BOOK REVIEW

BIOTECH BUSINESS GUIDE GIVES LITTLE GUIDANCE

Titled "Biotechnology Patents: a Business Manager's Legal Guide," the first of a series of four Special Reports in the Bureau of National Affairs (BNA, Washington, DC) Series on Biotechnology falls short. While providing a fair description of the decade-old history of patent law as applied to biotech issues, the author, Harold Wegner (Wegner & Bretschneider, Washington, DC), is selective in his coverage. He often wanders into an arcane legal analysis at the expense of providing hands-on guidance. For example, missing is any reference to the John Moore case or the questions of patentability and ownership rights to human tissues and commercially useful cell lines—clearly an appropriate business issue. And while his advice on how a company can cope with deposit requirements stemming from the decision in *In re Lundak* is useful, he fails to anticipate upcoming practical problems of filing, such as the Patent and Trademark Office's poorly-thought-out proposals on filing amino acid sequence data in standardized computer-readable formats.

Wegner rightly complains that patent protection for first-generation biotech products is unfairly tenuous. Yet in extending the analysis to second-generation products, he fails to bring in timely examples, such as whether different end termini on a CD4 molecule will affect patentability. And while the final section on worldwide licensing strategies is laid out well, there is no equivalent discussion or examples of cross-licensing among U.S. companies. Wegner often appears out of touch with today's commercial scene. When describing the intricacies of patent interferences, for example, he refers to a "hypothetical" company called California Biotechnology (Calbio)—of course a very real one.

The second Special Report, "U.S. Biotechnology: A Legislative and Regulatory Roadmap," prepared by the staff at BNA, is more timely and complete. Just released, it outlines well the dilemma facing regulatory agencies in evaluating deliberate release—including the proposed draft Environmental Protection Agency rules—and existing agency jurisdiction. And while it does not go into details—e.g., in describing the pitfalls a company may encounter at the Food and Drug Administration during the clinical trials process—this volume does give a good introduction to the workings of federal agencies.

One trap the authors do fall into is in offering the "anti-biotech" point of view. They cite Jeremy Rifkin and his Foundation on Economic Trends (Washington, DC) far too often, at the expense of the more mainstream ecological and environmental groups. More discussion of how companies are dealing with issues of public perception at the local level also would have been welcome.

Parts 3 and 4 of the series, to be released later this year, will analyze biotech financing and biotechnology law, respectively, for the 1990s.

—Mark Ratner

The BNA Special Report Series on Biotechnology (ISBN 1-55871-133-3) is available from the Bureau of National Affairs, 1231 25th Street, NW, Washington, DC 20037. Tel.: 800-372-1033. The four-part series is $380; individual reports are $95 each.