CHAPTER - I
INTRODUCTION

"Genomics is the use of genome-wide analytical tools to study the effect of genes, proteins and other gene products on the biological processes of an organism".1

1.1 General Introduction

Biotechnology sounds like a neologism, but was actually coined early in the twentieth century by a Hungarian agricultural engineer called Karl Ereky, who included within its meaning “all such work by which products are produced from raw materials with the aid of living organisms”.2 Over time biotechnology has acquired a consuming variety of definitions. It may be defined quite broadly or much more narrowly. Typical of a broad definition is that of the United States Office of Technology Assessment, “Biotechnology, broadly defined, includes any technique that uses living organisms or parts of organisms to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses”.3

Biotechnology, globally recognized as a rapidly emerging and far-reaching technology, is aptly described as the "technology of hope" for its promising of food, health and environmental sustainability. The recent and continuing advances in life sciences clearly unfold a scenario energized and driven by the new tools of biotechnology. There are a large number of therapeutic biotech drugs and vaccines that are currently being marketed, accounting for a US$40 billion market and benefiting over a hundred million people worldwide. Hundreds more are in clinical development. In

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addition to these there are a large number of agri-biotech and industrial biotech products that have enormously helped mankind.\textsuperscript{4}

Biotechnologies may be divided by generation. Thus the first generation includes traditional technologies like beer brewing and bread making. These go back at least to the Sumerians of ancient Mesopotamia. The second begins with the microbiological applications developed by Pasteur and continues with the mass production by fermentation of the antibiotics. Tissue culture and modern plant and animal breeding also fall within this generation. The third generation includes techniques like recombinant DNA, monoclonal antibodies, polymerase chain reaction (PCR) and cloning, whose emergence was triggered by post-Second World War advances in molecular biology and the even newer science of genomics.

Genomics is inspiring the development of very large longitudinal cohort studies and even studies of entire populations to establish repositories of biological materials ("bio-banks") for discovery and characterization of genes associated with common diseases.\textsuperscript{5} With these "bio-banks", an important advance in human genetics will be the identification and characterization of numerous common genetic variants at specific loci and in combination with other genes and with various chemicals, physical, infectious, pharmacological and social factors.\textsuperscript{6} Pharmaco genomics which is an important branch of genomics is a rapidly growing segment that provides a wealth of information pertaining to defective or missing genes, which call for differentiated medicine – a new avenue for drug research. This emerging discipline combines both infotech and biotech skills in augmenting high-speed data mining of both genotypic and phenotypic information with a view to evolving new forms of medical diagnostics and therapies.

\textsuperscript{4} National Biotechnology Development Strategy, Draft for public comments by May 16, 2005 Department Of Biotechnology / Ministry Of Science & Technology / Government Of India 10\textsuperscript{th} April, 2005.
\textsuperscript{5} Khoury, M.J, The Emergence of Epidemiology in the Genomics Age, International Journal of Epidemiology, 936, 2004, p. 33
Gene regulation and other bio-algorithms will form the core of a new wave of diagnostics that are now being referred to as 'theranostics'.

For Arthur Kornberg, a Nobel laureate for his pioneering research on DNA synthesis, 'the most rational understanding of life' is 'its reduction to the molecular details of chemistry'. This conceptualization of life as essentially chemical, embodied in and promoted through the discourse of biotechnology, is undoubtedly appealing to those who esteem modern science for its progressiveness and rationality. Using this way of imagining life to base arguments for extending protectable subject matter to microorganisms, plants and animals played a significant role in the evolution of patent law in various countries from 1980s, and ultimately in the global regime too.

The advent of molecular biology is the major breakthrough in the history of life sciences. According to French Scientist Michel Morange, ‘Molecular biology is a result of the encounter between genetics and biochemistry, two branches of biology that developed at the beginning of the twentieth century. It is not a new discipline, but rather a new way of looking at organisms as reservoirs and transmitters of information’

In 1944, at the Rockefeller Institute of New York, Oswald Avery, Colin McLeod and Maclyn McCarty discovered that DNA carries genetic information. Soon after, it became apparent to scientists that DNA, and not proteins as many of them had thought, provides the chemical language of instruction for the transmission of genetic traits. James Watson and Francis Crick in consequence of the above discovery came up with the double helix model, which was announced in 1953 in Nature.

