LAW AND ETHICS OF LIFE PATENTING

Dissertation Submitted in Partial Fulfilment of the Requirement
for the Degree of

MASTER OF LAWS

at the National Law School of India University, Bangalore

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1997

DECLARATION

I hereby declare that this dissertation is written by me during the period (1997) at the National Law School of India University, Bangalore. The work in this dissertation is original except for such help taken from such authorities, as has been referred to at the appropriate places. This work has not been submitted either in part or in whole for any degree at any university.

Bangalore

1.9.1997

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ACKNOWLEDGMENTS

I am obliged to all of those whose comments and suggestions have helped me to write this dissertation.

My greatest debt is to my guide, Dr. N.S. Gopalakrishnan at the National Law School of India University, Bangalore, who have tried to teach me something about IPRs.

I acknowledge the profound influence Prof. Mitra has on my academic life. I am benefitted from the critical comments made by Dr. N.R. Madhav Menon during the presentation of the seminars.

I am also benefitted from a number of discussions with Dr. Biswajit Dhar and Dr. Suman Sahai. Fr. Joy Karayampuram S.J., offered detailed and exceptionally helpful comments on the manuscript.

My friends and collegues, Kedar, Motilal, Tissa, Saroj, Dinky, Tripathi and Sharma have provided valuable comments and constructive criticisms on aspects of this dissertation. I acknowledge the continuing moral support of Anirban. I am indebted to Mr. Srinivas, Kamal and Padmaja for giving shape to this work.

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ABBREVIATIONS

CBD	:	Convention on Biological Diversity
DBT	:	Department of Biotechnology
DNA	:	Deoxyribonucleic Acid
EC	:	European Council
EMR	:	Exclusive Marketing Rights
EPA	:	Environmental Protection Agency, U.S.
EPC	:	European Patent Convention
EPO	:	European Patent Office
EPO TBA	:	European Patent Office Technical Board of Appeal
ESTs	:	Expressed Sequence Tags
EU	:	European Union
GMOs	:	Genetically Modified Organisms
IARI	:	Indian Agricultural Research Institute
IPRs	:	Intellectual Property Rights
NIH	:	National Institute of Health
OJEPO	:	Official Journal of European Patent Office
PTO	:	Patent and Trademarks Office, U.S.
rDNA	:	recombinant DNA
R & D	:	Research and Development
TRIPs	:	Agreement on Trade Related Aspects of Intellectual Property Rights
USC	:	United States Code
WIPO	:	World Intellectual Property Organisation
WTO	:	World Trade Organisation.

CHAPTER I

INTRODUCTION

Patent is a statutory monopoly right granted to an inventor for a limited period which secures him the exclusive right to make use or sell his invention.[1] The purpose of granting the monopoly is to work the invention and to vend the resulting product.[2] The word patent has its origin in the expression *letters patent.*[3] *Letters Patent* or *Literae patentes* means open letters issued by the Crown.[4]

The early origins of the institution of patents can be traced back to the British Crown's practice of giving monopoly right to traders.[5] Monopoly was

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1 *Wharton's Law Lexicon* (Sweet & Maxwell, 14 ed., 1993), p.584.

2 See Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (Government of India, 1959), p.9.

3 Anthony William Deller, *Deller's Walker on Patents*, (Vol.1, 2nd ed., 1964).

4 The British Crown in olden days used to issue open letters which bind the subjects at larger see *Webster's Encyclopedic Unabridged Dictionary of the English Language* (Random House, 1996), p.823.

5 For details see Roman A. Klitzke, "Historical Background of the English Patent Law", 41 *Journal of Pat. off. Socy*, 615 (Vol.XLI, 1959).

granted to anyone who brings a new invention to England irrespective of whether he is the real inventor or not.[6] There was no need to disclose an invention nor was it necessary to be a new manufacture.[7] Infact the consideration for the grant of monopoly was the establishment of an industry.

From this early history the institution of patents has travelled a long way before it acquired its present form.[8] During the course of this development its basic concepts have undergone drastic changes. At different points of time judiciaries and legislatures have attempted to redefine the basics of patents.[9] This gradual evolution finally resulted in fundamental changes in the basic concepts of patents. Conceptually speaking from the very beginning itself patents seem to have its foundation on social interest notions. The built in expiry of the period of monopoly, the compulsion for

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6 *Ibid.*

7 See Wyndham Hulme, "The History of the Patent System under the prerogative and at Common Law" 12 *L.Q.R.*141 (1896), p.141, as cited in N.S. Gopalakrishnan, *Intellectual Property and Criminal Law*, (NLSIU, 1994), p.183.

8 *Ibid.*

9 For a detailed analysis of the judicial and legislative development of patent laws see N S Gopalakrishnan, *Intellectual Property and Criminal Law*, (NLSIU, 1994), pp.182-201.

disclosure of the invention and the insistance of actual working have strengthened the social interest basis of patent regimes.[10] These provisions are aimed at an increase in the common stock of knowledge accessible by all, which facilitates scientific and technological progress.

