INTRODUCTION

Management of intellectual property rights (IPR) in biotechnology research sector involves many intricate issues. IPR policies and management strategies are required to be founded on social, moral, and philosophical justifications specifically pertaining to an area seeking protection. Dramatic growth of technology, research and development has lead to many strategic and conceptual divergences in the area of intellectual property rights. As the intellectual property management adopts diverse and unconventional strategic approaches, in order to accommodate changing technological growth, the justification for adopting these new management tactics has become quite inconsistent with the ultimate objective of the traditional IPR regime.

Biotechnology and intellectual property rights are two major disciplines supposedly complimenting each other and have an unimaginably high stake in the present day world. Both the two disciplines as technology and guardian of technology are continuously developing areas. Biotechnology, an area adding value to life and intellectual property to technology, are both revolutionary in their own spheres. Both intellectual property and biotechnology have played a significant role in transforming the world of research as it exists today. There has been an explosive growth in the filed of biotechnology and hence recognising the significance and managing the scientific enterprises to take full advantage of the results generated by researchers, attract pivotal importance.

Intellectual property has generally been considered as one of the most important drivers of new innovations in science and technology because it allows researchers, institutions and inventors to recover their investment in the shape of limited monopolies to their ideas.[1] Traditionally, biotechnology relies on patent protection to safeguard the innovations. However, there exist lot of ambiguities regarding the patent protection of gene and gene fragments and this is evident from raging debate and continuing litigations in biotechnology research sector. Biotechnology-innovations relating to the gene and gene fragments are considered to

[1] Andres Guadamuz Gonzalez, *Open Science: Open Source Licenses in Scientific Research,* 7 N.C. J.L. & Tech.321., p. 325 (2006).

be discoveries in the biotechnology exploration path. It is also argued that they are also the products of nature and are not patentable. [2]

Apart from these specific issues on genes, there are other arguments against the applicability of patents to biotechnology research. One of the arguments 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 the subject matter of protection until recently. However, there is a growing trend towards excessive commercialisation and protection of scientific data, which is usually considered outside the realm of patenting. It is argued that the patent protection normally will cause a patenting rush causing too many property rights, resulting in 'anti commons' effect which may impede future growth.[3]

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. Availability of and access to research data generally pose many serious problems to ongoing research, and patent protection helps the researcher to fence down the area of research and thereby restricts or curtails access to the area of research. Thus, in a way, patent protection impedes access to research data. However, the scientific community seem to be divided on this issue. 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. Others believe that they are potential commodities to be patented, licensed, and marketed through the application of exclusive proprietary rights.[4]

Intellectual property issues in the area of biotechnology research are far more diverse than we can ordinarily foresee. Safeguarding biotechnology research data in the ambit of IPR regime has become a major cause of concern in the area of scientific research. Different researchers have different views as to which area of IPR can

---

[2] Matthew Rimmer, *The New Conquistadors: Patent Law and Expressed Sequence Tags,* Journal of Law, Information and Science, Vol. 16, p.22 (2007).
[3] Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anti- commons in Biomedical Research*, 280 Science 698, p.698 (1998).
[4] Sara Boettinger and Dan L. Burk, *Open Source Patenting*, 1 JIBL. 221, p.221 (2004).

protect their inventions. Traditionally biotechnological researchers were opting patent protections to safe guard their inventions. However, due to certain inadequacies in the patent system, they were forced to think of an alternative form of protection.[5] Another option available with researchers was to rely on copyright regime to protect their research databases. But copyright protection is available to databases only if they are creative and original compilations. The biotechnology research data by nature are only raw 'non creative' and 'non original' database which is not protected under copyright laws.

The recently emerging trend in biotechnology research is the adoption of open source licensing 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 relies on copyright principles to ensure the protection of data and management of the licensing terms. Application of open source concept to the field of biotechnology is a much debated issue in the area of developmental IPR today.

BACK GROUND OF THE STUDY

(a) STRONG PATENTS CAN ERECT BARRIERS IN SCIENTIFIC RESEARCH

A patent is a property right granted for a limited period of time. It gives an inventor exclusive right to exploit his invention in a country where the patent is granted.[6] A valid patent must also meet certain legal criteria for patentability such as utility, novelty and non-obviousness. A patent application has to describe the invention precisely and completely and must make an enabling disclosure by way of patent specification. Further, the patentability also depends on the fact that the invention is not obvious to the person skilled in the art.[7] Disclosure is the central pre-requisite of patent protection.

