CONCLUSION AND SUGGESTIONS

Biotechnology as the term suggests is futuristic in all respects. Anyone who is trying to explore what is happening in the area of biotechnology research will be astonished to see the magnificent developments that are taking place. Gone are the days of technology of cross breeding, brewing bear and making bread using yeast; biotechnology today is a science where you can program your cell to meet your biological requirement. The genomic research once amazed every one with revelation of genetic mark up and genetic codes. The tiny little cells and the complexity of genetic regulation inside them are great wonders of nature. But it represents a daunting challenge to unravel the mysteries of this complex structure.

As the biotechnology research kept unravelling these mysteries, it burdened upon the traditional legal system to safeguard the Intellectual Property Rights (IPRs) associated with it. The biotechnology research involved huge amount of intellectual and financial investment. The protection of biotechnology research and innovations became a major challenge to the researchers and legal experts. Biotechnology research has some peculiarities when compared to other areas of science. The nature of genomic research is a kind of gene exploration which normally forms only discoveries which are basically against the traditional patent philosophy. Another issue is that the biotechnology research is the unveiling of an already existing product of the nature which again is unpatentable. An in-depth analysis of these issues is made in the preceding chapters.

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

The study, streamlined according to the chapterisation based on the above scheme attempts to establish the entire hypothesis to be true. It is well understood that the traditional patent system failed to abridge the three potential areas of proprietary concerns, social interest and scientific growth. It is also proved that the basic research data relating to gene sequences and isolated proteins fall outside the ambit of traditional patent regime. Another possible alternative mechanism to protect the research data was copyright, which is again confronted with many shortcomings. The study successfully establishes that the open source licensing concept, similar to that in the software sector, can alleviate many problems faced by biotechnology. Thus, the study establishes that the intellectual property licensing based on open source concept, is an effective research data management strategy to foster innovation by maintaining a perfect balance between proprietary concerns and social interest.

Summary of Chapters

The theme of this research is centered around the contemporary area of biotechnology research and the allied intellectual property rights. A basic understanding of biotechnology as a subject is very essential to understand the intellectual property issues relating to it, and it makes this area slightly interdisciplinary. The first chapter gives a detailed introduction to biotechnology, its basic concepts, historical aspects, classification, technology application, areas of application and so on. The purpose of the chapter is well served, as it briefly and clearly narrates almost all the relevant areas required for the continued understanding of the issues of intellectual property rights.

The chapter explains the basic terminology of “biotechnology,” its definition and the major activities relating to it. It makes a detailed historical analysis of the development of the modern biotechnology research and a maximum effort is made to
bring in almost all the relevant intellectual property events in the biotechnology development path. Further the chapter makes a detailed reference to the cell structure, what a Deoxyribonucleic Acid (DNA) is and what it encodes. The chapter explains the relationship between DNA, Ribonucleic Acid RNA and the proteins in order to give a basic understanding about the cell function. Further the chapter illustrates some of the basic technology applications like bio-processing technologies, cell or tissue culture, recombinant DNA technologies, cloning and so on.

Chapter one also gives a detailed illustration of the types of biotechnology applications like medical biotechnology, agricultural application and so on. It also explains the most contemporary areas like bioinformatics, nano-biotechnology, genetically modified organisms, Single Nucleotide Polymorphisms (SNPs) and Expressed Sequence Tags (ESTs). These are the most significant areas in biotechnology research which pose many contemporary intellectual property issues in biotechnology research. This section of the chapter is particularly relevant in this study because the subsequent chapters of the study are largely related to the intellectual property issues pertaining to these main areas.

Chapter two deals with many paradoxical issues related to patent protection in biotechnology research. It gives a brief historical analysis of the patent system followed by a detailed explanation of patent philosophies and theories. The evaluation of the various theories shows that they are envisioned to protect either proprietary interest or the interest of the society. Most of the reciprocal arrangements envisaged by these theories are made only with an objective of securing their respective views. This situation can be better illustrated with an example. The natural right theory claims patent as a natural right for time and money the inventor has expended in bringing out the new product. Hence patent is an incentive to invent. Whereas the incentive to disclose theory argues that the exclusive protection granted to the inventor is for disclosing the invention to the public.