But within the patent regimes, there has been an ongoing conflict between the social interest notions as against the individual rights of the patentee in his economic gains. Patent systems now seem to be predominated by individual right notions resulting in the dilution of the social interest basis.[11]

In India the patent system owes its origin to a legislative process which began in the middle of the 19th century.[12] It ended up in the enactment of the

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10 Patents are granted for a predetermined period. For e.g., in India except in case of process patents on food drug or medicine the term of patent is fourteen years. In case of such inventions the period is five years from the date of sealing of the patent or seven years from the date of filing the patent whichever is shorter. See Sec.53 of the Patents Act, 1970.

For the provisions relating to disclosure see Sections 2(1)(m), 7, 9, and particularly Sec.10 of the Patents Act, 1970.

11 For an elaborate analysis of the conceptual basis of IPRs see Justin Hughes, "The Philosophy of Intellectual Proeprty", 77 *George Town Law Journal*, 287 (1988).

12 See *supra n.2.*

1911 Patent Act which remained in the statute book in one form or other till 1970.[13] In 1970, the Patents Act was enacted. The patent legislations, originally enacted by the British were intended to protect their trade interests.[14] But the 1970 Act was drafted in a different line so as to guarantee the interests of the public writ large. This is evident from a number of provisions in the Patents Act.[15] A clear reflection of the predominance of public interests in the working of the Indian Patent System can be seen in the provisions which exclude product patenting of drugs, medicine and food.[16] The purpose behind these provisions was to protect the larger social needs relating to food security and availability of drugs and medicines. Therefore the Indian patent law as it stands today seems to reflect the social needs at large.

The Final Act of the WTO which is signed in Marrakesh on 15.4.1994 brought into existence the World Trade Organisation. The Agreement on the

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13 See Rajeev Dhavan *et. al.*, "Whose Interest? Independent India's Patent Law and Policy", 32, *J.I.L.I.*, 429, (1990).

14 See *Raja Gopala Ayyengar*, *op. cit.*, pp.9-12.

15 See generally Chapter XVI of the Patents Act 1970. Chapter XVI deals with working of patents, compulsory licenses, licenses of Right and Revocation.

16 See Sec. 5 of the Act. See also Sec. 3 of the Act.

Trade Related Aspects of Intellectual Property Rights forms part of the WTO charter.[17] The incorporation of intellectual property rights into the GATT negotiations has a long history.[18] At present the members of WTO are under an obligation to comply with the mandates given in the TRIPs Agreement. The Agreement gives some time to implement the provisions to the developing and the least developed country members, taking into account their economic and technological developments.[19] The basic purpose of TRIPs is to bring a global intellectual property regime so as to avoid IPRs becoming barriers to international trade.[20] For this purpose the differences existing in between the domestic intellectual property regimes are to be

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17 See the Final Act of WTO.

18 See generally Muchkund Dubey, *An Unequal Treaty, World Trading Order After GATT*, (New Age, 1966). Vandana Shiva, GATT and the Biodiversity Convention, *E.P.W.*, April 3, (1993). N.S.Gopalakrishnan, "Diversity related Intellectual Property Rights, GATT Final Act, the Convention on Biological Diversity and the Challenges", *The Academy Law Review*, Vol.18, 1 & 2, p.62, (1994), Chakravarthi Raghavan, *Recolonisation: GATT, The Uruguay Round and the Third World.*

19 See Artiicles 65 and 66 of the TRIPs.

20 See the Preamble of TRIPs.

reconciled. Therefore TRIPs mandates for certain amendments in the domestic laws of the member nations.[21]

India being a member of WTO is under an obligation to comply with the requirements of the TRIPs Agreement. One such obligation as it stands today is to provide patent protection for microorganisms and microbiological processes.[22] Microorganisms being living subject matter,[23] this implies the

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21 As far as India is concerned one immediate obligation is to provide Exclusive Monopoly Rights (EMR) under Art. 70(8) r/w Art. 27, on pharmacuetical and agro-chemical products.

22 See Art. 27 of TRIPS. Art. 27 provides for patentable subject matter which include microorganism and microbiological processes.

23 The word microorganism is not defined in any legal documents. Microorganisms generally mean to include organisms which are visible only through a microscope. *The proposal for the EC Directive on the Legal Protection of Biotechnological Inventions* in Art.2(1) defines biological material as any material containing genetic information and capable of self-producing or capable of being reproduced in a biological system. See *The Proposal for a European Parliament and Council Directive (EC) on the Legal Protection of Biotechnological Inventions*, DOC. COM(95) 661 final of 13. Dec. 1995. The Examination guidelines of the European Patent Office explains the term microorganism as follows:

> "Microorganisms" include not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e., all generally unicellular organisms with dimensions beneath the limits of

case of patenting of life forms. At present there is no specific provision in the Patents Act, 1970 to provide patent protection for microorganisms and microbiological processes. But TRIPs gives a period of ten years to amend the Act to comply with the mandate.[24]

Patenting of life forms seems to have a long history.[25] But the issue attracted the attention of the academic circles after the decision of the U.S Supreme Court in the *Chakaraborty case*.[26] In *Chakraborty* the U.S Supreme Court held that a man made microorganism is patentable.[27] Subsequently in a number of decisions the courts in U.S and Europe expanded their patent laws so as to include within their purview various forms of living subject matter as patentable.[28]

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vision which can be propagated and manipulated in a laboratory. Plasmids are also considered to fall under this definition.

