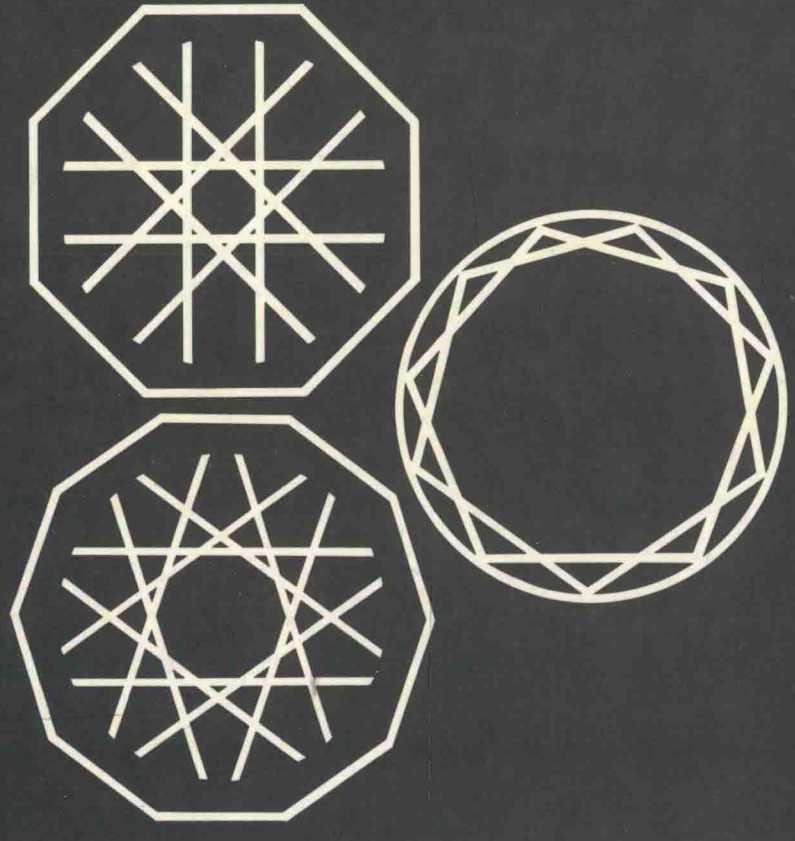
INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE

Stephen A Bent Richard L Schwaab David G Conlin Donald D Jeffery



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The designs on the cover are each stylized renditions of a different configuration of the DNA helix, viewed from the top of the molecule. The B configuration (bottom design) is that of the familiar, right-handed DNA helix, and predominates in biological systems. The A and D forms (middle and top respectively) are variants of the right-handed helix — a third C variant is also known — wherein base pairs are tilted relative to the longitudinal axis of the molecule. Yet another configuration (not shown) is characteristic of the *left*-handed double helix of Z-DNA, so named because its backbone zigzags around the molecule. The Z form is nearly the complete inverse of A, and its base pairs are displaced 180° away from the position they occupy in the B form. The biological significance, if any, of Z-DNA is unclear. (Cover illustrations by Sarah Moseley).

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FOREWORD

Perhaps more than any other single event, the 1980 Chakrabarty decision of the U.S. Supreme Court increased the awareness of lawyers, technologists and businessmen as to the possibilities of obtaining intellectual property protection, and particularly patent protection, for innovations in biotechnology. In the wake of that landmark case, numerous courses sprang up to inform the interested circles about opportunities for protecting the exciting, new advances in applied biology, and it was in these courses that the present book had its beginnings.

In 1981, at one of the first seminars in the United States on biotech intellectual property law, David Conlin presented materials pertaining to trade secret protection and property rights in applied biology. During the following year, Conlin and fellow attorney Richard Schwaab lectured together on the subject of protection for biotechnological innovations internationally. At that time, Schwaab presented extensive course materials, incorporating information collected from practitioners and governmental authorities from around the world, that dealt with international law and national patent law relevant to the field. Later in 1982, based in part on Donald Jeffery's extensive experience with protecting plant-related inventions, the law firm in which Jeffery and Schwaab were senior members was awarded a contract from the Office of Technology Assessment (OTA) of the U.S. Congress to prepare an in-depth survey of intellectual property protection for biotechnological subject matter, including plants, under both international treaty provisions and the national laws of the principal nations. In view of his expertise on trade secret protection for biotechnological subject matter, Conlin was asked to collaborate on that section of the OTA report.