The moral and philosophical rationale of the patent system has been justified by various patent theories. Another significant area which the chapter explains is the various motivations behind the inventive activity. Motivations for innovators involved in inventive activities are generally classified as intrinsic and extrinsic. Self driven
individuals, with out commercial objectives, can be considered intrinsically motivated. Whereas, the extrinsic motivations are those which are driven by economic incentives. The evaluation of these concepts proves that intrinsic motivations are more powerful than extrinsic ones and they contribute to fostering of innovation.

The second chapter exhaustively deals with the major issues posed by the traditional patent regime when applied to the area of biotechnology research. One view held by the economists is that the patent system will cause rent dissipation. The concept of rent in economics means, returns over and above the costs required to produce the goods or to keep them in production. The Intellectual property rights can sometimes give rise to socially wasteful duplicative or uncoordinated inventive activities resulting in wastage of socially desirable resources. In simple language, the concept of rent dissipation in economics, suggests that IPRs may cause socially wasteful resources. Further, this chapter also evaluates various research and empirical studies conducted by different scholars and it is shown that the patents are the most expensive IPRs to maintain. They involve huge transaction costs and the patent litigations are the most expensive among all IPRs.

The study reveals that too many patents relating to a particular area have caused patent proliferation resulting in patent thickets and research bottlenecks. Further, the patent proliferation has resulted in widespread anticommons effect in biotechnology research. The term ‘anticommons’ describes a situation where several individuals own patent rights to exclude others. By using their exclusive rights, they are in a position to restrict other’s access to use the common resources. The “tragedy of the anticommons” is a result of the proliferation of fragmented and overlapping intellectual property rights.

The second chapter also analyses various other unhealthy practices adopted by patent right holders. One of the prominent issues raised in this regard is the “evergreening” or “continuation practice”. This is believed to have commonly prevailed in the pharmaceutical sector. ‘Evergreening’ is a process whereby the patent holder attempts to extend the term of his patent by obtaining related patents in modified forms of the same drug. It is difficult to distinguish between the legitimate
incremental innovations and the improper attempts of evergreening. The problem of evergreening is considered a misuse of the patent system.

Another significant problem with the patent system as discussed in chapter two is the problem of patent tolls (toll booths) and patent trolls. These two concepts are fundamentally different. Patent toll is a concept whereby the initial inventor imposes a toll on all subsequent innovations that rely on the initial invention. Later inventors therefore have to incur heavy transaction costs and they must pay licensing fees before they can further refine a technology. Whereas patent trolls “try to make money out of a patent which they are not practicing. In fact, they have no intention of practising the inventions and in most cases they have never been practiced. One more point discussed in this chapter is the issue of submarine patents. A submarine patent, in reality, is the patent applied earlier but not known to the public. These patents surface after many years when the patented technology is put to use by another new company. The result is that this new company working in the same area is automatically put into infringement liability. This again will lead to a costly licensing arrangement or abandonment of the product as such.

Thus, the second chapter successfully highlights various patent philosophies. It also analyses the motivations behind innovations that contribute to the innovative process. The detailed analysis of the patent system as applied to scientific research sector, successfully highlights the shortcomings of the patent regime specifically relevant in biotechnology research. The above discussed problems indicate that the patent system as applicable to scientific research, tends to slow down the pace of research in a number of ways and it hampers the progress of biotechnology research.

The third chapter evaluates the judicial and legislative interventions meant for streamlining the biotechnology patenting issues. Detailed analyses of conceptual disparities are made with the decided cases from different jurisdictions. The patent system and its applicability in biotechnology research, especially DNA research, have been a subject matter of continuing debates. The chapter explains various international conventions and treaties addressing the issues of patentability of biotechnological inventions. These conventions and treaties addressing the
biotechnology patent system itself, point towards the need of making a more efficient system of protection in biotechnology research.