Guidelines for Examination, *E.P.O*, C-IV, 3.5.

24 See *supra n.*19.

25 For a detailed discussion see Chapter III.

26 *Diamond v. Chakraborty* (SC) 447 US 305.

27 For details see Chapter III.

28 For details see Chapter III.

The development of law in this area is to be seen in the light of various factors, the most important of which is the advancements in the field of biotechnology that have commercial potentials.[29] Biotechnology uses either directly or indirectly, living beings as the subject matters as its experiments.[30] Life patenting has become a controversial issue because of the recent innovations in this area.[31] These technological developments succeeded in introducing genetic changes in organisms with specific ends.[32] The outcome of this technology was living organisms exhibiting novel qualities. This resulted in claims for patent protection for biotechnological inventions which are living organisms. A background understanding of these scientific developments seems to be necessary for a proper appraisal of the issues relating to patenting living beings, especially when it comes to the value conflicts between scientific advancements and social norms.

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29 The Discovery of *DNA* structure by Watson and Crick and the subsequent development of *re-DNA* technology resulted in the emergence of the *New Biotechnology*. For a detailed analysis see Chapter II.

30 For the meaning and content of biotechnology see Bull, Holt and Lilly, *Biotechnology: International Trends and Perspectives*, (OECD, Paris, 1982).

31 *Ibid.*

32 See generally Chapter II.

As said earlier the Indian Patent Act does not specifically provide for patenting of living subject matter. But the *TRIPs compulsion* for patent grants on life forms now force us to address the various issues relating to it.

The economic dimensions of the issue are primarily related to two factors. One is the high commercial viability of the biotechnological inventions and the other the huge investments made thereby.[33] These factors resulted in the emergence of a global *bio business.*[34] The economic issues relating to the patent protection of biotechnological inventions require a very wide canvas, therefore are out of the purview of this research. But while addressing the vital issues involved in life patenting its economic dimensions stand as a background for the research.

The existing literature on the topic reflects two divergent interests. One set of writings are trying to look at the issue in terms of the social and economic benefits deriving out of providing patent grants on life forms.[35]

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33 See Mitchel B. Wallerstein *et. al.*, ed., *Global Dimensions of Intellectual Property Rights in Science and Technology*, (National Academy Press, 1993).

34 Examples of biotech based industries are Monsanto, ICI, Ciba Geigy, Genentech, Hoecht and SB.

35 See generally, Brier, Crespi and Straus, *Biotechnology and Patent Protection*, (OECD, Paris, 1985). Robert Al Sherwood, "Why a Uniform Intellectual Property System makes sense", Mitchell B.

These writings argue that better patent protection encourages scientific progress which in turn brings social benefits. The other set of writings discard these arguments largely on the basis of biodiversity preservation and rights of indigenous people over traditional knowledge systems.[36] Some of

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Wallerstein et al., *Global Dimensions of Intellectual Property Rights in Science and Technology*, (National Academy Press, 1993), Rogee A. Sedj and R. David Simpson, "Property Rights, Externalities and Biodiversity", Ian Walden, "Preserving Biodiversity: the Role of Property Rights", Timothy M. Swansen ed., *The Economics and Ecology of Biodiversity* (Cambridge University Press, 1995). Justin Hughes, "The Philosophy of Intellectual Property", 77, *George Town Law Journal*, 287.

Apart from these writings the following treatises provide the conceptual basis and justifications for private property, John Locke, *Two Treatises of Government*, (Laslett, rev., ed., 1963). Robert Nozick, *State, Anarchy and Utopia* (Oxford University Press, 1975). John Rawls, *The Theory of Justice* (Oxford University Press, 1986).

[36] See generally, Vandana Shiva, *Captive Minds and Captive Lives: Ethics, Ecology and Patents on Life* (Research Foundation for Science, Technology and Natural Resource Policy 1995). Andy Coghlan, "Licensed to Sell the Stuff of Life", *New Scientist*, 11 Feb. 1995, No.1964, p.12, Stephen Brush and Doreen Stabinsky, ed., *Valuing Local Knowledge: Indigenous People and Intellectual Property Rights* (Island Press, 1995). Suman Sahai, "Patenting Genetic Resources: The Case of Developing Countries", *Indian Farming*, Oct.1993, p.7., Madhaw Gadgil and Preston Devasia, "Intellectual Property Rights and Biological Resources, Specifying Geographical Origins and Prior Knowledge of Uses", *Current Science*, Vol.69, No.8, Oct. 25, p.637, 1995, "The Dunkel Draft and Developing Countries"

the writers in the latter school highlight the environmental hazards of the unfettered deployment of genetic engineering.[37]