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The first commercial application of molecular biology was after the 1973 development of the recombinant DNA technique (rDNA) by Stanley Cohen at Stanford University and Herbert Boyer at University of California at San Francisco (UCSF). The technique, which enabled foreign genes to be inserted into microorganisms and passed on to others through cell division, was patented by Stanford and licensed widely, earning over $200 million in royalties between 1975 and 1997, which was the period. After recombinant DNA the next major scientific breakthrough with commercial implications was the 1975 development of hybridoma technology.

Before 1980s, the patent situation with respect to biotechnology processes and products was highly uncertain. Life forms were not given patents basing on nature doctrine i.e, organisms or substances as they occur in nature cannot be considered as inventions and are not patentable. This situation began to change in 1980 with US Supreme Court decision in Diamond vs. Chakrabarty\(^\text{10}\) to allow the patenting of a new man-made oil-eating bacterium by General Electric Company. Prior only Pasteur's yeast culture product patent exclusively covered living organisms. The product of nature doctrine had since the 1880s apparently precluded the patenting of any further life forms till the decision of Diamond vs. Chakrabarty.

The decision in Diamond vs. Chakrabarty was the first success in a campaign by industry to clarify patent rules in the biotechnology field. During the 1980s and 1990s, genetic engineering became increasingly sophisticated, with genes being transferred not just to microorganisms but also to plants and animals. For example, genes have been inserted into crops that make them resistant to insect pests or to herbicides and to increase the shelf-life of agricultural produce. And a cancer-causing gene was inserted into a mouse, resulting in the controversial Harvard oncomouse that was patented in 1988.

\(^{10}\) 447 U.S. 303 (1980).
Another new technique developed during this period was animal cloning based on nuclear transfer. In 1996, the now world famous sheep called Dolly was cloned by Ian Wilmut and Keith Campbell in Scotland from a cell taken from a mature sheep's udder. It was not the first cloned animal but the first to be cloned from an adult mammal.

From 1990, the Human Genome Project (HGP) began as an immense research collaboration between public researchers in the US and Europe. Genes and gene fragments came to be identified in larger quantities. The major breakthrough in the Biotechnology and Genomics era is the Human Genome Project which was launched as an international public consortium with the objective of sequencing every one of the three billion nucleotides within the 23 chromosomes pairs found in human cells, and publicly disclosing the data for the benefit of science and was completed in February, 2001, when International Human Genome Sequencing Consortium and Celera Genomics announced that they had compiled almost complete human genetic sequences by publishing their work i.e., draft sequences of the euchromatic part of the human genome in Nature and in Science Journals.

A spate of patent applications on the DNA sequences and part sequences followed, together with many attendant claims for their cloning and expression as proteins. The utility of these inventions tended to be vaguely identified as, for instance, “a scientific probe for the discovery of genes or expressed sequence tags (ESTs)”. A second wave of applications has followed as the human genome map speeded up towards its draft publication. The change of pace grew out of a scientific difference of opinion about how the mapping should proceed.

The advance of genetics in 1990s has shifted the frontiers of the rapidly evolving discipline. In particular, much of the former hard labour of identifying

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genes, their associated proteins, the receptors through which they enter cells and
the pathways they pursue, has ceased to be a matter of laboratory searching.
Genome maps are now available for over 50 animal and plants and the number is
mounting rapidly. Computational genetic searches, for such matters as gene
identification between different species of animal, and for variations in the genetic
make-up of individuals through automated micro-arrays, are increasing the role of
bio-informatics using giant computers. Knowledge of the biological function or
functions of individual genes allow changes in cell types and tissues to be
monitored, showing, for instance the presence of tumors or susceptibilities to
cancer.\textsuperscript{13}

Hence, Genomics information has become a crucial importance in drug
discovery and opened completely new commercial opportunities and spawned different
types of businesses such as technology providers who manufacture the DNA sequences
machines and equipment, information providers that collect and organize sequencing
information etc.\textsuperscript{14} The importance of genomics in the agricultural sector also developed
very rapidly.