---

[5] Arti Rai and James Boyle, *Synthetic Biology: Caught Between Property Rights, The Public Domain, and The Commons*, 5(3) PLoS Biol e58., p.389 (2007).
[6] David Bainbridge, *Intellectual property,* 4th ed., (London, Pitman Publishing. 1999) p.317.
[7] Ibid.

The patent system is usually justified on utilitarian grounds as a tool to stimulate innovation and development of inventions for the greater good of society. Thus, according to its proponents, the system promotes the interests of the inventor, who is given a means to recuperate the financial investments made for his invention, and serves public interest, because the information is disseminated to the public instead of being kept as a trade secret.[8] Another argument is that, the patent regime is granting this monopoly to the inventor not merely as a personal right but as an incentive for disclosing the invention. "Its inducement is directed to disclosure of advances in knowledge which will be beneficial to society; it is not a certificate of merit, but an incentive to disclosure."[9] Patent and copyright laws are designed to deliver privately held information into public hands. Therefore intellectual property protection is intended to encourage the release of intellectual creativity to the public domain for public benefits.[10]

However, there are many arguments for and against the applicability of patents to scientific research area. Commercial biotechnology regards an invention to be potential commodities to be exploited for financial gain by the application of exclusive proprietary rights. But application of patent by biotechnology researchers was subjected to a large amount criticism. Some of the aspirational normative researchers regard new biological discoveries as public resources and their exclusive protection by way of patent will hamper future research in a particular area.[11] It is also argued that, though patent regime aims to stimulate innovation by granting a monopoly to the inventor, he is also given the right to restrict others from using and modifying his invention.[12] Further those who make improvements in the core technology will be entitled to apply for patent rights on the improvements and these improvement patents will lead to 'Splintering of Rights'.[13] Innovations are sequential or cumulative, later inventions are dependent on earlier research results. Research without coordination associated with information exchange, can result in duplication

---

[8] Edwin C. Hettinger, *Justifying Intellectual Property Rights*, 18 Phil. & Pub. Aff. 31, p.48 (1989).
[9] *Sinclair & Carroll Co. v. Interchemical Corp*., 325 U.S. 327, 330-31 (1945).
[10] Robin Feldman, *The Open Source Biotechnology Movement: Is It Patent Misuse,* 6 Minn. J.L. Sci. & Tech. 117, p.120 (2004).
[11] Yann Joly, *Open Source Approaches in Biotechnology: Utopia Revisited*, 59 Me. L. Rev.385, p.391 (2007).
[12] Robin Feldman, *The Open Source Biotechnology Movement,* p.120.
[13] Ibid.

of researchers' efforts and wastage of resources. Hence it can be seen that granting patent rights to pioneering inventors can create barriers to subsequent innovations.

Further it is also pointed out that these situations will cause a patenting rush resulting in patent proliferation and thereby leading to various consequences like patent thickets, research bottlenecks and "tragedy of anticommon". This will lead to many complicated issues like blocking patents and complimentary patents resulting in anti trust problems. This will further lead to costly litigations. Another potential argument is that the patents are very expensive to maintain and to enforce. This makes patents more affordable for large companies than for small inventors.[14] Violations of intellectual property rights are more prevalent in the area of patents and the patent enforcement mechanisms are considered to be the most unrealistic, time consuming and expensive.[15] All these issues are elaborated in the following chapters.

(b) COPYRIGHT PROTECTION FOR RESEARCH DATA BASES

Periphery of patents is only to new products or processes, whereas copyright protects the original expression of ideas. According to copyright law, copyrighted work has certain exclusive rights, including the right to reproduce and distribute the work. Copyright protection covers published as well as unpublished works. This is one of the major advantages of the copyright regime. A work can be simultaneously protected as copyright and as a trade secret.

