

Law relating to Biotechnology (Book Review)

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ABSTRACT

The book attempts to present the law relating to biotechnology regulation at international, regional and national levels. The various legal issues pertinent to biotechnology including but not limited to policy issues, intellectual property issues, trade related aspects of biotechnology, environmental concerns of biotechnology, biodiversity matters of biotechnology, human rights concerns in biotechnology have been debated with the help of various international documents and judicial decisions made by the international legal institutions and as well judicial bodies in the select regions such as USA, UK, Europe and India. At the outset the book attempts to present and analyze the law relating to biotechnology in a lucid way while analyzing the historical, colonial, 20th century and as well contemporary developments in this regard. At the moment there is no book which is similar to the current one analyzing most of the touching issues of law and policy on biotechnology.

Introduction

In the introductory chapters of the book¹, the scientific analogy and development of biotechnology and also varied applications and commercial uses of biotechnology that raises legal concerns have been presented in a lucid manner. Further, it highlights the varied legal issues pertinent to biotechnology at the same time presenting the development and applications of biotechnology. In the later chapters, Intellectual property, trade policy, environmental concerns, biodiversity issues, human rights connections of

biotechnology have been lucidly analyzed, discussed and presented by the author in an interesting manner. The various legal concerns have been discussed from the perspective of the USA, Europe, the UK and India. In fact, there is one exclusive chapter on biotechnology regulation in India, which highlights regulatory canopy on biotechnology in India. The author has made an attempt to showcase different legal aspects of biotechnology promotion, protection, regulation and governance at international, regional and domestic levels. Law and policy issues pertinent to the most promising, sophisticated and yet

¹ Law relating to Biotechnology, the book is published by Oxford University Press (OUO), London in 2016

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controversial technology in the contemporary world have been discussed, debated, analyzed and presented in a simple, the scientific and specific manner by the author. The book is an interesting must-read for all those working directly and indirectly in and around the field of biotechnology, its application and regulation. The chapter-wise discussion on varied issues in the book could be inferred as follows.

1. Biotechnology: The science of wonders

The first chapter introduces the concept of biotechnology by defining it and by providing an understanding of biotechnology with conceptual analysis and clarity. The nature of biotechnology is debated by dwelling on its quest for a quest for perfection and the urge for more. The different classifications of biotechnology are provided. The origin and development of biotechnology have been traced in the chapter. The development of biotechnology through its humble beginning, early times and middle ages have been analyzed. Expansion of boundaries of biotechnology, genetic research and the new face of biotechnology has been highlighted. Biotechnology and its capacity to cater to different needs of the community, biotechnology and its interface with information technology, its dominance over nature are presented. The origin and development of biotechnology as a science of wonders are analytically presented and highlighted in the chapter. This chapter enables the reader to understand biotechnology from its scientific point of view with precision to gain the ability to analyze

the same in the context of law and policy issues that may crop up in the use, application and exploitation of biotechnology.

1. Biotechnology Dynamics and Applications

The second chapter discusses the dynamics of biotechnology and its varied business applications. The dynamics have been presented through analyzing various milestone innovations and techniques of biotechnology such as plant breeding techniques, tissue culture, hybridoma technology, genetic engineering, cloning, human genome project, penicillin, antibiotics, vaccines, insulin, transgenic organisms, a transgenic plant, transgenic animal, genetic material, and stem cell research. Further varied business applications of biotechnology in the fields of agriculture, food, medicine, environment and sustainable development, livestock, energy sector have been discussed while debating on the multidisciplinary approach of biotechnology. The intention was to analyze and present various dynamics and business applications of biotechnology where law and policy interaction could be felt. For mapping law and policy interaction, for debate on legal and policy issues in biotechnology, there is a need to have the scientific and technological understanding of the various dynamics and business applications of biotechnology. This chapter enables the readers to understand the varied uses and applications of biotechnology in its exploitation for commercial purposes. This understanding is very much essential to apply the law on the use of

biotechnology in its various fields, as detailed in the chapter.

2. Evolving Policy Framework for Biotechnology

The third chapter explores the policy framework for biotechnology. The evolution of science and technology policy in different countries, its constitutional background and mandate are discussed from the perspectives of India and the USA. The role played by fundamental rights and duties in promoting the cause of science and technology is presented and debated. Ministry of science and technology and its endeavours for the purpose of promotion of science and technology in particular biotechnology are analyzed. The biotechnology policy and strategy in India and developing countries are highlighted. The major components of technology law, various issues and challenges pertinent to biotechnology have been presented. The significance and coverage of biotechnology law as such and also the Indian policy response to biotechnology upsurge is discussed. At the outset, the chapter aims to present the policy response, its coverage, content and broader policy framework for biotechnology. This chapter enables the reader to analyze the policy response to biotechnology before making or applying the law. At the Indian domestic level policy response ranging from fiscal policy, industrial policy, five-year plans, science and technology policy, biotechnology policy and strategy from time to time have been analyzed which would strengthen the understanding of the

reader with respect to the kind of policy response that biotechnology had since the previous century and how such policy response culminated to either making of law or evolution of the law on biotechnology. The policy analysis is very much required as the policy when it gets into the formal legal structure to address various issues, challenges and opportunities that biotechnology throws open through its varied use and applications. From the next chapter onwards, the author has tried to debate on the most prominent legal issues and challenges that biotechnology gives rise to.