The third chapter makes a detailed study of various issues relating to biotechnology from the perspective of patent protection. Patenting of genes and gene fragments, to be more specific ESTs and SNPs have triggered many controversies. ESTs and SNPs can be used as probes and they do not necessarily identify the exact function of the gene or any proteins they encode. Although some SNPs and ESTs may not directly identify genes, they may still be extremely useful and thus may satisfy the utility requirement stipulated by the patent law. For example SNPs can be used for tracing ancestry or parentage and ESTs for chromosome identification and gene mapping. Both can be used to identify genes that contribute to predisposition to diseases and so on.

As per the analysis made in the third chapter, a major section of researchers believe that the ESTs and SNPs are only exhibiting raw genomic data derived during a gene probe or exploration. It is strongly contented that the patent protection will impede future research in this area. Another argument is that the genomic research data are basically discoveries and are not eligible for patent protection. Still another view is that the result of genomic research is the product of the nature. These arguments have been subjected to judicial scrutiny in a number of cases since the Diamond v. Chakrabarty.\(^1\) The decisions rendered by the courts in various cases failed to affirmatively hold the genomic research to be a patentable subject matter. Most of the cases on ESTs and SNPs were denied patent either on the ground of failure to establish credible and substantial utility or lack of written description. This chapter also deals with the patentability of genetically modified organisms and multi cellular animals.

The study makes a detailed analysis of the latest case laws relating to biotechnology research in order to understand the current trend in two major regions of the United States (US) and the European Union (EU). The Unites States being one the leading nations where biotechnology research flourished and which made significant contributions in shaping intellectual property concepts relating to

biotechnology research. The Intellectual property issues in biotechnology research appeared very complicated until the decision came in the *Diamond v. Chakrabarty* case. This was followed by a patenting rush in the area biotechnology research. Though *Diamond v. Chakrabarty* gave a favourable decision, the situation changed as the nature of research transformed into genomic research and protection was sought for the research data being a part of the naturally occurring gene.

The recent high profile cases from the US which caught the attention of the world includes *In re Fisher*, *Lab. Corp. of Am. Holdings v. Metabolite Labs.* *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad)*, *In re Kubin*, *In re Deuel*, *Prometheus Laboratories, Inc. v. Mayo Collaborative Services,* and *Classen Immunotherapies, Inc. v. Biogen*. The detailed analyses of all these cases, point to a more confused scenario in biotechnology research. Evaluation of these cases shows that even though the cases were decided favoring patent protection, they caught the attention due to the descending judges’ opinion. These cases have established a negative trend towards biotechnology patents.

Chapter three also makes a detailed analysis of the recently decided cases in Europe. A similar scenario persists in Europe, in spite of the enactment of the EU biotechnology directive. The analyses of the recent cases from different regions of the EU also show a similar situation. The cases evaluated for the purpose of study include *Biogen Inc. v Medeva Plc*, *Monsanto Tech. LLC v. Cargill Int’l. SA*, *Monsanto Tech. LLC v. Cefetra*, *Eli Lilly & Co v Human Genome Sciences Inc.*, *Eli Lilly & Co v Human Genome Sciences Inc.* Here again, all the reviewed cases show a less favorable trend towards genomic patents.