Biotechnology research data involve enormous amount of intellectual efforts and financial investment. Protection of biotechnology research data under copyright regime can provide more flexibility to the researcher in the management of the research data. Copyright provides various licensing options to the creator of the database. It also provides more flexibility in terms of access to the database by the public. The copyright protection will enable the database owners to meet both social and proprietary interests.

[14] Mark A. Lemley, et al., *What to do about Bad Patents,* 28 Reg.10, p.12 (2005).
[15] Ibid.

However the problem with copyright is that it protects the data only if it is an original compilation. Traditional copyright protection is not available for raw data[16] or non- creative and non original data. According to copyright law terminology, a database is a compilation formed by the collection and assembling of pre-existing materials or of data that are selected, coordinated or arranged in such a way that the resulting work as a whole constitutes an original work of authorship.[17] The term compilation also includes collective work. Another problem with the copyright protection of database is that it protects only the structure of database. No protection is granted to the content of the databases.

The problem with biotechnology research data is that genomic research data normally do not fall under the category of compilation. The raw biotechnology research database normally falls under the category of non creative non original databases, which attract no protection under the copyright regime. Further the content of the biotechnology databases are more significant than the structure of the databases.

(c) RESEARCH DATA AND EU DATABASE DIRECTIVE AND EU COPYRIGHT DIRECTIVE.

The issue of protection of biotechnology research data still remains controversial. Researchers are not clear whether to opt for the confusing patent protection or for a more fragile copyright protection. Since biotechnology research involves both inventor's right and a social obligation of public accessibility, a more appropriate protection, meeting the specific nature of the biotechnology research is highly warranted.

---

[16] *Feist Publications v. Rural Telephone Service Co,* 499 U.S. 340 (1991).
Holding that, the factual information in the white pages of a telephone book lacked creativity and originality in selection and arrangement, and was not copyrightable.

[17] 17 U.S.C. Section 101. Explains a compilation as:
A "compilation" is a work formed by the collection and assembling of preexisting materials or of data that are selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship.

The fist attempt to provide legal protection to database was made by the European Union by enacting EU Database Directive[18] and EU copyright directive[19]. The protection offered under the directive is originally given to the structure of the database and no protection is given to the content of the database.[20] However the Directive creates *sui generis* protection against unauthorized use or extraction of the contents in the database.[21]

The database directive imposes a higher standard of originality than that required under the copyright act. In order to qualify for protection under the EU directive, a database must contain information arranged in a qualifying way. This means that the data must be a systematic collection of individually accessible data. Further the database must have been created through a substantial investment[22].The exclusive rights granted to the database owner under the directive are reproduction, adaptation, distribution, communication and display or performance to the public[23].Interestingly the EU database directive remains as the only isolated attempt to safeguard non-original non-creative database. No other region in the world could effectively implement similar approaches in protecting non-creative databases. Hence this *sui generis* provision is definitely favourable to biotechnology research databases

---

[18] Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases.

[19] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society.

[20] Article 3 Section 2 of the Directive 96/9/EC reads as:

> The copyright protection of databases provided for by this Directive shall not extend to their contents and shall be without prejudice to any rights subsisting in those contents themselves.

[21] Article 7 section 1 of the Directive 96/9/EC provides for *sui geneirs* right which reads as:

> Member States shall provide for a right for the maker of a database which shows that there has been qualitatively and/or quantitatively a substantial investment in either the obtaining, verification or presentation of the contents to prevent extraction and/or re-utilization of the whole or of a substantial part, evaluated qualitatively and/or quantitatively, of the contents of that database.

[22] Ibid. at Article 7 (1); and Article 1 (2) of the Directive 96/9/EC reads as:

> For the purposes of this Directive, 'database` shall mean a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means.

[23] Article 5 of the Directive 96/9/EC explains exclusive rights of the copyright owner as:

> "In respect of the expression of the database which is protectable by copyright, the author of a database shall have the exclusive right to carry out or to authorize: (a) temporary or permanent reproduction by any means and in any form, in whole or in part; (b) translation, adaptation, arrangement and any other alteration; (c) any form of distribution to the public of the database or of copies thereof. The first sale in the Community of a copy of the database by the rightholder or with his consent shall exhaust the right to control resale of that copy within the Community; (d) any communication, display or performance to the public; (e) any reproduction, distribution, communication, display or performance to the public of the results of the acts referred to in (b)."

provided they are blended with some of the more flexible option available with copyright regime.

