

## INTRODUCTION

Biotechnology research is an area which witnesses a revolutionary growth. Its growth is evident from the magnificent developments that are taking place in this sector today. Biotechnology once was about cross breeding, brewing beer, making bread using yeast and so on. But today it has grown beyond ordinary man's imagination. It amazes every one with revelation of genetic mark up and genetic codes. The tiny little cells with the complexity of genetic regulation inside them, is one of the great wonders of nature. Biotechnology presents a daunting challenge to unravel the mysteries of these complex structures.

The revolutionary growth of biotechnology research has posed some major challenges to the traditional legal system in safe guarding the intellectual property rights associated with it. Intellectual property protection is highly indispensable as the biotechnology research involves huge amount of intellectual and financial investment. Handling these situations requires many strategic and conceptual divergences in the area of intellectual property rights. As the intellectual property management adopts a far more diverse and unconventional strategic approaches, the justification for adopting these new management tactics has become quite inconsistent with the traditional IPR regime.

Traditionally, biotechnology relies on patent protection to safeguard the innovations. However, there exists lot of vagueness regarding the application of patent protection of research in biotechnology especially in the area of gene and gene fragments. The major arguments against the application of patent in biotechnology innovations relating to gene and gene fragments are based on two reasoning. Firstly they are considered to be discoveries in the biotechnology exploration path. Secondly biotechnology innovations are believed to be the products of nature and hence they are not patentable.

Apart from these specific issues on genes, there are other arguments against the applicability of patents in biotechnology research. One such argument is that the enhanced intellectual property protection may actually have adverse effects in the development of future research. Basic research is not usually considered to be a subject matter of protection until recently. However, there is a growing trend towards

excessive commercialisation of scientific research data which is against the norms of science.

It is argued that the patent protection normally causes a patenting rush resulting in too many property rights leading to a wide spread 'anti commons' effect which may impede future growth. This also results in patent proliferation leading to diverse problems of research 'bottlenecks,' 'patent thickets,' blocking patents and many other unfair practices leading to anti-trust problems. Problems like submarine patents, patent trolls, patent tolls, 'evergreening' or continuation practice are the direct result of unhealthy patent practices in the area of biotechnology.

Another area which has been a subject of debate is authenticity and access to research data. Research data are very crucial in any research especially in biotechnology. The success of the research depends on the access to earlier developed tools and research data. Nonavailability and lack of access to research data generally pose many serious problems to ongoing research. Patent protection enables the right holder to fence down the area of research and thereby restricting and curtailing access of others to the area of research. This issue is especially relevant because some researchers believe that these research data are mere discoveries of an already existing product of the nature, hence they are shared public resources and cannot be protected by attaching intellectual property rights. These concerns are further aggravated by the recent court cases which have taken a more or less negative trend towards application of patent protection for biotechnology research data.

The major issue here now, is how to protect the intellectual property in biotechnology. Another option available with researchers is to rely on copyright regime to protect the research database. But copyright protection is available to databases only if it is a creative and original compilation. The biotechnology research data by its nature form only raw 'non creative' 'non original' database which is not protected under copyright laws. These issues have placed biotechnology research in a very delicate and insecure situation.

The recently emerging trend in biotechnology research is the adoption of open source licensing concept similar to that in the information technology field as an alternative method to overcome these problems. Open source movement is a recent development

in the area of information technology which has gained wide popularity. It is alleged that open source concept is an anti-intellectual property movement. This was due to a misconception that open source movement is against the autocracy of proprietary software. However a basic understanding of how open source concept works, reveals that it is perfectly founded on intellectual property rights. Open source relies on copyright principles to ensure the protection of data and the management of the licensing terms. Application of open source concept to the biotechnology is a much debated issue in the area of developmental IPR today.

The central theme of the study is to explore these major issues and to analyse how open source concept can be effectively adopted in biotechnology research sector. The analysis of open collaborative research endeavours based on open source models in biotechnology, reveals that it is undoubtedly a better management strategy for fostering biotechnology research. An attempt is further made to understand whether this concept is capable of maintaining a balance among proprietary interest social interest and the growth of public domain of knowledge in biotechnology sector.

## **SCHEME OF CHAPTERS**

This thesis is divided in to four analytical sections. The first section introduces and explains various concepts and technological jargons related to the area of research in biotechnology. The second section comprising of chapters two, three and four narrates various intellectual property issues related to biotechnology research. This particular section covers issues related to patenting of biotechnology innovations, and it contains patent philosophies, current trends, major shortcomings and finally Judicial and legislative attempts to harmonise them. The section also covers the contemporary problems related to protection of biotechnology research data in copyright landscape under chapter four. The third section introduces the open source concept in software sector, the philosophy, development methodology, classification, advantages and its legal foundations under chapter five. The fourth and final part of the work was brought in chapter six and it explores the open source analogy as a new intellectual property management strategy in the biotechnology sphere. It evaluates various open source initiatives, and open collaborative endeavours and the concept of patent pooling based on open source concept in order to see whether open source management strategy is effective in fostering innovations.

