Biotechnology is frequently identified as one of the fastest-growing industries in the world. To speak of a single “biotechnology industry,” however, is quite misleading. Biotechnology applies the myriad branches of the life sciences (for example, the various medical and surgical specialties, biology, biochemistry, pharmacology, biomedical engineering, genomics, proteomics, regenerative medicine, nanotechnology) to the development of products and technologies useful in a broad range of industry sectors (for example, human health care, veterinary care, food and agriculture, textiles, chemicals, alternative energy sources, biodefense). Some of biotechnology’s applications, such as stem cell research, may challenge our preconceived notions—and, indeed, our comfort level—about the very nature of life. Other applications of biotechnology are more mundane—the enzymes that improve our laundry detergents or enhance the flavors of our foods. There are nascent products of biotechnology under development that pose potential solutions to some of the world’s greatest problems: disease, famine, environmental pollution, nonrenewable energy sources.

The twentieth century looked to physics and chemistry to better the human condition. The twenty-first century looks to the life sciences with the same hope. This is not a North American or European or Asian phenomenon; it truly is global. These days, intellectual property developed in collaboration across a variety of technological specialties and industry sectors, in a number of countries on several continents, typically underlies any major medical breakthrough. Winston Churchill once said, “The empires of the future will be empires of the mind.” He could have been talking about the so-called biotechnology industry when he spoke those words.

Not surprisingly, companies developing biotechnology products have very broad legal needs. Seminal technology often originates in universities and nonprofit research organizations. Government and private grant money plays a crucial role in fostering this fledgling technology. Once the academic institution licenses the technology to a company (frequently a start-up organized for this very purpose), the company takes on the task of raising enough capit-
tal to advance the technology toward commercialization. Financing, always
difficult for a start-up business, is further complicated by the tremendous
risks and long lead time involved in bringing a product from concept to mar-
ket. In the case of pharmaceuticals and biologics, it often takes more than 10
years to navigate the U.S. Food and Drug Administration approval process—
and most products never achieve marketing approval. In addition, many prod-
ucts also must contend with the regulations of the U.S. Department of Agri-
culture, the U.S. Environmental Protection Agency, and their foreign
counterparts. Although the European Union rules are similar in some re-
spects, they are not the same. These great risks, long lead time, and regula-
tory complexities encourage collaborations by smaller players with more
established, deep-pocketed companies. The expenses involved almost man-
date a worldwide marketing strategy involving one or more strategic part-
ners. Even after achieving marketing approval, these products can expose
their companies to substantial risks of patent infringement claims, product
liability claims, government reimbursement and pricing claims, regulatory
compliance actions, and a host of other legal nightmares.

Successful leaders of biotechnology companies will view these issues as
related. Rather than pieces of a puzzle, they will see them more as strands of
a rope, separate but intertwined. Their lawyers need to view them the same
way. The legal adviser to a biotechnology company, whether in-house or
outside, needs to take a holistic approach in order to serve that company’s
strategic needs. This is difficult to do: these legal problems cover numerous
disciplines, any one of which requires years of experience to practice well.
No one person can be master of all these specialties. As a result, lawyers (and
the biotechnology clients they serve) need a resource that will enable them to
spot legal issues critical to companies in this industry—a tool that will, at
very least, tell them the right questions to ask in order to avert difficulties.

Two years ago, the Biotechnology Committee of the American Bar As-
sociation acknowledged the pressing need for such a resource. Committee
members, and especially the then chair and chair-elect, Julie Fleming Brown
and Erika Lietzan, respectively, recognized that lawyers practicing in this
area (and the clients they serve) needed a comprehensive reference book.
Books then available were typically so technical that a non-lawyer, or a law-
yer outside a given legal discipline, would find them daunting. The Commit-
tee proposed a primer providing sufficient information to introduce the issues in each legal discipline that are critical to a biotechnology company.

Before a word of the book was written, a year and a half was invested in developing the book’s format and scope. Hugh Wellons, the subsequent Committee chair, assembled a dedicated editorial team to carry the task forward: he and Eileen Smith Ewing as co-editors-in-chief; Robert F. Copple as stylistic editor and Erika Lietzan and Bill Wofford as topic editors. Benefiting from the input of other legal experts, this editorial team shaped the book’s content and recruited as chapter authors national experts in a range of fields. The topic editors assumed editorial responsibility based on their individual areas of expertise: Erika oversaw the scientific and regulatory chapters, and Bill shepherded the business law chapters. Subsequent chapter drafts, polished by their authors under Erika’s and Bill’s guidance, were further edited by the editors-in-chief and by Bob, who was in charge of style and consistency of content. In short, each chapter was edited multiple times in a grueling process that took well over a year from first drafts to last.

This, however, gives too much credit to the editors. The authors are the true stars of this book. They worked hard to meet demanding deadlines; they accepted our suggestions graciously; and they embraced the difficult task of distilling their complex professional expertise into simple explanations. We editors found it an education to work with these experts; we hope you will feel similarly enlightened by their work.

And now, the disclaimer: this book is meant to be a primer. No chapter will educate you sufficiently to practice in that area. The information in the book should not be taken as legal advice; given space and scope limitations, it does not seek to address all legal and regulatory concerns that companies or lawyers might have to consider in a specific situation. Each chapter could have been expanded into a book, but that was not our mission. We hope this primer will provide enough information for counsel and management to plan strategically, and enough guidance to know when you need an expert’s advice.

This book was clearly a team effort, and many thanks are due. The ABA, especially its Biotechnology Committee and Division of Science and Technology, have provided a great deal of support. The ABA’s book publishing division has been generous with its help and guidance. The American Association for the Advancement of Science provided general advice, and the
University of California–Berkeley Division of Agricultural and Natural Resources was kind enough to allow us to use its fine glossary of materials. Authors relied on various sources, which are identified in the individual chapters. We sincerely thank all the authors and the editorial staff—they have created a book in which they can take great pride. Special thanks go to our firms and our families, who put up with longer hours, fewer billings, and increased stress. We hope they, too, will take pride in the results.

Hugh B. Wellons and Eileen Smith Ewing
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