Some of the important arguments against the directive are that, it narrows the educational and scientific community's right to invoke fair use with respect to copyrightable databases under copyright law[24]. It is also argued that the new Directive produced significant problems including overprotection of data which forms new barrier to database integration, leading to erosion of the public domain[25]. Further, the term of protection granted as per the directive is only fifteen years under *sui generis* form of protection. This is far less when compared to the term of protection granted by copyright. Hence, the new directive was not widely welcomed by the scientific communities as the best mode of protection to their research data.

RATIONALE OF THE STUDY

(a) MAINTAINING A BALANCE BETWEEN PUBLIC GOOD ASPECT AND PROPRIETARY CONCERNS

The question of whether and how databases should be protected by the law has never been an easy one to answer to any intellectual property researcher. The basic reason why this issue is still a hotly debated one is that, it necessarily involves finding a balance between two potentially conflicting public goals: the goal of providing adequate incentives for their continued production of databases and the goal of ensuring public access to the information they contain. Application of patents and copyright to the biotechnology has left behind many questions unanswered. Patent is a commonly used mode of protection in biotechnology. However the recent court cases show that patent protection cannot be granted to gene and gene fragments unless they establish substantial utility criteria[26]. There is no doubt that patent protection will restrict access; however, copyright could only offer a very fragile protection to the research results. Striking a balance between public good and proprietary concern is

[24] Jerome H. Reichman and Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 Vand. L. Rev. 51, p.79 (1997).
[25] Dov S. Greenbaum, *The Database Debate: In Support of an Inequitable Solution*, 13 Alb. L.J. Sci. & Tech.431, p. 442 (2003).
[26] *In re Dane K. Fisher and Raghunath V. Lalgudi*, 421 F.3d 1365 (Fed. Cir. 2005).

determinable only by finding which the most appropriate mode of protection in biotechnology is.

(b) OPEN SOURCE MOVEMENT AS CATALYST FOR INNOVATION

Open source movement is a relatively new approach widely accepted in computer software field. Open source doesn't merely mean access to the source code[27]. This is essentially a licensing agreement stipulating the way in which the software is to be distributed under licensing terms. Currently there is a divergence of opinion between different groups, whether one should use the term "open source" or "free software" to define the movements[28]. According to the definition given by *www.opensource.org,* a licensing term must contain free distribution of the software with source code. The license must allow modifications and derived works must allow them to be distributed under the same terms as the license of the original software. The concept of open source licensing began with Free Software Foundation (FSF) GNU General Public licence. [29]

The software industry has a different objective and a definite strategy for IP protection. They aim at a wider dissemination of software by retaining the copyright protection over the work and then distributing it using a license. This specific license may be inclusive or exclusive of the source code. In case of open source licensing, wider community will have access to the software's source code. Open source software allows later modifications by the user or other developers by providing access to the source code through the use of a permissive license generally termed as open source license[30]. Under open source license, the copyright remains with the owner of the program. This method is also adopted as a marketing strategy for wider use of the software. Even though software is also a subject matter of patent, copyright is widely used in the field of software to protect the programs. Open source licensing relying on copyright protection proved to be highly successful in the sphere of software.

---

[27] http://www.opensource.org/
[28] Richard Stallman. *Why "Free Software"'is better than "Open Source"*, (1998). Available at www.gnu.org/philosophy/free-software-for-freedom.html, last accessed on 12-5-2011.
[29] GNU is a recursive acronym for "GNU's Not Unix!"
[30] Andres Guadamuz Gonzalez, *Open Science: Open Source Licenses in Scientific Research ,* p. 325

(c) OPEN COLLABORATIVE ENDEVEORS TO REJUVENATE BIOTECHNOLOGY RESEARCH

Biotechnology is one of the fast expanding areas in scientific research with enormous economic potential. There is a growing trend towards excessive commercialization of biotechnology research and it has lead to many problems. Traditionally scientific researchers were opting patent to protect their research data. However, due to over-emphasis on patent protection and associated problems researchers are now opting for an alternative system of Intellectual property management. To overcome the inadequacies of patent regime, biotechnology researchers began to use open source concepts as an alternative, borrowing the ideas developed by programmers in the information technology sector[31]. The relationship between biotechnology and information technology is very deep. There has been a significant convergence of the life sciences and the computer sciences. However, biotechnology innovations are far more diverse in composition than software development. It is difficult to say that open source movement founded on the basis of copyright philosophy is a better alternative to patent.