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by Public Interest Research Group (PIRG) voices, Vol.17, No.3, Sep.1993, Suman Sahai, "Patenting Life Forms What It Implies," *EPW*, April 25, p.878, 1992, Tracey Clunies Ross, "Creeping Enclosure; Seed Legislation, Plant Breeder's Rights and Scottish Potatoes", *The Ecologist*, Vol.26, No.3, May/June 1996. H K Jain, "The Biodiversity Convention: More Losers than Winners", *Biotechnology and Development Monitor*, No.21, Dec.1994, p.23. Vandana Shiva, "Dispossession of Knowledge, Theft of Third World Resources and Intellectual Property", *The Ecologist*, Vol.26, No.3, May/June 1996. Suman Sahai, "The '*Sui Generis*' System", *EPW*, Dec.11, p.2702, 1993, Robin Pistoriss, "Was the US refusal to sign the Biodiversity Convention Necessary?", *Biotechnology and Development Monitor*, No.11, Sep.1992, Muchkund Dubey, *An Unequal Treaty: World Trading Order After GATT* (New Age 1996). John Mugabe and Evans Duke, "Control over Genetic Resources", *Biotechnology and Development Monitor*, No.21, Dec.1994, p.6. Suman Sahai, "Intellectual Property Rights over Life forms: What Should Guide India's Position", *EPW*, Jan.15, 1994.

[37] Richard Hind Marsh, "The Flawed sustainable promise of Genetic Engineering", *The Ecologist*, Vol.21, No.5, p.196, Sep./Oct. 1991. Peter R. Willis, "The Ecological Hazards of Transgenic Varieties", *Third World Resurgence*, No.53/54, p.30, Paul Hatchwell, "Opening Pandora's Box: The Risks of Releasing Genetically Engineered Organisms", *The Ecologist*, Vol.19, No.4, p.30, 1989, Mae-Wan Ho, "Genetic Engineering: Hope on Hoax?", *Third World Resurgence*, No.53/54, p.28, Vandana Shiva, "Why the Engineering Paradigm in Life Form is Flawed", *Third World Resurgence*, No.53/54, 1995, p.25. Andre de Kathen, "The Impact of Transgenic Crop Release in Developing Countries", *Biotechnology and Development Monitor*,

However, no comprehensive and in-depth study has been conducted on the issue, highlighting its legal, ethical and environmental ramifications. It is felt that the literature available on the topic do not address the issues critically. Therefore this research proceeds to analyse the legal, ethical and environmental implications of patenting life forms. But the basic questions involved in this area are so conjoined that sometimes a clear distinction would not become possible. But the crux of the problems involved in each of the areas are separately identified and analysed.

The research centres around the following hypothesis.

- Whether patenting of life forms is desirable or not?

The research questions are classified into three groups. One set of questions address the legal issues. These issues can be identified in two planes, one conceptual and the other in the realm of employing the concepts. In the conceptual level, the legality of life patenting poses certain

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No.28, Sep.1996, p.10, "The need to Regulate and Control Genetic Engineering", Cover Report, *Third World Resurgence*, 53/54 Jan/Feb.1995. David Dickson, "UK Clinical Geneticists Ask for Ban on the Patenting of Human Genes", *Nature*, Vol.366, No.6454, Dec.1993, p.391. Philip J. Regal, "Critical Issue in Biotechnology", *Third World Resurgence*, No.53/54, Jan/Feb 1995, p.33, Lawrence Busch, "Eight Reasons Why Patents Should not be extended to plants and animals", *Biotechnology and Development Monitor*, No.24, Sep.1955, p.24. Darryl R.J. Macer, *Attitudes to Genetic Engineering* (Eubios Ethics Institute, 1992).

jurisprudential questions. In a more practical realm it involves the problems of reconciling the TRIPs and the Indian Patent regime. The legal issues relating to life patenting as far as India is concerned directly relates to the harmonisation of the Indian Patent regime with the global model as incorporated in the TRIPs. The problems in this context are to be analysed in the light of several factors like the case law developments in the west and the basic legal principles of the Indian patents Act. The following issues are raised in this context.

1) the permissibility of patenting life forms in the light of the "*public order, morality and the natural law principles*" clauses in the Indian Patents Act.

2) Do the "*public order morality*" clauses in TRIPs and the Indian Patents Act encompass the moral and ethical components identified in the context of patenting life forms.

Questions become complex when it is all about life. The same is the case of a conceptual enquiry as to the ethics of life patenting. The questions central to this enquiry are:

1) Is *life* intrinsically valuable according to the well established principles of natural law?

2) Do patents on life forms violate the intrinsic values of life?