3. Intellectual Property Rights in Biotechnology

The fourth chapter presents intellectual property rights issues in biotechnology. It analyses various fields of intellectual property where possible protection and promotion of biotechnology could be found. The expansion of patent law canopy in the USA and Europe, which resulted in patenting biotechnology innovations across the world, including India, is analyzed. Vivid theoretical and doctrinal debates on patenting biotechnology are presented with the help of a number of classical and landmark case laws. Trademarks and trade secrets protection of biotechnology is debated and presented alongside patent protection. Developments in this regard from the perspective of the USA, Europe and India have been analyzed through questioning on patenting of plant, animal, genetic material and such other biotechnology products. The aim was to explore the intellectual property law regime to

ensure possible protection for living innovations of biotechnology under different fields of intellectual property law in different regions. The number of judicial decisions ranging from jurisdictions such as the USA, Europe, the UK and India has been analyzed and presented. Case laws that were decided more than 100 years back have also been interpreted in the debate with respect to the evolution of IPR and Patent legislation on biotechnology. At the outset, the IPR spectrum of laws response on biotechnology upsurge has been very well analyzed in terms of its history, theoretical background, international mandates, social underpinnings and as well the much required normative legal framework².

4. Biotechnology Trade and Environment

The fifth chapter focuses on the biotechnology trade and environment. The issues concerning trade in biotechnology and genetically modified organisms (GMO) have been highlighted in the context of environment and biodiversity. The various legal frameworks within the WTO and international trade regime, including GATT, TBT, SPS agreements, Codex, have been highlighted, and their role in regulating international trade in GMOs is presented. At the same time, given the risks involved in business in GMO regulation of environment and biodiversity concerns have been debated through discussing convention on biological diversity, bio-safety protocol and their

role in GMO trade for ensuring the safety of the environment and sustainable development. Judicial responses to GMO trade and environmental concerns are mapped through discussing milestone court decisions in regions including the USA, Europe which have laid the law in force on GMO trade. The chapter highlights the interface between trade law and environmental law in the context of GMO trade. In this chapter, the author has analyzed judicial decisions from various international legal institutions such as International Court of Justice, International Criminal Court, WTO Dispute Settlement Mechanism, Law of the Sea Tribunal and European Court of Justice.

5. Human Rights concerns in biotechnology

The sixth chapter highlights the human rights concerns in biotechnology. In this regard, responses from the govt of the USA, European response and also the Indian government response has been attempted to be mapped. Various international human rights conventions and agreements have been analyzed in the context of biotechnology and connected human rights concerns. EU directive on biotechnology says on human rights, US and Indian policy response to biotechnology in the context of human rights is highlighted. Human rights issues connected with cloning, genetic research, GM foods have been highlighted. The concept of GM foods, its efficacy, acceptance and associated consumer rights, right to food and such other human rights issues have been debated. Further, the right to health in the context

² The author of the book is a well known author on Intellectual Property Law and his book on the subject have been published by international publishers such as Penguin, USA and LexisNexis, India which are widely available

of biotechnology and genetic research is discussed. The aim was to discuss and debate various human rights concerns involved in biotechnology research, development, innovation, use and exploitation. Two schools of thoughts on biotechnology such as the one thought which considers biotechnology to be the promoter of human rights through ensuring the right to food and medicine through the positive application and use of biotechnology in the food and medicinal sector and the other school of thought that consider biotechnology to be the violator of human rights through its interference in the medical and human sector by commercializing medicine and reducing the living beings to be marketable commodities is extensively debated in this chapter.³

6. Biotechnology Regulation in India

The seventh chapter dwells on the regulatory structure of biotechnology in India. Ranging from 1989 rules on manufacture and use of genetically engineered organisms till the 2013 biotechnology supervisory authority of India bill, all the rules, regulations, guidelines, protocols, bills on biotechnology regulation in India have been discussed and analyzed. The institutional mechanism for regulation of biotechnology in India comprising of various technical, review, advisory and approval committees have been presented and appraised. Government of India approach towards biotechnology promotion,

Parliaments concerns on biotechnology in agriculture, supreme court technical appraisal of biotechnology promotion and regulation have been debated and highlighted. The objective of the chapter was to present, analyze and highlight the existing and prospective regulatory mechanisms in India on biotechnology with its policy underpinnings from different organs of the government of India. The various piecemeal mechanism that India currently is having on the matters of biotechnology regulation is analyzed in detail in this chapter. The infamous Biotechnology Regulatory Authority of India Bill, its concerns and the failures have been analyzed, and at the same time, certain other Bills such as DNA Profiling Bill have also been analyzed. At the outset, the author tries to analyze the regulatory spear on biotechnology in India, which is still at the nascent stage.

Inferences

Law relating to biotechnology is a growing field of law, which in precision puts together different disciplines of law such as IPR Law, Trade Law, Environmental Law, Biodiversity Law, Human Rights Law and such other connected laws together. It also includes various international, multinational, regional and national level legal instruments and initiatives on the subject of governance of biotechnology together in one go. Any attempt to analyze the law that is an application to biotechnology may not be fruitful without touching these finer and familiar aspects of law at multi-levels. Through this book, an attempt has been made to present and analyze the law on biotechnology

³ The author of the book is also well known for his writings on human rights where in his book Human Rights and Development is published by Penguin Publications, Bloomington, Indiana, USA in 2016.

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while detailing on select laws with policy debates and implementation perspectives. Various judicial decisions and international, regional and national levels have added to the fulfilment while the mapping of international, regional and national level legal texts and documents either enacted or adopted have put together and codified the evolving law on the point of argumentation. International society and as well the domestic spears have been in the mode of realizing the potential of biotechnology and varied legal challenges; its use and application are throwing open. In this perspective, efforts have been continuously made on the suitable law for the regulation and governance of biotechnology⁴.

⁴ The book review is done on the invitation of the Canadian Forum for International Law Expertize, (CIFEL) at Toronto, Canada.