

Biotechnology and Intellectual Property Rights

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Legal and Social Implications



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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. 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 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.

In the process of writing this book, the support provided by the individuals and institutions is noteworthy. In this context, I most sincerely convey my deep sense of gratitude to my supervisor and guide in LL.M. and Ph.D., Prof. G. P. Verma, Law School, Banaras Hindu University (BHU), India, for his remarkable guidance and academic support during my work. As a supervisor, he has always encouraged me to produce quality work with his scholarly inputs. I am grateful to Prof. M. P. Singh, Law School, BHU, for igniting my thought process to cover some vital issues pertaining to my topic by his critical observations. I wish to express my sincere gratitude to Prof. Ali. Mehadi and Prof. R. K. Murali of Law School, BHU, for their encouragement and support they offered me during the work. I am grateful to Mr. Vinai Kumar Singh, Indian Society of International Law, New Delhi, for his great cooperation and support extended during the preparation of the book.

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List of Abbreviations

ACLU	The American Civil Liberties Union
AIA	American Invents Act
AIPLA Q.J.	American Intellectual Property Law Association Quarterly Journal
All ER (EC)	All England Law Reporter (European cases)
Art.	Article
ASU	Arizona State University
C. J.	Chief Justice
C.A. Fed. (Cal.)	Court of Appeals, Federal Circuit., California
C.A. Fed. (N.Y.)	Court of Appeals, Federal Circuit, New York
CAFC	Court of Appeal for Federal Circuit
CBAC	Canadian Biotechnology Advisory Committee
CBD	Convention of Biological Diversity
CDISC	Clinical Data Interchange Standards Consortium
CGIAR	Consultative Group on International Agricultural Research
CIHR	Canadian Institute of Health Research
CLIA	Clinical Laboratory Improvement Amendments
Co.	Company
Corp.	Corporation
CRP	Community Research Projects
Cust. & Pat. App.	Court of Customs and Patent Appeals Reports
D.C.	District of Columbia
DAS	Distributed Annotation System
DDBJ	DNA Database of Japan
DNA	Deoxyribonucleic Acid
DOE	Department of Energy
e.g.	Exempli Gratia
E.P.O.R	European Patent Office Reports
ed.	Edited by
edn.	Edition
eds.	Editors
EMBL	European Molecular Biology Laboratory

EMR	Exclusive Marketing Rights
en banc	In the bench
ENCODE	Encyclopedia of DNA elements
epo	Erythropoietin
EPO	European Patent Office
EST	Expressed sequence tag
et.al.	Among others
EU	European Union
F.T.R.	Federal Trial Reports
FAR	Federal Acquisition Regulations
FOSS	Free and Open Source Software
GATT	General Agreement on Tariffs and Trades
Hap Map	Haplotype Mapping Project
HC	High court
HGI	Human Genome Initiative
HGP	Human Genome Project
HIPAA	Health Insurance Portability and Accountability Act
HUGO	Human Genome Organisation
i.e.	That is
I.P.L.R.	Industrial Relations Law Reports
Ibid	Ibidem (in the reference immediately cited)
ICTSD	International Centre on Trade and Sustainable Development
Id	At the same
IDA	International Depository Authority
IMTECH	Institute of Microbial Technology
in re	In the matter of
Inc.	Incorporation
IP	Intellectual property
IPR	Intellectual Property Rights
IRB	Institutional Review Board
ITPGRFA	International Treaty on Plant Genetic resources for Food and Agriculture
JPO	Japan Patent Office
LDCs	Least developed countries
MCH	Miami Children's hospital
MPOP	Manual of Patent Office Practice
MPPP	Manual of Patent Office Practice and Procedure
MTAs	Material Transfer Agreements
MTCC	Microbial Type Culture Collection
N.D.Cal.	Northern District of California
NAFTA	North American Free Trade Agreement
NCHGR	National Center for Human Genome Research
NCIC	National Cancer Institute of Canada
NIH	National Institutes of Health

NISCAIR	National Institute of Science Communication and Information Resources
No.	Number
OBF	Open Bioinformatics Foundation
OECD	The Organisation for Economic Co-operation and Development
OHIP	Ontario Health Insurance Plan
OJEPO	Official Journal of the European Patent Office
OTA	Office of Technology Assessment
P.A.B.	Patent Appeal Board
Para.	Paragraph
PBRA	Canadian Plant Breeders' Rights Act
dPCT	Patent Cooperation Treaty
PHOSITA	Person having ordinary skill in the art
PLT	Patent Law Treaty
pp	pages
PPF	Public Patent Foundation
PSA	Prostate-Specific Antigen
PTO	Patent and Trademark Office
Pvt. Ltd.	Private limited
PXE	Pseudoxanthoma elasticum
Quid pro quo	One thing in return for another
R&D	Research and development
RNA	Ribonucleic acid
S. Ct.	Supreme Court of United States
S.C.R.	Supreme Court Reports
S.D.N.Y.	Southern District of New York
SCC	Supreme Court cases
SDOs	Standards Development Organizations
Sec.	Section
SNP	Single nucleotide polymorphism
SPLT	Substantive Patent Law Treaty
Supra	Above or on an earlier page
TKDL	Traditional Knowledge Digital Library
TNF	The tumor necrosis factor
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TUA	Technology Use Agreement
U.S	United States
U.S.C	United States Code
U.S.P.Q.	United States Patents Quarterly
UCLA L. REV	University of California, Los Angeles Law Review
UK	United Kingdom
UNCTAD	United Nations Conference on Trade and Development
UNESCO	Cultural Organization
UPOV	Convention on Protection of New Varieties of Plants
USPTO	United States Patent and Trademark Office

v.	Versus
Vol.	Volume
w.e.f.	With effective from
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

About the Author

Kshitij Kumar Singh is an Assistant Professor at the Amity Law School, Noida, India. He obtained his Ph.D. (Law) from the Banaras Hindu University, Varanasi, India. During his doctoral study, he received the Canadian Commonwealth Scholarship Asia-Pacific 2010. The field of gene patenting and biotech law has been of special interest to him. Dr. Singh's LL.M. dissertation is on the topic "Human Genome and Cloning: Legal and Human Rights Issues"; he has also published many articles on biotechnology law. He gained related experience as a research intern (2009) and a visiting research fellow (2010) under the Canadian Commonwealth Scholarship 2010 at the University of Western Ontario, London, Canada. During this period he examined laws governing or needing biotechnology developments in India and Canada. The term was instrumental in expanding his research interest to the international aspect of the laws governing genetic patents and biotech research.