Preface

Biotechnology frequently is identified as one of the fastest-growing industries in the world. Speaking of a single "biotechnology industry," however, is misleading. Biotechnology applies the myriad branches of the life sciences (e.g., 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 (e.g., human health care, veterinary care, food and agriculture, textiles, chemicals, alternative energy sources, biodefense). Some of biotechnology's applications, such as CRISPR, transgenics, and 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, and nonrenewable energy sources.

The 20th century looked to physics, chemistry, and the microchip to better the human condition. The 21st 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, a major medical breakthrough often includes intellectual property (IP) developed in collaboration across a variety of technological specialties and industry sectors, in a number of countries on several continents. Winston Churchill once said, "The empires of the future will be empires of the mind." He could have been discussing 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 or nonprofit institution licenses the technology to a company (frequently a startup organized for this very purpose), the company takes on the task of raising enough capital to advance the technology toward commercialization. Sometimes the startup also must fund IP protection, particularly internationally, which raises strategic questions very early. Tremendous risks and long lead times involved in developing a product from concept to market complicate financing for a biotech startup.

In the case of pharmaceuticals and biologics, it often takes more than ten years to navigate the Food and Drug Administration approval process—and all but a few products never achieve marketing approval. In addition, many products also must contend with the regulations of the U.S. Department of Agriculture, the U.S. Environmental Protection Agency, and others, in addition to their foreign counterparts. Although the European Union rules are similar in some respects, they are not the same. These great risks, long lead times, and regulatory complexities encourage collaborations by smaller players with more established, deep-pocketed companies. The expenses involved almost mandate a worldwide marketing strategy involving one or more strategic partners. 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 speed bumps on a long road, separate but all part of the same journey. Their lawyers need to view them the same way. The legal advisor 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 the very least, tell them the right questions to ask in order to avert difficulties.

In 2005, the Biotechnology Committee of the American Bar Association (ABA) 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 reference book. Books then available were typically so technical that a nonlawyer, or a lawyer outside a given legal discipline, would find them daunting. The committee 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 the first time, 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 senior 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.

The first edition, published in 2007, was surprisingly successful. Totally unexpected, college and law school professors used the book to teach classes on this topic. In about 2014, we began discussing a new edition, but with changes to respond to comments we received. We deleted chapters that appeared to be of little interest or were outdated and added a couple chapters to respond to specific requests. We deleted the Glossary, even though we found it very helpful. In the years since the first edition, lawyers' habits have changed. Virtually everyone now looks up a definition online, rather than going to a book glossary. One of the added chapters covers bioethics. Bioethics technically is not "law." Like the law, what constitutes ethical standards moves over time, sometimes quickly. The law related to biotech also moves fast, involves a lot of risk, and can change during a product's development. Advising a client on "the law" early in the cycle may not protect them from the law to come. Since the state of bioethics often leads the law, we felt that a description of the concepts and approaches to bioethics

might provide a framework to help practitioners think through ethics considerations that sometimes predict where the law will be on new issues. For example, there seems to be a societal desire for greater transparency. Knowing that, a biotech developer may choose to provide more than the minimum information about a product to investors, regulators, and patients.

We had many requests from educators for a case study, so we provide one in Appendix A. We also had requests for samples of IP transfer licenses, so we provide an example of the University of Texas (UT) model, circa 2018. This is only an example, but it is very clear, and many universities have adopted forms initially based on the UT model.

In any book of this type, the authors are the true stars. 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. Frankly, it is more fun to write a chapter than to rewrite or update that chapter. Many authors did that graciously; others did not have time. We had to find new specialists to cover updates in a few cases. In a couple cases, the original authors could not be involved, so we had to start over on the chapter. This book also was delayed by busy authors trying to fit a grueling process into already busy schedules. Later than expected, the book finally is complete.

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 a specialist's advice.

This book was clearly a team effort, and many thanks are due. The ABA, especially its Biotechnology Committee and Section of Science and Technology, has provided huge support. The ABA's book publishing division has been generous with its help and guidance, particularly Sarah Forbes Orwig.

The American Association for the Advancement of Science provided general advice. We particularly thank Michael Hawes of Baker Botts, LLP for helping to find substitute authors and "updaters" and generally working to keep this edition "between the ditches." 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.

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