CHAPTER-V
CONCLUSIONS AND SUGGESTIONS

From its inception in 1790, the goal of the intellectual property law has been to stimulate technological advancement, particularly in the familiar areas of mechanical, electrical and chemical technology. Although advances were also made in horticulture and animal husbandry, the general perception was that plants and animals were "products of nature' and therefore not patentable. But over the past two decades, the advent of revolutionary techniques permitting the creation of micro-organisms that produce human hormones such as insulin, plants that are more resistant to disease, and animals that produce human proteins used in the treatment of disease have caused a rethinking of this view.

In 1980, the Supreme Court's landmark decision in Diamond v Chakrabarty\(^1\) supplanted the conventional wisdom that living organisms were not patentable. The case involved a Pseudomonas bacterium engineered to degrade four of the components of crude oil. The Court held that the inventor of the new bacterium, whose invention otherwise met the legal requirements for obtaining a patent, could not be denied a patent solely because the invention was alive. The Court ruled that the critical distinction was not between living and non-living entities, but between products of nature, living or not, and human inventions. According to the Court, patentable subject-matter includes "anything under the sun that is made by man'.

Biotechnologies are more important than ever before. Fluctuations in biotech innovation and research-funding affect scientific workforces, economic prosperity, social benefits, productivity trajectories and innovative pace. Advances influence social change and economic growth; new products/processes increasingly play a central role in daily lives, shaping communication, information processing, health and well-being. Genomic research in particular is resulting in increasingly sophisticated analyses of genes and their interactions and is expected to lead to targeted therapies for both simple and complex diseases, common and rare.

\(^1\) 447 U.S. 303 (1980).
With this broad statement, it seemed clear to the patent bar that any genetically engineered organism excluding humans, of course would be patentable if it met the other requirements of the patent law. Public fears about patenting humans were held baseless by prohibiting the ownership of human life. Moreover, a consensus exists today among experts that it would be unethical to modify humans genetically in such a way that the new traits are passed on to their offspring.

However, all the legal issues have not been resolved. Important questions remain on ways to meet what is known as the "enablement" requirement and on permissible and impermissible uses of patented organisms. A patent maybe viewed as a social contract. Society grants the inventor the right to exclude others from making, using or selling his invention for a limited period of time. In return, the patent must fully and publicly disclose the invention by describing it in sufficient detail to enable a "person skilled in the art" to make and use it. In this way, society can immediately begin to build upon the new technical knowledge.

In the case of genetically engineered organisms, it is often not possible always to provide a sufficiently detailed, reproducible written description. But inventors have been creative in overcoming this technical obstacle by placing samples of the organism into special depositories to become freely available after the patent is issued. But imposition of restrictions on access to deposits is an important issue which is rising day by day.

The other important concern which draws the attention is ethical, public order and moral issues in biotechnology patenting, because it includes claims for genomic DNA sequences, complementary DNAs, individual mutations, expressed sequence tags (ESTs), single nucleotide polymorphisms (SNPs) and stem cells. The coverage of these patents and their enforcement has global implications, between the private and public sector and between rich and poor countries. IP protection in biotechnology and genomic patenting needs to be subject to ethical analysis to examine whether it is suitable for a moral society.
The main focus of the modern society on biotechnology and genomic patenting is on human genes and proteins patenting because the criteria of human DNA, or human experiments, are objective selection criteria that can be used as markers for ethical review in a patent application. The ethical and moral groups posing question, whether the patenting of genes is an ethical activity, and if so, what conditions might make it more ethical. There are objections raised by scientists for the extension of IP protection into areas that were previously in the public domain, with debates over cases such as ESTs and basic research tools like polymerase chain reaction (PCR). The European Biotechnology Directive, emphasizes that patent law is not the forum to make a judgement on what types of research should be conducted or commercialized. However, as for any human activity where decisions must be made, both stages have moral implications. There are two distinct stages in the patent system i.e., the process leading up to the award of the patent, and the implementation and enforcement system.