The resulting report began to look like a book. As the three original writers were committing to the arduous task of making that book a reality, a catalytic event took place -- Stephen Bent joined the law firm in which Jeffery and Schwaab practice, bringing to the project a varied background in the biological sciences and a special interest in biotechnology patent law. He contributed the conceptual model of biotechnology innovation set forth in Chapter 2, which provided the framework upon which the remainder of the materials were organized.

All that remained was for four full-time practitioners in intellectual property law somehow to work into their schedules the completion of a treatise of daunting proportions. The delays to that end have been burdensome, both to their publisher and to their colleagues around the world whose contributions were critical. But the delays have also been propitious in that they allowed the authors to incorporate several important, late-breaking developments into a perspective on biotech intellectual property that is still evolving world-wide.

The authors wish to express their appreciation to all those persons (too numerous to mention here, but see the list of acknowledgements below) who contributed to this book, by supplying information, offering suggestions or giving of their time to collect and organize material, prepare manuscripts, proofread, review, etc. A special thanks goes to Ms. Pamela Hay and Ms. Carrie Bagwill for their assistance in the research and preparation phases of this project. We also gratefully acknowledge the assistance and support provided by Professors Beier and Straus in making available the invaluable research resources of the Max Planck Institute for Foreign and International Patent, Copyright and Competition Law in Munich.

The Authors

July, 1987

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We wish to thank the following institutions and individuals for their help in our ongoing effort to keep up with biotechnology developments worldwide. An omission of any one of our collaborators is a reflection only of the great number of colleagues who have graciously extended a helping hand to us over the last three years. Whatever errors have crept into this text, despite the best efforts of our publisher, are ours alone.

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ADDENDA

While this book was in press, decisions were publicized that affected two notable biotechnology patent cases.

(1) The first case involved a European patent No. 0 032 134, granted to Biogen, N.V. on August 15, 1984, corresponding to a U.S. patent discussed in Chapter 5 (text at note 65). The Opposition Division of the European Patent Office revoked Biogen's European patent in the face of objections raised by eight parties who had filed oppositions (and a ninth party-intervenor who had been accused by Biogen of infringement) in 1985. Decision of June 10, 1987 (copy provided by Patentanwalt Dr. W. Stockmair, Munich).

The Opposition Division ruled against the patentee on a crucial question of priority -- whether various claims of Biogen's European application were entitled, respectively, to the filing date of any of three earlier-filed applications -- but also on several other issues of specific relevance to biotechnology patents practice. It was decided, for example, that the prior existence (and 'public' availability, at least to Biogen) of a gene bank consisting of fragments of fetal human chromosomal DNA joined to bacteriophage DNA defeated the novelty of Biogen's broader claims to a 'recombinant DNA molecule,' even though (a) it was Biogen that had demonstrated, a posteriori, that the gene bank included a cloning-suitable (intron-less) DNA sequence encoding 'a polypeptide of the IFN-α type' and (b) it was acknowledged that there had previously been 'a possibility of success' for the skilled practitioner's obtaining such a DNA sequence from the gene bank. (For a case where a similar consideration aided the cause of a U.S. applicant, see Chapter 5, text at note 44.) It is expected that the revocation decision will be appealed within the EPO.

(2) The second case of note involved the holding of an English Patents Court that a claim to '[h]uman tissue plasminogen activator as produced by recombinant DNA technology' covered 'a product ... produced by any known or hereafter discovered route in the field of recombinant DNA technology' and, hence, was 'too wide.' Decision of July 7, 1987, 'In the Matter of a Petition by The Wellcome Foundation Ltd. to revoke Letters Patent No. 2,119,804 granted to Genentech Inc.' (petition granted; appeal pending) (copy of opinion provided by Hilary Newiss, London). The court thus opined, albeit indirectly, on the interpretation of product-by-process claims, an issue of considerable interest (see Chapter 6, text after note 97).

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