
Biotechnology and the Law

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This 957-page book covers a wide variety of topics pertaining to start-up and more established companies involved in the development and marketing of products of modern biotechnology methods, such as those in the pharmaceutical, medical device, and agricultural areas. Composed of 21 chapters written mostly by different authors, it is described as a primer or resource tool. The more substantive chapters range in length from roughly 25 to 65 pages. As a single publication it is rather daunting to read, which means that, perhaps, a two or three volume set might have been less formidable, at least in terms of overall presentation.

A number of important legal topics are reviewed. They include patents, technology transfer, litigation, health and environmental regulation, company financing, medical reimbursement, employment law, federal grants and contracts, company formation, R&D and commercial collaborations, litigation, and healthcare privacy matters. Since many of these legal areas are not necessarily unique to biotechnology, it is not surprising in some respects that the applicable laws are not always specifically addressed in this narrower context, although the title of

the book seems to suggest otherwise. On the other hand, even though most US laws and their implementing regulations have been adapted to apply to the various industries or products, new, tailored provisions do exist in some areas. Moreover, a lot of notoriety, including legal controversy, has sometimes accompanied such industries and the testing and marketing of their products. These types of details are sometimes left unaddressed or not fully explored, leaving the reader unaware of the nature or ferocity of the legal and other related debates.

Many sections of the book, explicitly or implicitly, primarily address human healthcare-related industries and products, typically drugs, with lesser emphasis on veterinary products. The food, medical device, and agricultural regulatory areas are also not as thoroughly reviewed. The title of the book therefore probably could have been more appropriately named *Basic Human Healthcare, Corporate and Technology Law*, although admittedly not perfect either and certainly much less alluring. Also, some of the titles of the individual chapters seem too generally worded. They are often limited to human pharmaceutical products or at least are more narrowly oriented than their titles suggest.

As might be expected of a compilation developed by multiple authors, a few chapters have some overlap and redundancy. The presentations also are sometimes uneven, resulting at times in a more colloquial approach with fewer, if any, references or footnotes. Other sections are much more formal with extensive footnotes. The first and last chapters which, respectively, lay the groundwork for the subsequent sections and list some biotechnology resources, are much less valuable and seem rather perfunctory. This also holds true for a number of the conclusions of the individual chapters. Specifically with regard to the resource list, for example, with the advent of the commercialisation of modern biotechnology methods nearly 30 years ago in early 1980, a plethora of laws, regulations, websites, treatises, journal articles, newspaper pieces, and other publications and sources of information exists. The use of well-framed search terms and the internet likely would be just as useful, if not more so.

The book nonetheless contains a wealth of basic information with various levels of detail, as alluded to at the outset. Nearly all the chapters present good overviews. This is particularly true of the more lengthy ones on topics such as patents, patent litigation, technology transfer, and company finances. Other commendable parts include the lists of acronyms, glossaries, appendices, and the use of frequent sidebars called 'Practice Points'. All of these vehicles help emphasise certain concepts or terms and make the presentations more readable. Further, all the main topic areas seem to cover and contain the basic language and substance of the relevant legal discipline. A few chapters also summarily address the key aspects of international regulation, particularly in the European

Union, an important player in the 'biotech revolution'.

Some other more general points about the nature of legal primers and treatises can further suggest the utility of the book for certain audiences. A key feature of legal primers is that they necessarily address a single topic or variety of topics, some more elaborately than others in the latter situation, without in-depth analyses. Moreover, where the technical area, in this case modern biotechnology, has a wide variety of R&D and commercial applications involving or impacting a number of diverse industrial sectors, not all the topics of a multi-chapter primer such as this one are relevant to such a varied readership. A few or many chapters will not be of value to all those who potentially would be interested.

By the same token, a feature of legal treatises is that general practitioners or specialists outside their areas can get lost quickly in the minutiae, often at the expense of gaining a good understanding of the basic principles. Designed as a primer, the book is not likely to present these types of problems, although a lot of details are still addressed. The nature of the legal and technical subject matter is necessarily steeped in its own jargon and other terminology, in this case with emphasis on a number of the chapters on technology development, management, protection, transfer, or commercialisation in the overall context of human healthcare. For the general counsel of start-up companies operating in such an area and, perhaps, for others, many of the chapters therefore can serve as handy reference tools.

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