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2 *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).
5 *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009)
6 *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995)
8 *Biogen Inc. v Medeva Plc* [1997] RPC 1
9 *Monsanto Tech. LLC v. Cargill Int’l. SA*, [2007] EWHC (Pat) 2257
11 *Eli Lilly & Co v Human Genome Sciences Inc* [2008] EWHC 1903 (Pat) (PatCt)
12 *Eli Lilly & Co v Human Genome Sciences Inc* [2010] EWCA Civ 33
The fourth chapter makes a detailed evaluation of the next available option which is copyright protection to the biotechnology research data. It deals with the scope of protection of biotechnology research databases under the copyright regime and the database directive. The chapter makes a thorough analysis of various kinds of databases and attempts to see how it can be protected under the ambit of copyright law. As per the copyright philosophy, any original compilation of data is entitled for protection under the copyright regime. Based on the nature of databases, they can be classified as 1) original and creative databases and 2) non-original and non-creative databases. Copyright protection for databases is limited to original and creative compilation of data. In order to attract the copyright protection to databases, the work must be an original compilation. However the protection is offered only to the structure of the databases, not to their contents. The position was clarified in *Feist v. Rural*\(^{13}\) where it was held that originality was the basic requirement though it required only a ‘modicum of creativity’. Prior to *Feist*, there was a strong view that the skill and labour involved in creating the databases must be recognised. This was based on the copyright doctrine of ‘sweat of the brow’ which gave emphasis on the value of skill and labour involved in the work.

However, the post *Feist* era has seen major challenges for database owners especially of for non-creative databases. The non-creative databases may be requiring less creativity but they require considerable amount of research and investment and also have tremendous commercial potential. The issues relating to protection of non-creative or non-original databases were thoroughly evaluated from an international perspective. This chapter makes a thorough study of the conflicting philosophies of originality requirement against the “Sweat of the brow” doctrine. It also evaluates various international initiatives to protect databases including non-creative and non-original ones.

The fourth chapter evaluates the nature and scope of biotechnology research database. The nature and extent of biotechnology research data are changing day by day. Once they contained sequences of information about isolated genes and proteins; but today they contain more complex information such as interaction between many

levels of biological information in DNA, RNA, proteins, and so on. Evaluation of these data is essential to understand how they work together. These research data with the aid of information technology are transformed into bioinformatics databases. This chapter explores the various bioinformatics and biotechnological databases and it also reviews the possibility of applying the copyright principles to them. Various possibilities explored include genome database as a copyrightable subject matter similar to literary works computer programs and copyrightable compilation. These attempts confronted with many issues because the genomic databases lack originality as envisaged by the copyright principles. It also cannot be considered equivalent to computer programs.

The analysis made in the fourth chapter shows that the copyright law fails to protect biotechnology research data because the nature of databases is non-creative and non-original. However, the *sui generis* protection as offered by EU database directive, may extend a more appropriate remedy for the database dilemma of the biotechnology research. This chapter attempts to highlight the problems confronted by the biotechnology research in the copyright landscape. It also successfully establishes the scope of a *sui generis* mode of protection for biotechnology research databases similar to the EU directive.

Chapter five gives an introduction to the open source concept in the software sector to explain how it differs form the proprietary software sector. This chapter deals with the various open source models and it examines how it shapes the area of the software sector. It explains the open source philosophy and the motivating factors working behind open source contributions. Open source was earlier treated as an initiative against the traditional Intellectual property regime. However, it proved to be extremely innovative and perfectly in line with intellectual property concepts. It used copyright based licensing strategies for wider dissemination of software and has established itself to be a widely accepted public good. The study reveals that open source projects hold much value in terms of product-value and quality.

The fifth chapter analyses various ‘closed source’ software and open source software to understand how they both vary. Unlike the closed source software, the OSS gives access to the source code and permits modifications to the original
software. The analyses of various open source software models show that they are holding the same principle as intended to maintain the public good aspect.

Further, the fifth chapter analyses various other aspects of the OSS and the reasons for the wide participation of contributors. It was found that the intrinsic motivation is a major driving force behind an open source-based production of software. A detailed analysis of the intrinsic and extrinsic motivations was made in chapter two. The study shows that the contributors to open source software are participating in the projects due to various reasons. The main reasons for OSS contribution are altruism, reciprocity, feeling of being a member of community or member of a tribe, working towards filling up of an unfilled market, reputation incentives, signalling incentives, gift culture and so on. The chapter makes a detailed evaluation of various motivations, advantages and justifications of open source software.