There are grounds already established for the exclusion of patentability based on ethical concerns in a number of patent systems, and these date back to more than a century. Article 53(a) in the European Patent Convention, and Article 6 in the Directive, says 'if the exploitation of the invention would be contrary to morality' a patent shall not be granted. These grounds are part of the societal governance of biotechnology, attempting to lead research in ways that are consistent with social values. If patent offices consider the ethical issues relating to inventions, they can provide an additional social mechanism for society to guide research interests, beyond the limits that are already partially imposed on publicly funded research, by limiting the fields of research that can receive public funds.

After the controversial debate of oncomouse patenting, ethical, public order and moral issues were greatly taken care. Genomics, a new science is not different from other sciences for IPRs. The trend to apply for patent protection on a large number of genes simultaneously has broad socioeconomic impact because a few companies are dominating genomic sequencing. The companies like Celera and TIGR, have sequenced a substantial proportion of the complete genomes to be sequenced, raising questions about
whether the new technology really should be subject to the same type of patent system. The extent of this expansion of patents is narrowed by the ethical and moral concerns which are required to be paid more and more attention while allowing the biotechnology and genomic related patenting.

Promoting and regulating research and innovation in emerging biotechnologies, and determining the social uses to which they are appropriately put is a sensitive undertaking. The recent history of genetic policy-making and regulation, has been one of controversy and criticism. One example is the attempted introduction of genetically modified food in Europe. The perception that the Government used public engagement processes as an ex post facto attempt at public legitimization caused an outcry and a demand for greater transparency in governmental processes in human biotechnological regulation. There emerged a shift from "government" toward "governance" and an increased role for public participation in policy making.

Participation was traditionally viewed by policy-makers and scientific authorities as a means of educating the public instilling greater public understanding of science. It was concluded that the transfer of knowledge to the public would alleviate some of the ambiguity around science and relieve the "crisis of trust" surrounding biotechnologies and their regulation. The new demand for "governance" gradually transformed this one-way educational model into a two-way dialogue; a more active public engagement characterized by information exchange. Thus, even within the context of the governance model, it was decided that the manner and function of participation needed to evolve.

The science of genomics, gave an enormous opportunity to the scientists to know and find the secrets of genes and their functions. The completion of Human Genome project gave the statistics that the scientists have already located over 30,000 genes on the 23 pairs of human chromosomes and have found markers. Scientists are now mobilising to map the entire human genome over the next several years, including the 4,000 genes that cause single-gene inherited diseases such as cystic fibrosis. That effort would likely be followed by sequencing identifying and locating every one of the three
billion nucleotides that make up the DNA in the human genome. The information is expected to be a major step towards new understanding of inherited diseases as well as more common illnesses such as hypertension, heart disease, cancer and diabetes which are caused or influenced by the joint action of several genes. Estimates of costs for the project which could take as long as 20 years run as high as $3 billion. Molecular biologist and Nobel Prize winner Walter Gilbert has called this project the "holy grail of human genetics'. The sole issue involved is the ownership of human genome.

Many private organizations, started to create a database that would be available to other scientists and doctors for a price and demanding for copyright protection for that data. many geneticists have expressed concern that such actions would impede or even prohibit their own ability to do research on the human genome and to collect and publish data.

It is fairly clear that private organizations will be able to copyright his data. In fact, this would be a more or less straightforward application of traditional copyright law to a new area of technology, equivalent to copyrighting a book or an information database. Copyrights will simply protect the results of those corporation's efforts when those results are compiled in a particular format.

However, the underlying information itself cannot be copyrighted. Copyright traditionally has protected the particular form of expression, not the underlying idea or different forms of expression of the same idea. Therefore other scientists will be able to develop exactly the same data on their own and use it as they see fit. This means that the corporation which is going to develop the genomic database would be simply offering a service to those who wish to avoid some of the time-consuming collection work.

Some legal commentators have argued that genes themselves can be copyrighted, in the same way that computer programs are copyrightable. Both store information. DNA stores information that is used by living cells to create proteins. A cellular mechanism reads the type and the sequence of the nucleotides that make up a strand of DNA and
from this information assembles a protein. There are a number of esoteric legal arguments for and against such an outcome.

