

A Guide to Biotechnology Law and Business*
By Robert A. Bohrer

Reviewed by Lawrence M. Sung, J.D., Ph.D.**

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Perhaps the most challenging final examination question I have experienced was through during my undergraduate astronomy course where the professor asked, "Describe the origins of the universe. Be brief." Such a task demands a complicated dynamic of content and expression that applies aptly to the endeavor to address the legal and business aspects of biotechnology in a comprehensive, yet detailed, manner. However, Professor Bohrer successfully earns a high mark with his effort. Beyond the substance, he offers a clear, well-written work.

According to the author, the book seeks to provide a "big picture" overview of biotechnology law and business by setting forth a practical and integrated discussion of the issues that face biotechnology product developers. Furthermore, the book anticipates a readership that includes intellectual property (IP), Food & Drug Administration (FDA), and business lawyers, as well as biotechnology executives seeking a concise introduction to the fundamental topics. The text begins with a presentation of the definition and basics of biotechnology. At the outset, Professor Bohrer delivers a nice review of the essential science that is easily accessible to the lay reader. Moreover, he begins with a consideration of the how the science feeds the commercial enterprise to establish the industry.

This interplay continues logically with the explanation of the role of technology transfer from academic institutions to biotechnology companies. In this chapter, Professor Bohrer describes the Bayh-Dole Act and its facilitation of a symbiosis between academic research and commercial development. In this regard, he teaches an esoteric subject in plain language masterfully. This discussion is arguably the highlight of this book and serves to distinguish the book from other written works that have purported to explain technology transfer in the biotechnology field.

The next section of the book considers the legal governance of biotechnology through the procurement and enforcement of IP, particularly patent, rights as well

as FDA regulation of biotechnology products and processes. Nested in this section are also two chapters on the start-up of a biotechnology company and the complexities of financing the venture. Once again, Professor Bohrer reveals his experience and excellent insights into the business aspects of biotechnology. These chapters are also must-reads.

If there is a weaker aspect of this book, it rests with the treatment in Chapter 4 of biotechnology patent rights. The overview properly acknowledges the statutory framework and the operative standards, but falls somewhat short in recognizing and articulating the highly nuanced nature of the scope of patent claims and its implications for the patentability and enforceability of biotechnology inventions in the maintenance of true marketplace exclusivity. Notably absent is a discussion of the impact of the patent infringement exemption of the 35 U.S.C. § 271(e)(1) safe harbor and of the effect on biotechnology inventions of the process patent infringement provisions under 35 U.S.C. § 271(g).

Another concern is a bit more holistic. In the physical sciences, a researcher can dedicate her life work to climbing the highest mountain and be confident that on the day she summits, she will have seen all there is to see. In the biological sciences, by contrast, upon the summit only then does a researcher see that indeed in the distance there are even greater mountains she never before knew existed. This inherent complexity with living systems defies true characterization when viewed through a single lens. In turn, the ethical, social and legal implications of the biological sciences face problems in convention and in the design of meaningful governing principles. In other words, because the nomenclature and our understanding of the science are subject to change, the governance of such science must also be capable of change. But, at least with the law, the guiding hand of the controlling weight of precedent based on the rule of stare decisis resists paradigmatic shifts. Therein lies the problem – and moreover, conundrums can give rise to legal unpredictability, which is the bane of commercial enterprise.

The book, of course, is also not immune to fast changing standards. In the time since the book's publication, several significant patent law decisions of the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have issued that will have a profound impact on the patent rights associated with biotechnology inventions, principally in the doctrines of inherent anticipation and obviousness. Furthermore, the pending patent reform legislation before the U.S. Congress and the rule change proposals by the U.S. Patent & Trademark Office to streamline its administrative examination functions may have adverse effects on the ability to obtain and enforce biotechnology patent rights.

Nevertheless, the establishment of a common frame of reference is a critical starting point in evolving an understanding of the field. In this regard, Professor Bohrer starts the reader off in the right direction. But because the patent rights play such a significant role in the creation of investment backed expectations

about biotechnology, further guideposts (and possibly alerts of traps for the unwary) would be instructive. In addition, the reader would be helped by information about the increasing role that contracts play in the biotechnology industry as mechanisms to govern research and commercial behavior outside of the default, traditional IP rights doctrines. For example, many reagents and other research tool suppliers are relying upon conditional sales or product-associated licenses that restrict researcher uses to certain purposes in ways not readily apparent to, or heeded by, the consumers, particularly academic researchers.

The FDA regulatory discussion provides a good overview of the federal regulatory scheme that pertains to drugs, biologics, and devices. Perhaps because of a distinction between biotechnology products and pharmaceuticals that the author might have drawn, there is little, if any, indication of the pervasive (and economically overwhelming) litigation between brand name drug and generic drug manufacturers that arise under the Hatch-Waxman Act based upon the filing of an Abbreviated New Drug Application with the FDA. While not all biotechnology companies or their affairs might be engaged in such contentious matters directly, many experience collateral investment and market effects based on their relationships with brand name drug manufacturers (“Big Pharma”).

The remainder of the book addresses the ethical considerations surrounding biotechnology and includes a particular discussion of human gene therapy issues. There is a mention, albeit brief, of the ethical issues that are raised in the context of human embryonic stem cell technology. Lastly, a brief introduction to products liability concerns that attach to biotechnology is included. The recent (February 2008) decision of the U.S. Supreme Court, in *Riegel v. Medtronic*, that a plaintiff may not sue under state law to challenge the safety or effectiveness of a medical device to which the FDA has given premarket approval will surely also have some future effect on tort liability involving biotechnology products.

In summary, Professor Bohrer’s book is a highly recommended resource for the library of anyone interested in understanding the biotechnology industry from a practical, non-historical, perspective. The discussions about the commercialization of biotechnology products and processes through academic technology transfer and start-up establishment and financing are especially strong. The book also provides a solid foundation on the aspects of IP rights, FDA regulation, and ethical implications of biotechnology. In these latter regards, however, the book would best assist the reader’s understanding of the biotechnology industry as a starting point for further learning about the complex interdisciplinary interactions that frame the commercial enterprise, only a small part to which the general public is privy through other media outlets.