The first chapter makes an attempt to familiarise the concepts and terminologies in the sphere of biotechnology. It covers a brief historical perspective of biotechnology and its modern development. This chapter explains various definitions and illustrates the basic elements of biotechnology research. One section of this chapter deals with the technology applications and classification of biotechnology based on the area of application. Further the chapter also briefly explains various other contemporary issues like genetically modified organisms, nano biotechnology, bioinformatics and so on. It further tries to give a brief introduction to Express Sequence Tags (ESTs) and Single Nucleotide Polymorphisms (SNPs) and the areas where the biotechnology and intellectual property rights are in conflict with.

The second chapter deals with the patent regime and its applicability to modern biotechnology. The chapter starts with a brief historical perspective of the patent system and explains various concepts and philosophies of traditional patent system. It further explains various doctrines and theories of patenting. It attempts to explore the various inconsistencies of the traditional patent system while applying to the modern biotechnology sphere. It also exhaustively covers all the major issues and contradictions related to biotechnology research. Patent philosophies related to motivation leading to intellectual creativity are clearly illustrated in this chapter. Access and protection of biotechnology research data relating to gene and gene fragments and their sequences is proved to be a subject of contemporary relevance. This chapter attempts to highlight, certain inherent problems with the patent system when it is applied to this particular area of biotechnology research.

The third chapter explains the judicial and legislative trends in resolving biotechnology research problems. A series of judgments starting from *Diamond v. Chakrabarty* onwards which attempted to resolve the issues relating to biotechnology form the basis of the study. Earlier positions affirming the validity of biotechnology patents show a negative trend today. The recent high profile cases are negating the patent protection to biotechnology research results, especially to ESTs, SNPs and other protein sequences. The common view adopted by the courts in patent cases relating to biotechnology is that the sequences are products of nature. The first section of this chapter gives a brief explanatory note on various international initiatives touching biotechnology research data protection. This chapter also makes a detailed

evaluation of judicial trends based on patentability criteria, in its earlier sections followed by a detailed analysis of the reported case laws relating to biotechnology research in two major jurisdictions of the US and the Europe.

The fourth chapter deals with the scope of protection of biotechnology research data bases under copyright regime and the database directive. The chapter makes a thorough analysis of the nature of biotechnology research databases, in order to see the most appropriate mode of protection available to them. It also examines the various categories of databases and the nature of protection available to them. The issues relating to protection of non-creative or non-original databases are thoroughly evaluated from an international perspective. The positive attempts made by European Union in the form of copyright directive and database directive were made a subject of detailed analysis from the point of view of biotechnology research databases.

Chapter five makes an analysis of open source concept in software sector to see how it differs from the proprietary software sector. It deals with the various open source models and examines how they shape the area of the software sector. It explains the open source philosophy and the motivating factors working behind the open source contributions. It also analyses various merits of the open source concept based on which it is established as a successful alternative to proprietary software. This chapter explains the legal status of open source licence on the basis of decided case laws.

The sixth chapter analyses the nature and scope of open source movement in biotechnology. This chapter evaluates the scope of open collaborative research as a means of fostering innovation. A brief discussion on the nature of biotechnology research and norms of science is made in the earlier section of this chapter to understand the scope of application of open source concept in biotechnology research. The norms of sharing in science and its impact on research progress are scrutinised to justify the new trend of openness in the biotechnology research sector. An in-depth analysis of various open collaborative projects and their potential impact on research are carried out to understand the feasibility and desirability of open collaborative endeavours in biotechnology research. The chapter also examines the concept of patent pools which essentially follow a similar concept. The chapter analyses the viability of open source concept as an effective strategy for intellectual property management ensuring scientific progress.

Finally the thesis concludes with summarisation of the entire chapters. The conclusion puts forth some constructive suggestions and recommendations for effective intellectual property management strategies in biotechnology research. The research comprehensively analyses the open source concept in biotechnology research from the backdrop of major problems and inconsistencies prevailing in the patent and copyright landscapes. The research founded on these fundamental intellectual property issues, successfully establishes that open source movement in biotechnology research is the most effective intellectual property management strategy for protecting research data. This analysis categorically establishes that open source model is a well-organized system of intellectual property management and it is destined to meet three major requirements: public domain of knowledge, intrinsic and extrinsic values of the researcher and the progress of science.