The identification of disease related genes and the design of new drugs to act on
specific targets involve very high investments. So, research institutions and
pharmaceutical companies are all acutely aware of the need to make the most of
intellectual property potential in the resulting inventions. The Intellectual Property
Rights in the field of genomics are being vigorously pursued and patents for number of
specific genes or gene elements have been applied for.

Celera genomics data was copyright protected by PE Corporation and also
claiming that primary sequence assembly and the presentation thereof, are copyrighted

\textsuperscript{13}Typically, this is achieved by high throughput screening in which a microarray of nucleic acid probes is
immobilized on a solid substrate, each probe having the ability to bind to its cognate partner in given
mRNA in a complex mRNA expression mixture. William Cornish and David Llewelyn, Intellectual
Property : Patents, Copyright, Trade Marks and Allied Rights, 5\textsuperscript{th} edition, Sweet and Maxwell, London,
2003, p. 826.

\textsuperscript{14}Graham Duffield, Intellectual Property Rights and the Life Science Industries : A twentieth Century
works. In the UK Genetech were able to claim "human tissue plasminogen activator as produced by recombinant DNA technology", the first biopharmaceutical product i.e., genetically engineered human insulin. The patenting human DNA sequence thought not raised much concerns, filing of patent applications for EST's became a hot debate among scientific community as well as various international and national organizations which lead to changes in national legislations such as EPC, US Patent law and Japan Patent Act to allow patents for genomic inventions.

In early 1993, the NIH filed US patent application claiming 2,421 EST's, for which the structure and function of the full gene was unknown. It raised issues regarding the patentability requirement of utility with respect to EST's. In 1996, the USPTO agreed to grant patent over EST's but conditioned that purified and isolated DNA composition comprising the EST sequence should meet the requirements for enablement and written description.

The growth and consolidation of the US biotechnology sector is closely linked to the expansion of patent law into the protection of life forms and their structural and functional components. It created a wave in the European Community member states and Japan, which led to the regulatory changes in their patent regimes. A provision in the international scenario supporting the introduction of patents for genomic inventions is Art.27 (1) of the TRIPs, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

16 UK Patent 2,119,804.
17 Express Sequence Tags
20 Ibid p.14.,
For the patent protection of genomic inventions EPO\textsuperscript{22} and USPTO\textsuperscript{23} introduced new guidelines i.e, Directive 98/44 on the Legal Protection of Biotechnological Inventions i.e., "Biotechnology Directive"\textsuperscript{24}, Utility Examination Guidelines (2001) 66/4\textsuperscript{25} respectively. Special Genome efforts also took root in UK\textsuperscript{26}, Japan\textsuperscript{27}, France\textsuperscript{28} and Canada\textsuperscript{29} also.

Biotechnology patenting especially in the field of genomics, raises a number of important issues such as policy questions, ethical issues, public policy and moral issues, environmental issues, social and legal issues. When it comes to fundamental objections relating to policy matters, these patents clearly do challenge some quite fundamental tenets of patent law and jurisprudence. Patent law clearly mentions that only inventions are patentable. But by allowing the patents on life forms render the invention/discovery distinction meaningless and thereby allow pure discoveries to be patented. For example in the case of DNA, if it is naturally occurring then there should not be patent. But some of the opinion that cDNA (Complementary DNA) sequence should be patented, provided that they fulfil the criteria of novelty, inventive step and industrial applicability. US Guidelines clearly mentions that DNA sequences such as ESTs and SNPs (Single Nucleotide Polymorphisms) can be patented if the applicant discloses specific utilities such as that the sequence is useful for chromosome mapping or identification, gene mapping, tagging genes with known function such as including increasing predisposition to a disease, and forensic identification.\textsuperscript{30}