In order to fully appreciate these questions certain fundamental issues are also analysed in brief. They include the value conflicts between the social norms which are set on the basis of the collectively constructed thoughts of generations of people and the new values coming up from scientific progress.[38]

The ethical concerns emerging from the granting of private property rights over living beings compel the research to address the morality of legalising a private monopolistic domain over living beings. This in a way raises a broader issue relating to the morality of private property. But the research does not address this question, in its stead confines to the morality issue relating to *private propertising* life forms.[39]

The importance of biotechnology in social progress cannot be undermined. It is generally accepted that the advancements in biotechnology generate economic benefits.[40] But the merits of biotechnology is to be

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38 For a detailed discussion see Chapter IV.

39 *Ibid.*

40 See Suman Sahai, "The Importance of Biotechnology for National Growth and Development" (Gene Campaign, 1997), "Industrial Property Protection of Biotechnological Inventions", Report of the

appreciated in terms of its relative demerits; i.e., the environmental hazards it creates.[41] This study analyses though not in detail the scientific arguments on the environmental hazards of biotechnological inventions. This analysis also has a theoretical plane, which addresses the bio-ethical aspects of life patenting. Since bio-ethics by itsself is a broad field of enquiry, the analysis here confines to certain specific issues. The purpose of this bio-ethical approach is to make it clear that the problems of environmental risks have a theoretical base. The enquiry then proceeds to address the possibility of striking a balance between the relative merits and demerits of biotechnological inventions by putting *reasonable restrictions* upon it. For this purpose the role of the patent regime and the biosafety mechanism are analysed. The research issues on this point are,

- is a ban on life patenting an effective step in curbing the environmental hazards of biotechnological inventions?

- is the biosafety mechanism in India effective to curb the ecological hazards of genetic engineering?

International Bureau, WIPO, BIG/C6/IV/2 (1988). Joseph Straus, "Industrial Property Protection of Biotechnological Inventions: Analysis of Certain Basic Issues", WIPO, BIG/281 (1985), Ludwig Baumer, "Protection of Inventions in the Field of Biotechnology, WIPO/Cornell University (1987).

41 See the discussion in Chapter V.

The biosafety mechanism in India is analysed because India is one among the very few countries in Asia having a biosafety policy.[42] The dearth of materials in this regard compelled the research to confine to the data available for the purpose of analysis. After having a critical appraisal of the roles of patent system and the biosafety mechanism in moulding the innovations in this field of science so as to effectuate a steady and healthier social progress, the enquiry addresses the question of the desirability of patenting of life forms.

This study is divided into six chapters. Chapter I is the introduction. Chapter II consists of an overview of biotechnology. Chapter III deals with the legal developments in life patenting. This chapter addresses in brief the interplay between Intellectual Property rights and biotechnological innovations. A detailed critical appreciation of the case law is also included in this chapter. Chapter IV focuses on the morality questions relating to patenting of living beings. It consits of a detailed jurisprudential analysis of the issue.

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[42] See generally, Jos Bijman, "Biosafety Regulation", *Biotechnology and Development Monitor*, No.18, March 1994, p.14, "The Prospects for Technical Guidelines for Safety in Biotechnology", Discussion paper in the Anglo-Dutch Initiative, Biotechnology and Development Monitor, No.20, September 1994, p.21, *Annual Report of the Department of Biotechnology*, Government of India, 1997, Sachin Chaturvedi, "Biosafety Policy and Implications in India", *Biotechnology and Development Monitor*, No.30, March 1997, p.10.

The Chapter V consists of four parts. Part I examines the scientific arguments relating the environmental hazards of genetic engineering. Part II analyses the biosafety mechanisms and its functioning. Part III addresses in brief certain bio-ethical issues and in Part IV an attempt is made to analyse the extent of patentability of biotechnological invention in the light of its environmental risks. Chapter VI is the conclusion. The hypothesis, i.e., whether or not patenting life forms desirable is tested in this chapter in the light of the discussions in the preceeding chapters.

CHAPTER II

BIOTECHNOLOGY: AN OVERVIEW

A. A Brief Introduction to Biotechnology

Biotechnology has a long history. Man from the beginning of human civilization started selecting organisms that improve agriculture, animal husbandry, baking and brewing. *'Bios'* in Greek means life and biotechnology seems to comprise the technology that uses living entities like animals, plants or micro organisms or causes organic change in them. The expression biotechnology, despite its long standing tradition is not properly defined. But several attempts have been made to comprehensively define the term biotechnology.[1] An OECD study defines biotechnology as the application of scientific and engineering principles to the processing of

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1 The Office of Technology Assessment of the United States Congress (OTA) has defined biotechnology as "the collection of industrial processes that involve the use of biological systems. OTA in its second report gives a more detailed definition of the expression according to which biotechnology includes "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals or to develop microorganisms for specific uses". *See OTA Reports* 1981 and 1984.

materials by biological agents to provide goods and services.[2] In a broader sense it is defined as the use of biological materials such as living organisms or parts thereof, to produce a useful product.[3]

From these definitions we can arrive at some general inferences which are as follows:

i) the scope and ambit of biotechnology is not limited to living entities.

ii) biotechnology covers a wide range of biological materials such as animal and plant cells,[4] animal and plant cell lines,[5] enzymes,[6]

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2 This is a study produced for the organisation of Economic Cooperation and Development (OECD). Bull, Holt and Lilly, *Biotechnology, International Trends and Prospectives*, (OECD, Paris, 1982), p.21.