There have been some major conceptual disparities between software and biotechnological inventions. Software involves collaborative industrial development strategies with commercial objectives. It does not require access to physical materials and uses sophisticated testing facilities. Software development testing and debugging can be done in a decentralized manner. In the case of open source computer programs, the development takes place through the efforts of a large number of decentralized programmers contributing their codes voluntarily through the internet[32]. To be more precise, the intellectual input is more decentralized in the software sector than in biotechnology. Whereas, in the case of biotechnology, individual intellectual inputs form the basis of every research output. It involves physical handling of materials and sophisticated testing devises. The open source movement in biotechnology involves much more heterogeneous issues than its information technology counterpart[33].

---

[31] Robin Feldman, *The Open Source Biotechnology Movement,* p.117.
[32] Donna M. Gitter, *Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases*. 43 Hous. L. Rev.1475, p. 1516 (2007).
[33] Yann Joly, *Open Source Approaches in Biotechnology,* p. 398.

Intellectual property management in the area of biotechnological research is a subject of extensive debate. Developing an effective mode of protection, by maintaining a perfect balance between proprietary and social interest has always been a tough task in the area of scientific research. Application of open source concept in biotechnology research is a significant attempt to address these issues. Many researchers are now resorting to open source analogy as an alternative to patents.[34] The question is how far these new movements can help the scientific community recuperate their intellectual investment by achieving social goals.

There are many arguments for and against this relatively new concept of open source movement. Some regard open source as an anti-intellectual property movement. However it can be seen that intellectual property law is at the heart of open source model. Open source system manages the licensing term based on copyright law. [35] Open source concept has many advantages like, wider dissemination of scientific knowledge, effective management and security of research databases and facilitating future development and growth. However this strategy is strongly opposed by the proponents of the patent system, stating that this concept will undermine the traditional patent regime. These conflicting concepts and philosophical justifications put forwarded by the proponents of both the sectors make it worthy of a detailed study. Hence the proposed research is an attempt to elucidate the feasibility of applying open source concept to scientific research, particularly in the area of biotechnology, as a new Intellectual Property management strategy.

RESEARCH METHODOLOGY

The proposed study envisages to delineate the effectiveness of different intellectual property management systems in protecting scientific research databases based on published works. Primarily an analysis of the various intellectual property management issues in the area of scientific research is made so as to put a framework for the basic studies. Accordingly, the role of patents in the area of scientific research data protection is thoroughly analysed so as to identify the key issues which are major

[34] Katherine M. Nolan-Stevaux, *open source biology: a means to Address the access & research gaps*?, 23 Santa Clara Computer & High Tech. L.J. 271, p.310 (2007).

[35] Francois Leveque and Yann Meniere, *Copyright Versus Patents: The Open Source Software Legal Battle*, Review of Economic Research on Copyright Issues, Vol. 4:1,27-46, p.27 (2007).

sources of concern for the research community. Social, moral and economical aspects of patents are scrutinised from the purview of scientific research data so as to analyse the proprietary concerns and social obligations in scientific research data protection. Inadequacies of patent regime forced the scientific research communities to resort to an alternative mechanism to protect their research findings are to be identified.

The study is intended to cover the various initiatives to protect the databases across the world so as to understand the scope of protection of biotechnology research databases. The study envisages to cover biotechnology research data protection and major issues relating to patent system and copyright. A detailed analysis of the open source concept is carried out to understand its feasibility in applying it to biotechnology research. Further various philosophical justifications and the economical, social and moral implications of adopting the open source movement are made the subject of thorough analysis. The analysis is carried out to understand how far it succeeds in protecting the interests of IP right holders and the society. The study eventually tries to find a solution to the major issues of database protection and how best we can utilise open source licensing concept as a management strategy for wider dissemination of biotechnology research results aid proper safeguarding the interest of the researcher.