\textsuperscript{22} European Patent Office
\textsuperscript{23} US Patent and Trademark Office
\textsuperscript{26} John Alwen, United Kingdom Genome Mapping Project: Background, Development, Components, Coordination and Management, and International Links of the Project, 6 Genomics 386, 1990.
\textsuperscript{27} Yoji Ikawa, Human Genome Efforts in Japan, 5 FASEB J. 66, 1991.
\textsuperscript{29} Advisory Committee on the Human Genome, A Genome Program in Canada, 1992 (Summary of committee recommendations prepared for Canadian Cabinet by Charles Scriver and David Spurgeon, Canada Commits Money for Human Genome Research, 357 Nature 428, 1992.
As for life forms, it is frequently argued that the patenting of genetically modified organisms should be banned on the basis that a living thing is not a human invention but a discovery or a creation of God. Religious objections on principle to the patenting of life forms certainly deserve to be respected, but one should not assume that inventions must be completely human-made to be classed legitimately as inventions. In Europe and North America, which have the most experience in the patenting of apparently natural substances, there has never been any kind of blanket exclusion of certain types of invention on the basis that because they were not 100 percent human made they cannot be patented.

For example, in the case of oncomouse, some arguments says that patents can be given to the procedure for creating the mouse, but not to the mouse itself. Another arguments mentions that oncomouse could be patented as long as it is produced by the technique described in the patent. In other words, we should allow a product-by-process patent but not a product-by-any process patent.\(^{31}\)

In consequence of recent developments in the field of biotechnology patenting, three situations have arisen which are policy related issues in the biotechnology and genomics patent regime and are of the major concern for the policy makers. First, a disproportionately large quantity of patents is being granted in relation to the number of commercial products based upon them. This is because of the enormous quantity of patents on genes and gene fragments, whose existence raises the cost of doing research owing to the need to license related parts of the genome that are 'owned' by different institutions. Second, the scope of a patent can sometimes be drawn so broadly as to allow monopoly protection to cover a range of possible products including many unforeseen by the applicant. Both situations can create perverse incentives, which may reduce the rate of innovation. Third, there is a consolidation of patent ownership and global market shares in the hands of a small number of corporate life science giants. This situation can be attributed to a combination of possible factors, some of which may

operate synergistically, including privatization of industry and of research, stricter environmental and/or safety regulation, trade liberalization, mergers and acquisitions, and also intellectual property rights.

Most developed countries have adopted various measures to support commercial biotechnology. To allow companies to appropriate commercially valuable knowledge, industry and the patent community have persuaded governments and courts to be permissive in terms of applying certain customary requirements and to expand the availability of intellectual property protection. Sometimes this has been done by relaxing the rules obliging applicants to fully disclose the invention and demonstrate its novelty, industrial applicability or utility, and inventive step, and by making new rules providing greater legal certainty. One of the ways in which inventors in this field have benefited from liberal policy making relates to the concept of exhaustion of rights. Once a patent-protected product is sold by the owner or the licensee, his or her rights over that product are usually exhausted unless there is a contract of sale imposing conditions on buyers. When it comes to living things, the rights are not exhausted when the ‘product’ is sold but extend to the progeny whether or not the progeny is ‘manufactured’ by the ‘inventors’. It is a type of concession to the biotechnology patent owner in order to make the patent monopoly meaningful.32

The countries like USA and Europe tried their level best to control the flow of patent applications for genomic inventions such as ESTs by fixing parameters such as invention, nonobviousness and utility or industrial applicability. The patent applications over genomic inventions were also be scrutinized by the parameters such as environmental, moral, ethical and social issues. The companies like Celera Genomics, has also applied for the data protection through copyrights for their genomic databases. The USA and European countries rejected the protection for genomic databases by mentioning that the available information in those databases is the raw resource which is useful for research advancement and hence not protectable under copyright regime.

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This created a huge hue and cry in the life science industry which is also of major concern.