The open source software licences were not legally recognised until recently. The fifth chapter analyses the legal status of open source license on the basis of decided case laws. The decision in Jacobsen v. Katzer\textsuperscript{14} was the first case which positively considered the validity and enforceability of the open source licence. Another popular case examined in chapter five is EDU 4 v. AFPA\textsuperscript{15}, popularly known as Paris GPL case. Interestingly this case also challenged the validity and enforceability of OSS but in a different perspective. The case was filed by a user of the software, not by a copyright holder. The Paris Court of Appeals decided that the terms of the GNU General Public License are valid and enforceable.

The analysis of the open source movement in chapter five reveals that the open source concept has emerged as a superior development methodology. The study reveals that open source software has dominated almost all areas of activities and is dominant in terms of quality and reliability. A detailed analysis of the open source market reveals that more than 60 percent of the web servers are running on open source projects (apache web server software). The open source software was widely

\textsuperscript{14} Jacobsen v. Katzer, 535 F.3d 1373
\textsuperscript{15} EDU 4 v. AFPA, Cour d'Appel de Paris, Pôle 5, Chambre 10, no: 294, (only in French)(16.09.2009)
accepted and the popular OSS includes Linux operating systems, Mozilla Firefox web browsers and Apache web server software.

The sixth chapter thoroughly evaluates the nature and scope of open source analogy in biotechnology research. The chapter commences with a brief historical review of open source concept in biotechnology research. Detailed discussions of the norms of science in the context of the present nature of biotechnology research are made in the early part of this chapter. The norms of sharing in science and its impact on research progress are scrutinised thoroughly; this justifies the new trend of openness in biotechnology research sector.

The evaluation of the norms of science revels that the earlier trends adopted by scientists were to publish the results of their work for ensuring that they remained openly accessible to the peers. The earlier scientific community was more interested in reputation incentives and so they contributed their works to the public body of knowledge. They believed in publishing their new discoveries through peer reviewed journals and were more interested in peer-recognition. The study reveals that scientific norms encouraged wider dissemination of basic research discoveries. The patent protection and trade secrets were considered undesirable for the protection of basic research.

The norms of science as described by Robert Merton comprise of four basic norms universalism, communism, disinterestedness and organized scepticism. An additional norm of ‘originality’ was added later to these four basic norms. The first norm “communism” refers to the sharing of scientific information among scientists. The second norm “universalism” describes that the science is a universal phenomenon. The third norm “disinterestedness” explains the impartiality or selflessness of scientists to any particular outcome and according to this norm they are mostly guided by passions and commitments. The fourth norm “organized scepticism” illustrates a methodological and an institutional norm which states that all ideas must be tested and are subject to rigorous, structured community scrutiny. The final norm of “originality” means novelty in research contributions. These norms explain the tradition of science which is in conflict with the current trends of enclosure movement. However it can be seen that these norms prove to be a precursor
of the open collaborative trends in biotechnology research. Further the study reveals that the sharing norms were the strong driving forces in scientific research.

The sixth chapter makes an in-depth analysis of various open collaborative projects and their potential impact on research and development in the biotechnology sector. These analyses are carried out to understand the feasibility and desirability of open collaborative endeavours in the biotechnology research. The most common belief is that the biotechnology research follows a similar analogy that is followed in software sector. However, it can be seen that the traditional norms of science emphasise on the sharing of research-finding and research tools. The study reveals that over emphasis on the protection of intellectual property rights with commercial objectives lead to the deterioration of the traditional norms of science. Application of open source concept in biotechnology research has brought-in some revolutionary changes in the biotechnology research.