3 Micheline L. Gravelle, "Biotechnology - An Overview", 10 *CIPR* 1, p.1.

4 Cell is the smallest structural unit of a living matter capable of functioning independently.

5 Cell lines are cells that acquire the ability to multiply indefinitely *in vitro*.

6 Enzymes are proteins that are produced by living cells and that mediate and promote the chemical processes of life without themselves being altered or destroyed.

plasmids[7] and viruses.[8]

iii) due to the rapid growth of science and technology a comprehensive definition of the term biotechnology cannot be permanently arrived at.

It is documented that the Sumerians and the Babilonians were aware of fermentation of grains using to prepare beer. Microorganisms play important roles in fermenting wine, leavening bread and making cheese and yogurt. However, it was in the 19th century biotechnology evolved from an art into a science.

B. Biotechnology: The Initial Development

Though the primary focus of this study is on the recent innovations in the field of biotechnology generally labelled as *'genetic engineering'* it will not be out of place to have a look at the classical areas of biotechnology.

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7 Plasmids are extra chromosomal self-replicating, circular segments of DNA. Chromosomes are the thread like components of a cell that are comprised of DNA (deoxyribonucleic acid) and a protein.

8 Viruses are submicroscopic agents infusing plants, animals and bacteria and are unable to reproduce outside the tissues of the host.

(i) The Traditional Methods of Breeding Plants and Animals and Treating Microorganisms:

Plant breeding was initially done by simple selection and later on a further augmentation of genetic diversity produced by gene mutation has been achieved by deliberate hibridization. Great advancement was made by this intraspecific variation known as *'Mendelian segregation and recombination'*.[9] Subsequently hibridization brought the most important improvement in plant breeding. *Ploidy*[10] and *backcrossing*[11] are two other plant breeding methods. In addition to these traditional plant breeding techniques one another method is *plant tissue culture*.[12]

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9 W.J.C. Lawrence, *Plant Breeding*, (London, Beccles and Colchester, 1968), p.1.

10 Ploidy is a method for exchanging or adding genes through altering the number of chromosomes. Ploidy describes the number of sets of chromosomes present in the organism.

11 Backcrossing is a technique capable of improving a commercially superior variety by lifting one or more desirable traits from an inferior one.

12 Tissues culture is used to generate large number of plants from masses of disorganised tissue proliferated 'in vitro' and from cultured organs and auxiliary buds proved more efficient than conventional methods of asexual plant propagation. Tissue culture on one hand forms part of the traditional plant breeding techniques and on the other hand can be deemed as a part of genetic engineering. See *supra* n.2, p.36.

(ii) Animal Breeding

Many scientific developments have taken place in animal breeding especially after the 1950's. Some of these developments are *sperm storage, artificial insemination, estrous synchronization,*[13] *superovulation,*[14] *embryo recovery, transfer and storage, sex selection and twinning.*[15]

(iii) Industrial Microbiology

The path breaking discovery of Louis Pasteur in the second half of the nineteenth century that fermentation is carried out by living cells was a milestone in microbiology. The discovery of penicillin fermentation marked the beginning of the age of modern microbiology. An industrial microbiologist tries to find an organism whose production is not well regulated. This is done by isolating one such organism from the nature or by screening culture collections. Once this is done, the physical and nutritional

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13 Estrous or *'heat'* is the period during which the female will allow the male to mate with her. Synchronization is achieved by the use of various drugs.

14 Hormonal stimulation of the female resulting in the release from the ovary a larger number of ova than normal.

15 See Seidel, Superovulation and Embryo Transfer in Cattle, 218 *Science*, 341, p.358 (1981).

parameters for optimum growth and production are to be determined. Thereafter a traditional product of the fermentation industry may be produced.[16]

C. Biotechnology: The Recent Developments

Modern biotechnology owes much for its advent to the *recombinant DNA technology* and subsequently to the *monoclonal antibody techniques*. Today biotechnology has become multidisciplinary in nature, involving the fields of biochemistry, molecular biology, genetics microbiology, immunology, chemistry and chemical engineering to name a few.

The advancement in the field of genetic engineering started with a discovery by Friedrich Miescher around 1870, which revealed that the chief constituents of the cell nucleus were *nucleoprotiens*. *Nucleoprotiens* are combinations of basic proteins and nucleic acid which is later established as *Deoxyribonucleic Acid* (DNA). The discovery of the structure of DNA finally resulted in the introduction of the *recombinant DNA (rDNA) technology*.[17] The structure of *DNA* is discovered by Watson and Crick in

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16 J. Straus, *Industrial Property Protection of Biotechnological Inventions*, (BIG. 281/1985), p.15.

