formulations, methods of treatment, and numerous other categories. Although the book remains a text on the law, not science, of pharmaceutical and biotech patents, we included general discussions of the science throughout the text when needed to provide context. We also provided an appendix that gives an overview of relevant scientific concepts, and a glossary that gives definitions for scientific terminology taken from court decisions to provide the reader with an understanding of how the courts view and apply these concepts. We included a chapter on antitrust and unfair competition issues which have arisen with increasing regularity in pharmaceutical and biotech patent litigations, and therefore have an impact on all aspects of patent procurement, licensing, and enforcement.

Although it is not the purpose of this volume to replace the many fine general treatises on patent law, a concise background on general patent law principles is also provided to give context to the issues that relate more specifically to the pharmaceutical and biotech industries.

We hope our book proves to be a valuable guide to this important and fascinating area of law.

David K. Barr
Daniel L. Reisner
Editors

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