# Biotechnology and Intellectual Property Rights

Kshitij Kumar Singh

# Biotechnology and Intellectual Property Rights

## Legal and Social Implications

Springer

Kshitij Kumar Singh
Amity Law School
Noida
Uttar Pradesh
India

ISBN 978-81-322-2058-9 ISBN 978-81-322-2059-6 (eBook)
DOI 10.1007/978-81-322-2059-6
Springer New Delhi Heidelberg New York Dordrecht London

Library of Congress Control Number: 2014948601



Printed on acid-free paper

Springer is part of Springer Science+Business Media (www.springer.com)

# 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.

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.

I take this opportunity to express my sincere regards to one of the most eminent scientists of India and great visionary, Dr. Lalji Singh, Vice Chancellor, BHU, who has always been a great source of inspiration for me regarding my academic pursuit. He encouraged me to work on law–technology interface. I am highly obliged to Prof. Mark Perry, who provided me an excellent environment to hone my research skills during my visit to Faculty of Law, University of Western Ontario, Canada, which helped immensely while writing my book. It was his guidance that broadened and advanced the level of my research and enabled me to develop global understanding of the subject. I am thankful to my friend Dr. Thomas Margoni, Institute of Information Law, Faculty of Law, University of Amsterdam, for sharing his thoughts over the topic of my book and encouraging my work. I am also thankful to my juniors Hemant, Bipin, Gaurav, Saurabh and Abhinav, who have been sincerely engaged with me during my work and extended their full support.

I sincerely acknowledge the support provided by the staff of Center for Cellular and Molecular Biology (CCMB), Hyderabad, India. I extend my thanks to the Library Staff, Law School, BHU, particularly Mr. Brijpal and Mr. Shobhnath for providing me valuable resources relating to my book. I must acknowledge the great support extended by the Library Staff of Faculty of Law, University of Western Ontario, Canada, Indian Law Institute, New Delhi, and Indian Society of International Law, New Delhi.

I am thankful to Sagarika Ghosh and Nupoor Singh at Springer India for their continuous support and cooperation and anonymous reviewers for Springer for their incisive and constructive comments.

Lastly, but most importantly, I acknowledge the contribution of my parents from the bottom of my heart, who have always pushed me to follow my dream and encouraged me to strive for academic excellence even in adverse situations. I wish to acknowledge and admire all kind of support and assistance provided by my siblings, Renu, Alok, Pooja and Prabhakar during my work.

NOIDA
May 2014

Dr. Kshitij Kumar Singh
Asst. Professor
Amity Law School NOIDA
Amity University U.P.

# Contents

# 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. | Exampli 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.