17 See *supra* n.3.

1953. The *DNA* is an extremely simple molecule composed of a small sugar molecule, a phosphate group (a phosphorous atom surrounded by four oxygen atoms) and four kinds of simple organic chemicals known as nitrogenous bases. These nitrogen containing bases are *adenine, thymine, guanine* and *cytosine*. The phosphates and sugars form two long chains with one nitrogenous base attached to each sugar molecule. The two chains are held together like the styles of a ladder by weak attractions between the bases protruding from the sugar molecules. In the presence of water the nucleotide chains do not stretch out to full length but twist around each other forming the *'double helix'*, which constitute the basic building block of all living matter.

(i) Recombinant DNA Technology

The basic purpose of *recombinant DNA (rDNA) technology* is to produce large quantities of a particular gene or *DNA* fragment or the protein that the *DNA* codes for. This is termed as *DNA cloning.*[18] The first cloning experiments were reported in 1972.[19] A *DNA cloning* is accomplished by the following process:

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18 *Ibid.*

19 See *The OTA Report*, 1981, p.39.

- making available the desired gene
- splicing the gene obtained into a vector to form a 'recombinant vector'
- separating the successfully engineered cells from the unwanted ones
- culturing the cells thus obtained so that they replicate and produce the desired fermentation product.[20]

Recombinant DNA technology allows the production of proteins in large quantities by a more efficient and less costly process. It has been applied for the production of several thousands of protein products. This new technology has made outstanding progress in the field of pharmaceuticals. Human insulin is the first therapeutic agent produced by means of *rDNA* technology. It came to the market in the year 1988.[21]

(ii) Somatic Cell Hybridization

In *Somatic Cell Hybridization* the cells are first isolated from plant tissues. The protoplast (the living component of the cell excluding the cell walls) are isolated by digesting enzymatically the cell wall in a medium. By a

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20 J. Straus, *Industrial Property Protection for Biotechnological Inventions*, (BIG/281), p.25.

21 Johnson, "Human Insulin from Recombinant DNA Technology", 219 *Science* 632 (1983).

fusion inducing agent the isolated protoplast is fused with the protoplast of another genus and is grown in a growth medium. This *Somatic Cell Hybridization* by protoplast fusion is a commercially promising method as it can create disease resistant crops.[22]

(iii) Monoclonal Antibodies Technology

The human immune system involves the interplay of various cells, proteins and chemical messengers. One type of protein involved in immunity is the antibody which are produced by *B-lymphocytes*. Antibodies are specific for the antigen to which it was created. Exposure to one antigen results in the formation of several types of antibodies. This mixture of antibodies are called *polyclonal antibodies*. But each *B cell* produces only type of antibody which is called a *monoclonal antibody*. This *monoclonal antibodies* are very useful as diagnostic reagents. (for eg: pregnancy diagnosis). *Monoclonal antibodies* are also used in therapeutics and in protein purification.[23]

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22 See *supra* n.20, p.29.

23 See *supra* n.17, p.8.

D. The Impacts of Biotechnology

Biotechnology is often described as the third technological revolution of 20th century, after nuclear energy and information technology.[24] The various technologies under genetic engineering are widely applied in a number of useful fields. An important area where biotechnology promises to make profound impacts is pharmaceuticals. For example, in the pharmaceutical sector, recombinant medicines such as ***recombinant insulin, human growth hormone, erythropoietin, interferon*** and ***tissue plasminogen activator*** are produced in commercial scales.[25]

Biotechnology improves the efficiency of agricultural production.[26] This gives rise to an increase in food production. This is achieved primarily by:

- facilitating gene transfers for desired characteristics.
- developing new varieties within short periods.[27]

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24 Suman Sahai, *The Importance of Biotechnology for National Growth and Development*, (Gene Campaign New Delhi, 1996).

25 Kiyoshi Yamashita, *Intellectual Property and Biotechnology*, (WIPO/IP/KUL/90/2), p.4.

26 See Jack Ralph Kloppenburg, *First the Seed, the Political Economy of Plant Biotechnology 1492-2000*, (Cambridge University Press, 1988).

27 See *supra* n.24.

Agricultural production can be increased by way of developing disease-resistent-plant varieties.[28] Another strategy is the development of hybrid seeds and plants. Pest-resistant plant varieties, bio-fertilizers and nitrogen-fixing microorganisms are also outcomes of biotech innovations.[29]

As regards animal improvement the major strategies of biotech research are increase in productivity rate and health care. Biotechnology involves mostly applied researches. Its commercial viability is very high. Therefore, most of the inventions in this field are having very high industrial applicability. For example, microorganisms and microbiological processes all are highly industrially significant. They are widely used for the production of various organic compounds[30]. Microorganisms are used for *biomining*[31] and pollution control. Microorganisms can be effectively used for the degradation of oil slicks and the disposal of hazardous wastes. Biological waste water treatment produces methane, which is an important energy source generally known as biogas. Another area where biotechnology has wide commercial applicability is the malting and brewing industries.