AIMS AND OBJECTIVES OF THE STUDY

The aim of this study is to have an in depth analysis of intellectual property concepts prevailing in scientific research especially in the area of biotechnology. One of the main objectives of the study is to analyse the conceptual disparities in the patent system and the relatively new open source concept based on copyright concepts. Another objective of the study is to analyse the economical, social and moral justifications of both the patent and the open source licensing concepts in order to find the best suitable Intellectual property strategy for biotechnology research data protection.

SCOPE OF THE STUDY

Biotechnology researches and developments play a prominent role in every walk of life. Hence the economical, social and moral justification of Intellectual

property rights in the field of biotechnology research needs to be perfectly balanced. IP protection in the area of scientific research should not act as a blanket covering, hindering the future growth purely on economical ground. Such protection is against the moral and social obligation envisaged by the intellectual property protection. How far the open source licensing can resolve the problems relating to the application of patent and copyright in the area of biotechnological research is the central focus of this research.

The study is intended to analyse the critical problems of the patent system regarding its applicability to scientific research especially in the area of biotechnology. The study covers the implication of patent in scientific research, its moral and social justifications and proprietary issues in Intellectual property management. The study attempts to identify the areas in patents which are the major causes of concern for the scientific research community. Whether applicability of patents could adequately protect the research data by fulfilling the social obligation is also investigated. Further the scope of research data under copyright regime is also a major area covered by this study. Another significant area analysed in this work is the feasibility of European Database Directive in protecting the scientific research databases. Finally the thorough evaluation of open collaborative endeavours is made to understand, how best the open source concept can be applied to the arena of biotechnology research as a better Intellectual property management strategy.

LIMITATIONS OF THE STUDY

The area of scientific research data is very vast. But this study is limited to the applicability of the open source concept founded on the concepts of copyright to the area of biotechnology research data in the light of issues in patents and database protection. Enormous materials relating to the research area are available in intellectual property publications, scientific journals and on the internet. However availability of authoritative books for references are comparatively limited, as the topic of research is a novel concept in the area of intellectual property rights. Empirical data collection has certain limitations as the expertise in biotechnology does not have a very good exposure in intellectual property law and the situation is still worse in the case of the exposure regarding open source concepts.

RESEARCH QUESTIONS

1. What are the major inconsistencies in the patent regime with reference to on going biotechnological research and data protection?

2. Does patent protection hinder the future growth of biotechnology research?

3. What is the role of copyright in database protection in scientific research?

4. How far the European database directive can provide adequate protection to research database?

5. How far did open source succeed in solving the Intellectual property issue in the area of software?

6. How feasible is it to apply open source strategy to biotechnology research?

7. What are the conceptual disparities between the open source software and the open source biotechnology?

8. Will the open source licensing undermine future value of patents?

9. How far open collaborative research can promote growth in biotechnology research and serve as public good?

10. What are the policy and legislative requirements to resolve the issues in biotechnology research data protection?

HYPOTHESIS

1. The traditional patents and copyright regimes are irreconcilable with the protection of biotechnology research databases.

2. Protection of “non creative” databases and their contents similar to EU database directive could rejuvenate the intellectual property protection in biotechnology.

3. Patent protection to biotechnology innovations impede access and will slow down the pace of biotechnology research.

4. Open collaborative research endeavours will enrich public domain and will foster innovation in biotechnology research

5. Open source licensing as an intellectual property management strategy is more appropriate and desirable in the area of biotechnology research.

SCHEME OF CHAPTERS

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 and single nucleotide polymorphisms and the areas where the biotechnology and intellectual property rights are in conflict.

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 the traditional patent system. It further explains various doctrines and theories of patent. 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 are 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 the 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 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 the protection of non-creative or non-original databases are thoroughly evaluated form an international perspective. The positive attempts made by the European Union in the form of copyright directive and database directive were made a subject of detailed analysis form the point of view of biotechnology research databases.

Chapter five makes an analysis of the open source concept in the software sector to see how it differ form 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 indepth 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 the summarisation of the entire chapters. The conclusion also verifies the hypothesis and put forward some constructive suggestions and recommendations for effective intellectual property management strategies in biotechnology research.