

## Author's Preface

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. Overbroad 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 selected 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, highlighting 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 developing countries given their relatively slow pace of scientific and technological development and the persistent conflict between developed and developing countries 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 licensing 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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