A growing number of private biotech companies have been collecting and storing our genetic information and bodily tissues and linking it to life-long medical histories. Many of these companies have close relationships with the public sector: they rely on public institutions to get access to certain medical data and tissue samples, while the public sector relies on those companies for commercial exploitation of the research. Despite the unique nature of the information collected and the sensitivity of genetic databases, these private bio-libraries are largely unregulated.

Genetic databases, biobanks, and population collections are already in existence in United States, the United Kingdom, Iceland, Canada, and Estonia. Of these, there are different types of genetic databases with diverse goals at heart. Forensic, military, commercial, and research databases, are a few. There are also various modes of control over genetic information: public, private, and a hybrid of the two - with the private sector relying on the public sector to get access to the data, and the public sector relying on the private one for commercial exploitation of the research. It raised number of issues like genetic discrimination, ownership and consent issues, confidentiality.

1.2 Significance of the Problem

Biotechnology and Genomics has stretched their feathers in all fields such as health sector, pharmaceutical sector, agricultural sector and commercial sector. As it is obvious that the inventions coming up from research in those fields needs protection through Intellectual Property Rights paradigm, it became crucial to identify the inventions which qualify for protection. As intellectual property rights are the monopoly rights, it became even crucial for the authorities to check and to keep a balance in the public and private interests. To strengthen the legal regime to suit to the present day vertical growth of science and public interest, in the international plane the TRIPs provides the minimum standards and in the domestic plane Intellectual Property
legislations are working. To suit to the modern technological advancements, many new amendments and modifications have been made to the existing legislations in world wide. In USA, they came up with "Utility Guidelines" and in EU "Biotechnology Directive" to meet the requirements. Through various judicial pronouncements, the parameters have been fixed in such a way to curtail the exploitation of technology and to prevent monopoly over the raw resources which are useful for further advancement of research.

It is expedient that intellectual property rights are created and amended to solve new problems created by technological developments by expanding the scope of Intellectual Property Rights. But there is every reason to doubt that policy makers have ever been able to shape and reshape such powerful economic rights in a dispassionate, informed and objective manner even when they have wanted to. To what extent, the policy makers able to draw a line between public and private interests is the important debate going on from past decade. Nodoubt, the main concept underlying behind Intellectual Property Rights is to encourage the inventors but at the same time it is also a duty of the authorities to examine whether such inventions are useful to the society at large or not. In particular, it is necessary to see whether the line drawn between the patentable and the unpatentable biotechnological and genomic inventions is objective and stable. Whether the existing provisions can balance the public and private interests by extending the meaning to biotechnology advancements or is it required to develop specific parameters! The techno-legal approach is new and it has become necessary to study the interrelationship between the science and the society, which is essential. Hence the researcher is very much interested in selection of this study which is a significant problem in the present day context.

1.3 Objectives of the Study

It is necessary to study the general aspects of which includes the historical background, origin and the growth of the Biotechnology and Genomics and their relationship with Intellectual Property Rights in the international and national planes in a comprehensive and authoritative way. The legal, moral, social, ethical dimensions of the
problem and its techno-legal management also would be studied. Hence, the researcher kept in mind the following are some of the important objectives of the study:

I. To study the historical development and growth of Biotechnology and Genomics to have a basic understanding of the study

II. To analyze the importance of patent protection for biotechnology and genomic inventions and various international treaties and national legislations related with biotechnology and genomics

III. To evaluate the scope of genomic database protection under copyright regime and various copyright related international treaties and national legislations related with biotechnology and genomic databases

IV. To critically evaluate whether the existing legal regime is appropriate to provide patent protection and copyright protection to vertically growing field like biotechnology and genomics and its database

V. To critically analyze the renowned judicial pronouncements which relied on the basic parameters of patents i.e., novelty, non-obviousness and utility for granting patent protection to biotechnology inventions in different countries and the position in India

VI. To critically analyze the public order, moral, public health, environmental, ethical issues related with biotechnology and genomic patenting

VII. To critically analyze the issues in providing database protection to genomic databases

1.4 Scope and Limitations of the Study

The researcher has chosen a problem which is facing by most of the countries (all the developing countries) in the world. The researcher tried his level best to collect extensive information to analyze the problem chosen and further confined to study only at country (India) level and limited the problem for socio, economic, technical and legal.
As the science and technology is a wide arena and the exponential growth of technology has broadened the scope of science, it became inevitable for the researcher to limit his research to a specific area. The emergence of human genome project created a new science called genomics which posed new challenges in the intellectual property rights regime and created a high scope for research. So, the researcher pinpointed his research to the burning problem i.e., Biotechnology and genomics in the intellectual property rights view point. The researcher limited his research to doctrinal method.

