

## BOOK REVIEW

**BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS-  
LEGAL SOCIAL IMPLICATIONS**

Author(s): **Dr. Kshitij Kumar Singh**, Year: 2014, **Format:** Hard Cover, **Edition:** First,  
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Undertakes the analysis of legal as well as social implications of biotechnology and Intellectual Property Rights by focusing particularly on human gene Provides insights of biotech patent trend and its implications in different social, political and economic set up Presents interpretation of facts and theories that suggests meaningful solutions to the contemporary problems

This book offers a valuable contribution to contemporary legal literature, providing deep insights into the interface between law and genetics, highlighting emerging issues and providing meaningful solutions to current problems. It will be of interest to a broad readership, including academics, lawyers, policy makers and scholars engaged in interdisciplinary research.

In the context of examining and analyzing the legal and social implications arising from the recent conjunction of biotechnology and intellectual property rights, the book particularly focuses on human genes and gene variations. Emphasis is placed on “patent law,” as a considerable percentage of genetic inventions are covered by patents. The book presents a comparative and critical examination of patent laws and practices related to biotechnology patents in the United States, Canada, European Union and India, in order to gather the common issues and the differences between them. The international patent approach regarding biotechnology is also analyzed in light of the constant conflict between differentiation and harmonization of patent laws. The book highlights the potential gaps and uncertainties as to the scope of numerous terms such as invention, microorganisms, microbiological processes, and essential biological processes under TRIPS. Also analyzed are

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the social and policy implications of patents relating to genetic research tools and genetic testing. The intricacies involved in providing effective intellectual property protection to bioinformatics and genomic databases are also examined. Bearing in mind the collaborative nature of bioinformatics and genomic databases, the book evaluates the pros and cons of open biotechnology and assesses the implications of extending intellectual property rights to human genetic resources, before explaining the ownership puzzle concerning human genetic material used in genetic research.

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, focusing 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 *Chapter 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 *Chapter 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 harmonization 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 BRCA-1 and BRCA-2 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 *Chapter 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 *Chapter 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 *Chapter 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 harmonization 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.

## **NATURE, PURPOSE AND FOCUS OF THE BOOK**

In the line of the foregoing discussion, the book analyses the legal and social implications arising from the conjunction of biotechnology (specifically, genetic technology) and IPR. The study concentrates on a particular aspect of biotechnology i.e. the human gene. Since the traces of human gene patents are deeply rooted in the development of biotechnology patents as a whole, the present study carries discussion on biotechnology patents. For the purpose of the book, legal implications mean the challenges posed by biotechnology (especially genetic technology) before the existing IP laws. Social implications mean the wider implications of the genetic patents on the society, comprising various stake holders as patients, researchers,

scientists, indigenous people and other social groups. The nature of the study is interdisciplinary, which focuses upon the interface of law and technology. In the discussion of the law-human genetic interface, ethical concerns are bound to come. These ethical concerns sometimes guide law to promote social good and reach legal excellence. Therefore, though the present study is primarily concerned with the legal and social implications, it also includes concerns relating to bioethics.

The book adds to the existing knowledge, giving fresh insights regarding the patent approaches of various countries to human gene patents. It analyses the potential gaps and ambiguities in international patent laws in the light of harmonisation and differentiation of patent laws. The book would be useful for India to develop better understanding of biotechnology patents by looking into the IP approaches of different countries and international practices and select the best, most appropriately suited to its own conditions.

## THE FRAMEWORK OF THE BOOK

The book is divided into seven chapters. *Chapter 1* introduces the topic in a lucid way, giving a proper legal and scientific background and connecting various aspects of the study. It contains the background of the book, conceptual framework of biotechnology and IPR, nature, purpose and focus of the book and the theme of the chapters.

*Chapter 2* analyses the different patent approaches adopted by the USA, Canada, European Union and India regarding biotechnological inventions (especially genetic inventions) to bring about common issues and differences among these jurisdictions.

In Chap. 2, the author analyses the patent approaches of the USA, European Union, Canada and India on the basis of patent laws, administrative decisions and case laws, bringing common points and differences among and between them. The author comes up with the conclusion that the selected countries for the study vary significantly in their approach to biotechnology in the degree of patent protection and patent exclusions; however, the common point among them is that they all recognize patenting of biotechnology invention, given its economic value. He concludes that patent laws in the entire four jurisdictions struggle to cope up with new biotechnology inventions. In the light of such struggle, the author insists upon a comprehensive review of existing patent laws to address the genetic inventions in tune with the information age. He maintains that lack of such approach may prevent some useful inventions from society. As regards to the divergence in patent approaches of countries opted

for the study, the author emphasizes that the patent approach should always follow the socio-economic conditions of a particular country. He adds further that while making a distinction between patentable and non-patentable subject matter, the degree of human intervention should be considered.

In *Chapter 3*, the author 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. He also discusses the impact of such uncertainties on developing countries given their relatively slow pace of scientific and technological development. The author explains the intricacies involved in providing an effective patent protection to new biotechnology inventions (that differ markedly from traditional subject matters of patents) at the international level in the light of technology neutral character of TRIPS.

*Chapter 4* includes the study regarding the implications of patenting of genetic research tools and basic genetic research on the accessibility of genetic innovation. It discusses the viability of research exemption clauses under patent laws, and other relevant statutes regarding the accessibility of genetic research tools. The emphasis is on the patenting of genetic tests for diagnostic purposes and their impact on the rights of patients, researchers and other stakeholders. In this chapter, the author undertakes a detailed study of Myriad Genetics' patents on BRCA1 and BRCA2 genes, which prevents patients from taking a second opinion and verification testing.

The author maintains that the social and policy implications of patents on genetic research tools and genetic testing cannot be adequately addressed only by making changes in the patent systems as patent law is not expected to provide solution to broad social and policy issues. He 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 author adds that exclusivity provided by aggressive patent licensing strategies may not be in the public interest, and there is a continuing need for active defence of open science.

In *Chapter 5*, the author 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 the present information age.

Keeping in view the collaborative nature of bioinformatics and genomic databases, the author evaluates the pros and cons of open biotechnology. He suggests that a variety of licensing schemes with or without intellectual property should be used to support the open nature of bioinformatics and genomic databases. The author adds that the intellectual property approach to bioinformatics should be balanced in such a way that it should not only incentivize the inventor or creator but also ensure the open and collaborative nature of bioinformatics.

In *Chapter 6*, the author analyses the extension of IPR to human genetic resources in the light of benefit sharing and informed consent. He 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 recognized.

Further, if researcher or sponsor conducting the research gains any benefit, the equitable sharing of that benefit must also be recognized. The author insists upon a careful application of IPR to human genetic resources. He also suggests that a clear distinction should be made between human genetic resources and nonhuman genetic resources and demands a specific legal approach to the former at the international level.