In the case of the human genome work, the reason for not granting is that it is only available for original works. In other words, if a scientist created a new gene by linking different nucleotide bases together, it could be an original "work" for which copyright protection might be available. However, to the extent a scientist was simply determining existing genes in the human genome, copyright protection would not appear to be available.

As patenting and copyrighting issues of biotechnology and genomic inventions and genomic databases is too complex and raises serious questions, some of the biotechnology related legislative provisions from the perspective of the primary moral approaches which emerged in the struggle over its passage, namely the utilitarian, human rights and dignitarian approaches can be summarized as follows.

The utilitarian approach weighs probable benefits and harms/dangers in answering whether a particular course should be pursued. The particular utilitarian approach which dominates the biotechnology related legislations is informed by neo-liberal capitalist ideology and assumes the traditional wisdom that permissive patentability encourages economic growth and scientific innovation. This approach justifies biotech patenting on the basis of its beneficial consequences, namely that it advances the dual objective/good of securing potential financial reward and advancing science for the potential benefit of humanity i.e. corporate self-interest results in outputs which benefit others. The primary value which underlies this approach is corporate/researcher autonomy self-governance and freedom of will which rests on the broad notion of valuing the worth of human beings.

Number of examples of the reification of this approach were found in the European Directive. Article 1(1), which extends patentability to biotech inventions, states that "biotechnological inventions shall be legally protected and Member States shall adjust
their patent legislation accordingly". Article 3(2) states that: "biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature".

Similarly, Art.5(2), which is supported by Recitals 20 to 22, stipulates: "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

Articles 3(1) and 5(2) deem that the isolation and purification of natural substances are capable of being inventions. Ultimately, they create a legal fiction and are much looser than the requirements for patentability elucidated for the United States in Chakrabarty. A more blatant reliance on this approach is apparent in Recitals 10 and 11, which generally state that patenting will encourage the development of environmentally friendly agricultural products/processes and broadly beneficial medical products/processes.

Although decidedly pro-innovation and pro-patenting, this approach limits patenting where the harms/dangers are too great. Such concessions to justice in the European Directive are found in the Art.6(2) list of processes which are banned from patentability, and in Art.11 which allows farmers to use the product of a harvest based on patented material for further propagation, and Art.12 which allows breeders to apply for compulsory, non-exclusive use of a patented invention. The value which underlies the latter provisions is a vision of distributive justice, which redistributes the benefits of genomic advances on the basis of macro distributive policies. There is little in the operative part of the European Directive supportive of the human rights approach, which generally emphasises human agency and individual autonomy i.e. physical, psychological, economic and legal liberty and freedom from coercion. However, Recital 43 notes that fundamental rights as contained in the European Convention on Human Rights 1950 ("ECHR") and Member State constitutional traditions must be protected. More specifically, Recital 26 states that human biological material that is the subject of a patent application must have been obtained in compliance with domestic laws relating to free and informed consent.
The dignitarian approach, which was espoused by Kantian, communitarian and religious adherents, decries human interference with the genetic building blocks of life which are viewed as common assets of humanity and the privatisation and commercialisation of life-based processes/products. It emphasises the values of sanctity of life i.e., human life and health above all other life and weighed equally as against other human life and human dignity. The human race's sense of its own importance and value should be maintained by affording it greater protection than other entities. It also supports autonomy the non-instrumentalisation of the person, but not to the extent that individuals are entitled to choose courses that compromise human dignity.

This approach is exposed by a number of articles which endeavour to set limits on the patentability of genetic material. Article 5(1) states that: "the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions". As evidenced by Recital 16, this is directed at erecting (minimal) limits to biotech patentability having reference to personal integrity and human dignity. Article 6(1) states: "Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation."