1.5. Hypotheses

The following are the plausible hypothesis formulated for the study:

I. Exponential growth of biotechnology and genomics created lot of confusion in granting protection through patents and copyrights

II. The basic parameters for granting patent protection and copyright protection for genomic inventions and databases changed from case to case and created a need for drawing a line for standardization

III. Fixing a strict protection paradigm for maintaining balance between the encouragement to the inventors for research and development and balancing the societal interest requires to be addressed

IV. The requirement for addressing the number of issues such as social, ethical, moral, environmental issues increased due to the result of endless growth of biotechnology and genomics and unexpected inventions resulting out of the same

1.6. Review of Literature

Review of literature is a part of the complete research process that helps the researcher to have a clear and wide knowledge in the field. Though the present study is not a completely unexplored area, but there are not many direct studies focusing all aspects. For the purpose of conducting review, the researcher made use of abstracts, index of journals in published and unpublished bibliographies, a thorough study of academic journals, international organization journals, conference proceedings,
government reports, committees’ reports, books, websites and online literature. Some of the significant reviewed studies are covered.


discussed about relating to Biotechnology and patent regime specifically between Europe and USA.

Donald S. Chisum, who is a Professor of Intellectual Property Rights in USA (2000) in his book, "Chisum on Patents", the author is a professor in IPR at USA made an exercise of developing this book into twenty two chapters which gives the comprehensive understanding of patent protection in USA.


UNCTAD-ICTSD (2005), “Resource Book on TRIPs and Development”, actually this is the project report of UNCTAD and the same was moulded into a book by which readers can get understand the impact of TRIPs at different nations of the world and explains the object of TRIPs.


Philip W.Grubb, (2004) in his book, “Patents for Chemicals, Pharmaceuticals and Biotechnology”, provides an elaborative understanding over the patent protection for the new technologies and sciences such as chemicals, pharmaceuticals and biotechnology and genomics.
Graham Dutfield's, (2003) book on "Intellectual Property Rights and the Life Science Industries A Twentieth Century History", is the compilation of articles relating to life science industries such as dyestuff industry, genomics, biotechnology, agricultural sector etc.,


Zakir Thomas(2005) in his book, "Agricultural Biotechnology and Property Rights: Challenges and Policy options", related with agricultural biotechnology and explains its interrelationship with various intellectual property rights such as patents, plant variety protection etc.,

A review of literature provides a better understanding of interrelationship between biotechnology and genomics and intellectual property rights. It provides a detailed outlook about the various legislations and judicial pronouncements related with biotechnology and genomics and their protection through various intellectual property regimes. Most of the available literature belongs to western countries such as European community perspective of IPR, American perspective of IPR etc. There is a dearth in literature of IPR broadly at Asian level, regionally at south Asian level and specifically at India level. No doubt states and several organizations are doing efforts to overcome the problem, but yet to reach the result. Hence an attempt is made by the researcher to overcome the problem and attain the result.
1.7. Methodology Adopted

The researcher had selected the problem with great interest keeping in mind the significance and impelling need of it in the society in the present day conditions, circumstances socio-legal and international binding issues.

Basically the study is doctrinal and the methods adapted to carry out the research work in descriptive, structural and functionally analytical. The relevant material is collected from the primary and secondary sources. Materials are collected from law and non-law sources like law journals, Biotechnology journals, publications of interdisciplinary seminars, and other related social sciences literature, news papers, internet and documents etc. are collected.