The chapter illustrates the capability of open collaborative concept in biotechnology research by analysing the successful open collaborative endeavours in it. The first and foremost among them was the Human Genome Project (HGP) which successfully attempted to sequence the human genome. HGP was the world’s largest collaborative venture involving scientists from many parts of the world. It could successfully sequence human genome much earlier than the targeted time, and released the data on the public domain. Many open source collaborations including HapMap project, The Genetic Association Information Network (GAIN), The Tropical Disease Initiative (TDI) The International Rice Genome Sequencing Project (IRGSP), The Alliance for Cellular Signalling (AFCS), and so on followed the HGP. Apart from these collaborative research projects there developed similar collaborations in bioinformatics software sector as well. Other collaborative movements in the biotechnology sector include various database repositories or databanks like Gene Bank and Protein Data Bank (PDB). Open collaborative initiatives in Software development tools like BioPerl and BioJava were also proved to be highly successful. The study reveals that the open collaborative endeavours have successfully accomplished its desired objective of fostering innovation. It has proved to be many times faster than the isolated research endeavours.
The chapter also examines the concept of patent pools which essentially followed similar open collaborative concept relying on patent regime. The patent pools are beneficial to both intellectual property owners and consumers. The study reveals that the patent pools help in avoiding anti-common problems. Patent system poses major issues when two patent right come in conflict with each other. This situation may sometimes lead to bottlenecks or can lead to a patent infringement litigation resulting in heavy transaction costs. It is again a problem when two patent rights are complementing each other. This situation will either result in an increased price of one patent or in reducing the value of the other patent. Patent pools can resolve this problem of complementary or blocking patents. Patent pools will reduce the Intellectual property transaction costs and distribute risks among the members of the pool and foster better exchange of information.

This chapter analyses the viability of the open source concept as an effective strategy for intellectual property management ensuring scientific progress. We can see that the open source concept can be adopted even if we choose to patent the inventions. Biological Innovation for Open Society project is a typical example of open source patenting. The projects like SNP Consortium and The Tropical Disease Initiative follow the same concept. The concepts of patent pools similar to open source, also gives a positive message of harmony to overcome some of the major issues in the patent system.

According to the evaluations made in chapter six, the fundamental aspect of open collaborative research is that the sharing of ideas and exchange of research data among researchers will speed up research and enrich the public domain of knowledge. However the private isolated research endeavors giving much emphasis on protection of intellectual property rights, commercialisation and restriction on access cannot contribute much to the progress of science. This chapter successfully establishes that open source concept is a superior development methodology in biotechnology research by fostering innovation. It has succeeded in maintaining a perfect balance among proprietary interests, social concerns and scientific progress.
VERIFICATION OF HYPOTHESES

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

This research focuses mainly on the major inconsistencies relating to intellectual property protection in biotechnology sector. The detailed analysis made in chapter 2, 3 and 4 exposes major intellectual property issues in biotechnology research. Chapter two of the present study explains various concepts, philosophies, doctrines and theories of the traditional patent system. The second chapter highlights certain inherent problems with the traditional patent system while applying to the contemporary area of biotechnology research sector. The analysis made in the said chapter positively establishes various inconsistencies of traditional patent system when applied to the modern biotechnology sphere. The third chapter makes a detailed analysis of various judicial and legislative attempts to harmonise these problems highlighted in chapter two. They again show a negative trend in patent protection of biotechnology research.

The fourth chapter illustrates major problems confronted in biotechnology research data. The chapter analyses the option of copyright protection to biotechnology research databases. The analysis proves that the copyright protection of non-creative non-original biotechnology research databases do not come under the realm of copyright protection. Traditional copyright system which protects the original compilations is not adequate to handle the raw biotechnology research data. The analysis made in the foregoing chapters 2, 3 and 4 categorically establishes that the traditional Patents and Copyright regimes are incompatible with protection of biotechnology research databases.

- Intellectual property protection of non-creative biotechnology database including its structure and contents could rejuvenate the biotechnology research.

