

**Biotechnology and Intellectual Property Rights: Legal and Social Implications.** By Dr. Kshitij Kumar Singh, Springer, New Delhi, 2015, Pp. x- 250, Price: \$99.00 (Handbook), ISBN: 978-81-322-2059-6.

Recent development in biodiversity, biotechnology, and bioinformatics has paved the way for commercial innovations and investments juxtaposing the regime of the global patent system and public welfare. As biodiversity provides the basic material for the apparatus of biotechnology for research and innovation to be used in bioinformatics, where such biological research data and information are stored, analyzed, and procured with the help of genetics and information technology. Increased commercialization of biological material, biotechnological research and bioinformatics tools has stimulated the research and business community to think seriously about monetary investments and intellectual property protection. In this context, this selected book offers an important contribution in recent literature on biotechnology and intellectual property rights (IPRs) interfacing law and technology.

This book has altogether seven chapters focusing on legal, social, and policy implications of patentability in biotechnological developments. In the introduction, the chapter sets out the background for biotechnology and IPR interface, providing legal developments. Then, chapter two makes a comparative and critical study of patentability of biotechnological innovations in the four jurisdictions, *i.e.*, USA, Canada, EU, and India. The third chapter tries to examine the legal norms for the patentability of biotechnological innovations under TRIPs, the Substantive Patent Law Treaty, and other international instruments. The fourth chapter deals with the humane genomes and related issues such as patentability, patent quality, and impact on public health. Fifth chapter discusses the IP protection of bioinformatics tools and databases, along with recent trends of open bio-development. The sixth chapter deals with the aspects of ownership, access, and benefit sharing (ABS) and prior informed consent (PIC) in relation to patenting of genetic inventions. The last chapter provides conclusion and further suggests certain innovative reforms at the end. Above all, the author has drawn attention towards these difficult and complicated issues, providing proper legal and technological background related to intellectual property and biotechnology with the aim of providing legal and policy implications in the contemporary age.

First chapter outlines the interaction of biotechnology and intellectual property protection which has posed unprecedented challenges before the established law and ethics. The author states that “the existing intellectual property laws struggle to cope up with challenges posed by biotechnology legal advances as they were framed in an age when such advances were not foreseen by the framers.” He points out that “the traditional doctrines of IPRs laws have been extended to new subject matters such as genes, proteins, and other molecular living organisms,” which has become beyond the purview of law. Because of this, there have been certain disputes and dissents arising in recent times due to “certain ambiguities and potential gaps in the existing laws, administrative decisions, and case laws.”

Chapter two provides “the patent approaches of the USA, EU, Canada and India on the basis of patent law, administrative decisions and case laws bringing common points and differences among and between them.” He finds that the common differences basically depend upon the socio-economic conditions of these countries. Finally, he concludes that

“patent laws in these four jurisdictions struggle to cope with new biotechnological inventions.” He henceforth demands a comprehensive review of the existing patent legal regime to address the gene-related invention or innovation in this digital age.

Chapter three provides analysis of “international patent legal regime relating to biotechnology”, and thus highlights the potential gaps and ambiguities in TRIPs text. The global patent regime dealing with biotechnology has been analyzed in the light of the differentiation and harmonization approach in the current scenario. The author also explores “the impacts of such uncertainties and difficulties for developing nations in view of their slow pace of scientific and technological development.” He concludes that such uncertainties and ambiguities have a great impact and implication in arriving the “harmonisation of patent law” and setting up a “uniform patent system” in the present technological age.

Chapter four discusses the imperatives of patenting the research tools and techniques in the name of genetic innovations. It relates the issues of accessibility and quality for public health from legal, social and policy prospects. The emphasis has been made on “patenting of the genetic tests for diagnostic purposes and its impacts on the rights of patients, researchers, and other stakeholders.” The author points out that “the social and policy implications of patents on genetic research tools and genetic testing cannot be adequately addressed only by making change in the patent system and patent laws.” Such laws have not been formulated to provide solutions to broad and dimension social and policy problems of different countries. Thus, the author insists upon preparing specific policies and enacting legislation for patent on gene research to regulate the patent practices in specific countries.

Chapter five further examines the interests and synergies involved with intellectual property protection to bioinformatics and genomic databases. It discusses the transition of biotechnology to bioinformatics, genetics to genomics, stimulating to legal protection under intellectual property rights law. He suggests further that “a comprehensive review of existing intellectual property laws in the light of the present information age is urgently required”. Keeping an account of the collaborative nature of biotechnological research, bioinformatics tools innovation, and genomics database, there has been evaluated scope and merits of open biotechnology with certain examples in the Human Genome projects. The author finds that the IP protection to bioinformatics and genomic databases has to be provided in a balanced way so that it should not be only helpful for inventors, creators, and intermediaries, but also ensure the collaborative and open nature of research to promote innovation in public welfare especially in developing nations.

Chapter six extends the debate for the extension of patent protection under the IPR regime to human gene in view of ownership, informed consent, and benefit sharing. The author expresses that the ownership issue on human genetic materials used in research has been raised from the beginning on social and ethical grounds. It has been considered a global genetic common, which is now converted into private property due to extension of IPR over them. The author suggests that “ownership rights on research subjects in their extracted genetic material must be recognized.” The author has also mentioned certain international legal instruments such as ‘International Agreement on Access of Human Genetic Resources and Benefit Sharing’, the CBD and TRIPs, in this regard. Further, the author highlights the issue of access and benefits sharing (ABS) by advocating that “if researchers and sponsors conducting the research, gain the benefits, the equitable sharing of that benefits must also be provided under the law.” The author at the end suggests possible solutions on these issues

through benefit sharing clauses, certificates of origin options and certain modifications in the existing patent system. Chapter seven concludes the overall observations and possible suggestions derived from the book.

Above all, this book gives fresh insights regarding biotechnology and law interface providing inter-disciplinary approach in current technological age. The author maintains that wider implications of biotech patents on society cannot be addressed by patent law exclusively, but it can be properly addressed by curving out significant legislative and administrative steps, streamlining licensing strategies and formulating effective public policies. However, the book's coverage on biotechnology patenting and relevant issues in four jurisdictions (EU, USA, Canada, India) is highly ambitious, which has not been balanced evenly and handled properly. The patenting of biotechnological innovations in USA and Canada has been analyzed heavily in twenty-five pages and eighteen pages respectively, compare to EU and India in around six and eight pages only. Even, author has not given adequate reasons for choosing those diverse countries European Union, Unities States America, Canada including India to this multi- jurisdictional comparative review on biotechnological patents. Besides, the book does not provide a case law index, as lots of cases has been cited on several times, which would have been quite useful for broad research community. Despite its weakness, this has been fair effort by the author to discuss the issues relating to biotechnological innovation and patent protection which would help the reader to know the national and international legal development in this regard. It will be quite useful for board readerships including law scholars, legal professionals, researchers, policy makers and those doing interdisciplinary studies.

*Amrendra Kumar\**

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\* PhD (Jawaharlal Nehru University, New Delhi); Assistant Professor, Law Centre-II, Faculty of Law, University of Delhi, Delhi, India.