Article 6(2) offers some guidance by stating that the following are unpatentable (i) processes for cloning human beings; (ii) processes for modifying the germline genetic identity of human beings; (iii) uses of human embryos for industrial or commercial purposes; and (iv) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

After a through study of biotechnology and genomics in the intellectual property rights view point, particularly focusing on patenting of life, ethical, social, environmental public order and moral issues, few inferences could be drawn by the evaluation of the law relating to patenting of biotechnology and genomic inventions and the database
protection under copyright law regime for genomic databases have resulted in a few findings. Similarly the study reveals various concerns raised by various religious, ethical and environmental groups in patenting biotechnology and genomic inventions resulted in specific findings. On the whole the findings can be summarized as follows

- The exponential growth of patenting of biotechnology and genomic inventions is not smooth but confusing. There is requirement to balance the patenting of inventions which are beneficial to the society at large.
- The role of judiciary in interpreting the legislations related to biotechnology and genomic related inventions and databases is appreciable and requires to be maintained more stringently because of the social harm hidden behind allowing the inventions which are harmful to the society.
- The stringent application of the basic requirements such are novelty, non-obviousness and utility for granting patent for biotechnology and genomic inventions is required.
- The biotechnology and genomic patenting in India is however less but not ready to face the future challenges which the biotechnology and genomic industry is going to pose in future. In EU and USA, as they are developed both technologically and legally, is dealing the same according to the requirements of the national importance and approach. India has to look into the approach of the world countries and is required to derive a suitable mechanism to face the enormous flow of patent applications which are going to come in future.
- The social, environmental, moral, public order and ethical issues which are arising out of biotechnology and genomic patenting is required to be taken care urgently because of the increasing wider scope of biotechnology and genomic research.
- There is a possibility of misusing the potential of biotechnology and genomics by producing destructive biological weapons against social order and to create 'bioterrorism' which is required to be taken care urgently.
- There is growing controversy regarding genomic databases, privacy and genetic discrimination issues, ownership issues etc., which are required to be addressed urgently.
• Though in India, currently there is no flow of biotechnology and genomic air as like USA and EU, Indian government has to take steps to prepare a proper legal and judicial approach to handle the upcoming problems in this field.

There is always some scope for improvement and there will always be a margin for developments. Likewise, the law relating to biotechnology and genomic inventions in the field of intellectual property law could be strengthened and streamlined by adopting certain strong legal regulations. On the basis of the findings of research work the following suggestions are made which, if adopted, will bring the existing law in tune with the latest developments in the field of biotechnology. The suggestions may be adopted for the proper regulation and management of biotechnology and genomic inventions.

Recommendations

• An international legal regime may be evolved to deal with biotechnology and genomic inventions patenting.

• The existing mechanism can be strengthened to avoid the misuse of the technology against the society. The basic requirements of patentability i.e., novelty, non-obviousness and utility may be interpreted more stringently.

• Establishment of Universal Declaration or Convention on the prohibition of transgenic human being and cloning of human beings for reproductive purposes is required.

• A common legal regime to deal with genomic databases may address the privacy concerns and genetic discrimination.

• The functioning of ethics committee should be made more stringent to take care of ethical, moral, social and public order issues, surrounding biotechnology and genomic inventions.

• The imposition of strong restrictions relating to labeling should be adopted to answer the threat posed by biotechnology and genomic inventions to environment.

• The MNCs producing genomic databases may be encouraged to freely exchange the materials and data.
- The ratification of Convention on Biodiversity should be made compulsory for the members of WTO, to strengthen the protection for biodiversity to address the threats posed by the inventions of biotechnology and genomics.

- The public participation should be made compulsory while legislating rules and regulations relating to biotechnology and genomic patenting.

- CBD and TRIPs should promote the protection to ecological balance and biodiversity by prohibiting misuse of biotechnology and genomic inventions.

- The protection to the genomic databases should be provided by adopting *suigeneris* protection rather than following conventional copyright protection.

- Copyright protection/database protection for Human Genome Project or SNP sequences may curtail the future research because they are considered as raw material / basic tools for research in this field. Hence granting should be avoided.

- The privacy, ownership and sensitivity issues attached to the databases should be addressed through domestic legislations.