The researcher visited Sri Venkateswara University library, Tirupati Sri Padmavathi Mahila Viswavidyalayam, Tirupati, Acharya N.G.Ranga Agriculture University, Tirupati, Central library, Tirupati, Sri Venkateswara Institute of Medical Sciences (SVIMS) Tirupati, Tirupati Regional Library, and other libraries in Tirupati, TERI (The Energy Research Institute, Deemed University) School of Advanced Studies, library Delhi, Research and Information System (RIS) library, Delhi, Indian Law Institute library, Delhi, Indian Society of International Law (ISIL) library, Delhi, The Library of Ministry of information Technology, Delhi, The library of Department of Biotechnology, Delhi, the library of National Research Development Corporation, Delhi, Delhi University library, Delhi, CSIR library, Delhi, Jawaharlal Nehru University, Delhi, ICSSR library, Hyderabad, NALSAR Library, Hyderabad, Osmania University Library Hyderabad, National Law University Library, Jodhpur, National Law School, Bangalore, Gujarat National Law University, Gujarat, Centre for Biodiversity and forest studies, Madurai Kamaraj University, Madurai The researcher also collected information by using internet and westlaw website, online library jstor website, online library, manupatra website, online library and had useful discussions with the concerned officials like Lawyers, Judges, Scientists, Academicians, Researchers, Officials and related personnel.
The results of the discussions are incorporated in the study. As a part of the study the researcher also participated and presented research papers relevant to this thesis in various seminars. They are “International Conference on Intellectual Property” held at Baroda University by Faculty of Law in collaboration with Canadian Studies, New Delhi in March, 2007 on “Genomics: A New Patent Regime – A study”, presented a joint paper in “National Conference on Intellectual Property Rights – Related issues”, on 24-26th March, 2006, held at Sri Acharya Nagarjuna University, Guntur, on “Impact of TRIPs on Patent Law in India”, presented a joint paper in “National Conference on Forest Biodiversity Resources: Exploitation, Conservation and Management”, on 21-22 March, 2006, held at Centre for Biodiversity and Forest Studies, Madurai Kamaraj University, Madurai, on “Biological Resources and Biotechnology: Socio-legal Implications of Intellectual Property Rights”, Participated in the Short-term Orientation Course on “Biosafety and Biotech Regulations”, held from 5-9th June, 2006 in New Delhi organized by “The Energy and Resource Institute (TERI)”, sponsored by Ministry of Environment and Forests, Government of India, participated in the Short-term Certification Training Programme on “Law and Agricultural Biotechnology”, held from 27th February to 3rd March, 2006 in New Delhi organized by “The Energy and Resource Institute (TERI)”, sponsored by Department of Biotechnology, Government of India, participated in the Short-term Certification Training Programme on “Law and Health Care Biotechnology”, held from 27th February to 3rd March, 2006 in New Delhi organized by “The Energy and Resource Institute (TERI)”, sponsored by Department of Biotechnology, Government of India. The collected information is systematically analyzed and placed in the appropriate chapters.

1.8. Scheme of the Study

The entire study is divided into five chapters

First chapter covers the introduction of the evolution of biotechnology and genomics and their protection through intellectual property rights and the issues related therewith,
significance of the problem, objectives of the study, scope and limitations of the study, hypotheses, review of literature, methodology adopted, scheme of the study.

The second chapter deals with the concept of origin, growth and development of Biotechnology, completion of human genome project and birth of genomics and its benefits, interrelation with pharmaceutical, health and agricultural sector and commercial biotechnology in various countries such as USA, EU and Japan.

The third chapter focuses on various intellectual property rights and various intellectual property rights treaties in the international plane and domestic plane of USA, EU and India in relation with biotechnology and genomics and genomic database protection.

The fourth chapter gives an understanding of legal, public order, moral, public health, environmental, social and ethical issues linked with biotechnology and genomic inventions protection through intellectual property rights regime.

The fifth chapter deals with the findings of the research problem and certain recommendations for the outcome of the identified findings.