Recent conjunction of biotechnology and intellectual property rights has long-term implications for law and society. Intellectual property laws that were framed in industrial age have proved to be insufficient in the current information age. In the present age, modern biotechnological inventions, particularly genetic inventions differ markedly from chemical and mechanical inventions that have been the traditional subject matter of patents. With the development of human genomics and success of Human Genome Project, gene becomes more important because of its informational content rather than its material qualities (physical attributes). Moreover, the emergence of bioinformatics and genomic databases has changed the face of biotechnology from lab-based technology to computer-based science, posing new challenges for intellectual property laws. In addition to legal implications, patents on gene and gene fragments have significant social and policy implications. Over-broad patent claims on genetic research tools and diagnostic genetic testing and aggressive licensing practices relating to them have serious implications for genetic innovation, health policies, patients’ rights and society at large. In genetic research, increased extension of intellectual property rights to human genetic material may have an adverse impact upon the interests of research subjects from whom the human genetic material is extracted. Against this backdrop, the book analyses the legal and social implications arising from the conjunction of biotechnology and intellectual property rights, focussing particularly on human gene and genetic variations.

The book locates emerging legal, social and policy issues pertaining to biotechnology and intellectual property laws and suggests some meaningful solutions to them. The discussion in the book is streamlined to respond to few important questions: whether existing intellectual property laws at national and international levels can cope up with the challenges posed by biotechnology (especially genetic technology); whether aggressive assertion of intellectual property rights to genetic research tools, fundamental genetic research and human genetic resources stands in conflict with the rights of patients, independent researchers and research subjects; and whether open and collaborative biotechnology promotes genetic research and innovation. There are numerous books on intellectual property rights which deal with biotechnology, however, the present book provides a comprehensive overview of biotechnology and intellectual property rights and connects various aspects of
the topic in an integrated manner, providing a fresh insight of law–biotechnology
interface in tune with the current information age. It is aimed at providing basic
and comprehensive knowledge pertaining to the topic to a wide range of audience
comprising legal practitioners, law students, researchers and scholars interested in
interdisciplinary research, policymakers and others interested in biotechnology and
intellectual property rights.

The book is divided into seven chapters. Chapter 1 introduces the theme of the
book and contains the background of the book, the concepts of biotechnology and
intellectual property rights and the framework of the book. In Chap. 2, the book
analyses the patent approaches of the USA, European Union, Canada and India on
the basis of patent laws, administrative decisions and case law, bringing common
points and differences among and between them. The book concludes that the se-
lected countries for the study vary significantly in their approach to biotechnology
in degree of patent protection and patent exclusions; however, all of them recognise
patenting of biotechnology invention, given its commercial potential. In Chap. 3,
the book analyses the international patent regime dealing with biotechnology, high-
lighting the potential gaps and uncertainties as to the scope of numerous terms such
as invention, microorganisms, microbiological processes, essentially biological
processes under TRIPS. It also discusses the impact of such uncertainties on de-
veloping countries given their relatively slow pace of scientific and technological
development and the persistent conflict between developed and developing coun-
tries regarding the harmonisation of patent laws. Chapter 4 of the book undertakes
the analysis of the social and policy implications of patents on genetic research
tools and genetic testing and comes up with the conclusion that these concerns
cannot be adequately addressed only by making changes in the patent systems as
patent law is not expected to provide solutions to broad social and policy issues. It
insists upon formulating policies and making legislations specific to genetic patents
to regulate the patent practices such as patent licensing in order to provide viable
solutions to such issues. The book analyses the ill effects of Myriad Genetics’ patent
claims on BRCA1 and BRCA2 gene, which prevents patients from taking a second
opinion and verification testing. It concludes that in diagnostic field, exclusive li-
censing of genetic tests often obstructs the accessibility of genetic innovation or
diagnostic genetic testing and advocates for non-exclusive licensing. In Chap. 5, the
book examines the intricacies involved in providing effective intellectual property
protection to bioinformatics and genomic databases and suggests a comprehensive
review of existing intellectual property laws in the light of present information age.

Keeping in view the collaborative nature of bioinformatics and genomic databases,
the book evaluates the pros and cons of open biotechnology. The book analyses the
extension of intellectual property rights to human genetic resources in the light of
benefit sharing and informed consent in Chap. 6. It explains the ownership puzzle
of human genetic material used in genetic research and suggests that ownership
rights of research subjects in their extracted genetic material must be recognised.
The book insists upon a careful application of intellectual property rights to human
 genetic resources. The concluding observations and possible way outs are provided
in Chap. 7.
Despite the complex nature of the topic, the book approaches the issues pertaining to the topic in a clear, integrated and meaningful way. Though the analysis of the patentability of biotechnology in the book is limited to four jurisdictions, it gives fresh insights of biotech patent trends in different social, political and economic setups. It would be helpful in striking a balance between harmonisation and differentiation of patent laws. The analysis of social and policy implications of genetic patents is limited to available literature and supporting data. Since the science involved in biotechnology is of evolving nature, it is difficult to come up with definite solutions, however, the book provides an insight of law–biotechnology interface, highlighting emerging issues and providing some possible solutions to the existing problems.

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