The study reveals that research databases form the most significant part of biotechnology research. A thorough scrutiny of the copyright landscape and the nature of biotechnology research reveal that the research data fall under the category of non-creative non-original databases and are outside the realm of copyright protection.
However protection of non-creative non-original databases as suggested by EU copyright and EU database Directives can effectively protect the intellectual property rights in biotechnology research. The study also reveals that open collaborative endeavours can effectively manage their portfolio if a more effective protection is granted to biotechnology databases. The biggest threat faced by the open collaborative projects today is the risk of data misappropriation by the “free riders”. The study confirms that the protection of non-creative non-original research databases in biotechnology can definitely rejuvenate the biotechnology research.

- Patent protections to biotechnology innovation impede access and slow down the pace of biotechnology research.

The intellectual property issues analysed in the previous chapter two show a trend of wide spread of anticommon problem due to patent proliferation in biotechnology research sector. Though the review of this problem as analysed in chapter two, does not empirically establish the anticommon effect; the study based on the various literature reviews along with case studies successfully establishes that there exists a prevalent anticommon problem in the biotechnology sector resulting in research bottlenecks and access problems. The various issues highlighted in chapter two including patent thickets, proliferations, research bottlenecks, anticommon effect and so on prove that they cause severe access problems in biotechnology research. The study firmly establishes that these problems scrutinised in chapter two cause to stifle down the ongoing research in biotechnology sector and thereby slow down the pace of research.

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

The open collaborative movements in biotechnology research and how they contribute to in fostering innovation are the central themes of this thesis. An analysis of open source analogy in the software sector, followed by an extensive analysis of open collaborative endeavours in biotechnology research goes to show that they are the most successful attempts in fostering biotechnology research. The analysis of open collaborative projects such as Human Genome Project and HapMap project demonstrate the magnitude of success accomplished by the collaborative endeavours
in this sector. These were followed by a series of open collaborative projects which released multitude genomic data on the public domain. These projects made the complicated sequencing efforts a much simpler process by sharing of ideas and tools. They could bring much faster results than isolated individual research accomplishments. The conceptual analyses made in the previous chapters five and six successfully prove that open collaboration will foster innovations and enrich the public domain of knowledge.

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

After the extensive analysis made in the foregoing chapters, this research positively affirms that open source licensing is the most effective, appropriate and desirable intellectual property management strategy in the biotechnology sector. Detailed exploration of scientific norms, evaluation of open source analogy in software sector and analysis of the most recent open collaborative movements in biotechnology sector emphatically suggests that open collaboration is the most effective strategy in fostering innovations leading to the enrichment of the public domain of knowledge. Further, the study also recognises that open source concept maintains a perfect balance between the proprietary interest and the interest of the society and progress in research sector. The open collaborative concept of sharing ideas, resources and data ensures scientific progress more than any other traditional Intellectual property management strategy. The interest of the database owner is also met by open source licensing strategy imposing royalties and licensing fees for commercial exploitation of research data.

**SUGGESTIONS AND RECOMMENDATIONS**

Biotechnology research plays a significant role in enhancing our living standards. The protection of biotechnology research data is the most valuable component of biotechnology research. The product and process relating to biotechnology are developed from these research data. Intellectual property protection of these research data poses many legal issues which are subjected to thorough analysis in the foregoing chapters. It is very important to frame a proper intellectual property management system to protect the research data to maintain a balance
between proprietary interest and social interest at the same time; it also acts as a catalyst to foster innovation by providing a platform for institutional collaborations and technology sharing. The following suggestions are put forwarded for the efficient intellectual property management in biotechnology research sphere.

- World Intellectual Property Organisation (WIPO) must take initiatives to develop a separate mechanism for protecting Intellectual Property Rights in biotechnology similar to the European Union Biotechnology Directive.

- A substantive proposal like “A2K treaty” shall be initiated under the auspices of WIPO for promoting cooperation, collaboration and technology sharing in biotechnology research sector for fostering innovations.

- A separate provision for protection of biotechnology research data shall be incorporated under trade-related aspects of intellectual property rights (TRIPs) agreement.

- Patent protection in biotechnology sector must be limited to pharmaceutical, essential therapeutic and diagnostic products and devices.

