Preface

The major advances in the identification of the human genome that took place from the early 1990s onwards triggered a significant increase in the number of patent applications concerning newly discovered human gene sequences that nevertheless failed to disclose the function of the isolated material, and thus did not meet the patent law requirement of industrial application. To address this issue, the 1998 Directive on the legal protection of biotechnological inventions (Biotech Directive) required patent applicants to disclose the industrial applicability of inventions covering human gene sequences and related proteins at the time of the patent application. Furthermore, the Biotech Directive established functionality-related protection for all types of genetic patents, thus restricting the scope of protection granted to these kinds of inventions to their ability to perform the industrial application disclosed by the applicant. The adoption of those criteria as regards the industrial applicability of gene patents did however contrast with the traditionally vague implementation of this requirement.

This book analyses the implications of the Biotech Directive’s approach towards the industrial application of human genes and fragments thereof in respect of three issues: the assessment of the industrial applicability of inventions concerning sequences or partial sequences of human genes; the distinction between discoveries and patentable inventions when the claimed subject matter is human genetic material; and the determination of the scope of protection awarded to patents over genetic information.

It is argued that the Biotech Directive’s stringent approach towards the requirement of industrial application can act as an efficient policy option for preventing the grant of patents over human genetic discoveries that are of no practical benefit to society, but also for impeding the issuance of overly broad patents in this field. At the same time, a strict interpretation of this requirement does not necessarily imply that the interests of patent applicants may be systematically overlooked, but it can form the basis of a balanced standard that serves to avoid the rise of undue barriers in the pursuit of research and innovation in this industry.