- No patent protection must be granted to research data, tools (software), processes and procedures in biotechnology research.

- Genes, gene fragments, proteins and such already existing products of nature shall be declared ineligible for patent protection.

- Patented inventions must be licensed for the purpose of experimental use.

- Experimental use exemption similar to fair use exception in copyright law must be allowed under patent laws for promoting future research.

- The experimental use of a patented invention for the purpose of future research must be allowed imposing reasonable restrictions and conditions preventing commercial exploitation of the patented inventions.

- The experimental use of patented invention for the purpose of future research must be coordinated, licensed and managed by the patent registry.
Compulsory licensing provisions must be used for the purpose of encouraging future research and the researchers must be allowed to invoke compulsory licensing provisions.

Mere discovery of a protein or purification of a naturally occurring protein must be declared ineligible for patenting.

Research databases such as SNPs, ESTs and protein sequences must be declared ineligible for patent protection.

Research database such as SNPs, ESTs and protein sequences shall be protected as databases.

Intellectual property protection of biotechnology research database must be ensured under the existing copyright regime by applying the “Sweat of the brow doctrine”.

Copyright protection must be extended to non-creative and non-original databases involving substantial investment and labour so as to cover biotechnology research data as well.

Basic research data like gene, gene fragments, genomic databases, ESTs, SNPs and such other non-creative and non-original databases in biotechnology must be protected by enacting special provisions under the copyright regime.

A separate *sui generis* mechanism, similar to the EU Database and Copyright directives may be enacted to ensure protection of biotechnology research data.

A Country wide registration mechanism for registration of ESTs SNPs and gene sequence data must be established.

The registration of these data and the genome data base must be carried out through a Genome Registry or a Gene Repository.
These registries must be maintained as a biotechnology-bioinformatics institute of the country and must be coordinated by the intellectual property and biotechnology experts.

A registration process granting exclusive right to the database owners on first to file basis, similar to patent must be developed for biotechnology research data.

The genomic databases that are registered with these repositories must be made available though Internet to the registered users imposing simple licensing terms.

The use of these online databases for educational and pure research must be provided without royalty obligation.

The commercial use of these databases must be allowed by imposing reasonable licensing fees and royalty obligations.

The databases registered with the repository must be provided with database protection and copyright protection.

These repositories must administer the licensing of research databases, distribution of the royalties and licensing charges to the owners of the databases.

These repositories must have dispute resolution mechanisms to avoid costly litigation obligation for the participants.

These repositories may also act as a platform for open collaboration in biotechnology research.

They must also provide technology transfer and licensing agreement services to manage the collaboration and their effective functioning.

The concept of patent pools, based on open source model, must also be encouraged to those areas of biotechnology research where patent protection is available.
Patent pools must be formed in biotechnology research sector especially in the areas of pharmaceutical, essential therapeutic and diagnostic products and devices.

The patent pools based on open source concepts may be encouraged to avoid the problems and costly litigations caused by blocking patents. This may also help in avoiding ‘anticommons’ problems in the biotechnology research.

The patent pools may be encouraged to avoid price escalation problems arising due to complimenting patents, as they arbitrarily control the pricing of the patented product.

Databases from publicly funded biotechnology research such as university research and government projects must be released to public domain of knowledge, so that, they are accessible to everyone.

The National Genome Registry shall coordinate patent pooling arrangement pertaining to specific diseases and other research targets.

The research comprehensively analyses the open source concept in biotechnology research from the backdrop of major problems and inconsistencies prevailing in patent and copyright landscape. The research is founded on these fundamental intellectual property issues and it successfully establishes that open source movement in biotechnology research is the most effective intellectual property management strategy for protecting research data. This contemporary 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.

This research sincerely attempts to cover a potentially unexplored area in intellectual property rights relating to scientific research. It is hoped that this work will prove to be a significant contribution to the area of intellectual property rights management in scientific research.