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28 See *supra* n.26

29 *Ibid.*

30 See *supra* n.25.

31 *Biomining* is an alternative resource-recovery mechanism. This involves microbial leaching of metalliferous ores and mine-waste talus. See for more details *supra* n.24, p.5.

Despite these merits, the advancement of biotechnology has brought with it many disadvantages. The major issue in this regard is the ecological risks involved in deploying biotech researches.[32] The potential environmental risks of biotechnology are yet to be estimated. Environmentalists argue that the risks involved in commercially applying most of the genetic engineering techniques are serious and irreparable.[33] These arguments seem to be scientifically well founded because the pro-genetic engineering scientific community has not so far ourightedly rejected them.

The above mentioned march of innovations in the field of biotechnology raised serious concerns regarding its probable misuse. Since the subject matter of genetic engineering is living beings this branch of science remains as a seat of perpetual controversies. Life patenting is a recent addition to this.

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32 See Chapter V for a detailed discussion on he environmental risks of biotechnology.

33 See Chapter I, n.37.

CHAPTER III

PATENTING LIFE FORMS: THE LAW AND PRACTICE

A. Introduction

Patenting of life forms raises serious legal issues because of its inherent complexities. Life forms in ordinary parlance means and include animals, plants and micro organisms. Though biological materials like plant and animal cells, human genes or plant tissues do not possess all these characteristics they are also animate substances. The advent of biotechnology, as we have already seen, proved possible the creation of 'new' life forms through genetic manipulations. This has resulted in the 'creation' of more and more higher forms of life which now reached in transgenic mammals. Patent laws have also travelled a long way from the original stands along with this scientific revolution.

Most of the national legislations as they originally stand do not provide *perse* for patenting of life forms. In order to critically appreciate this, patent laws of certain countries are analysed. In fact, some national legislation indirectly exclude patenting of life forms. The analysis of the legislative provisions on patentability is intended to reveal the original stand taken by

different countries. It is felt that irrespective of the basic policy differences there was a common stand against patenting of life forms.

The legal development in the area of patenting life forms was primarily because of the judicial interpretations broadening the patentability norms. There are many socio-economic reasons which prompt the judiciaries to broadly interpret the patent statutes so as to recognise patenting of life forms. But whether the judicial reasonings have gone into the crux of the issue in understanding its merits and demerits in a long term perspective is yet to be assessed.

B. Patenting Life Forms: A Retrospect

It is generally believed that patenting of living organism is an issue of recent origin. But as early as in 1843 a patent was granted in Finland for a living organism which was a yeast (*"ferment de poche"*).[1] In 1873 the U.S. patent and trademark office granted a patent to Louis Pasteur, which was for a *"yeast free from organic germs of disease as an article of manufacture"*. Patents were granted in the US for an antitoxic serum in 1877, for a bacterial

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1 J. Straus, *Biotechnology and Intellectual Property, Biotechnology* (Vol.12, 2nd ed), p.283.

vaccine in 1904 and for a viral vaccine in 1916.[2] After the discovery of the antibiotic penicillin patents were also granted for astreomycin, streptomycin, tetracycline etc.

In the Federal Republic of Germany, the Federal Supreme Court in its decision of 27 March 1969 in the *Red Dove Case* explicitly declared that animal breeding methods and their resulting products are patentable subject matter.[3] This decision has remained unnoted but a decision of the U.S.Supreme Court in 1980 in the *Chakroborty Case* has attracted wide public attention. We will see the socio-legal implications of these judicial exposition later.

C. **Patentability in General**:

Broadly speaking patents laws require an invention to be new, to comprise an inventive step and to be industrially applicable in order to be patentable.

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2 *Ibid.*

3 Norbert Marterer, "The Patentability of Microorganisms *per se*", 18 I.I.C. 666 (1987).

(i) Novelty

As regards the condition of novelty patent laws generally contain a provision which stipulates that an invention is new if it has not been disclosed to the public either in writing or orally by use or otherwise before the date of filing or the priority date. Nowadays the prior use - prior publication test is applied to test the novelty requirement. There exists a number of judicial pronouncement on the novelty as a requirement for patentability.[4] In *Liardet v. Johnson*[5], Lord Mansfield interpreted novelty to mean the absence of continuous and successful prior use or the lack of common knowledge of the substance in trade.[6] The English Courts interpreted the prior publication expression as a publication which is

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4 See *Harris v. Rothwell*, 3 Ch.D. 416. *Pickard v. Presscott*, 9 R.P.C. 195. *Lallubhai Chakubhai Jariwala v. Sakalchand Shah*, AIR (1934) Bom.407, etc.

5 *Morning Post*, Feb.23, 1778 as cited in N.S.Gopalakrishnan, *Intellectual Property and Criminal Law* (NLSIU, 1994), p.187.

6 *Ibid.*

accessible to all.[7] If an invention seeking patent is known to the public by a prior publication novelty is lost.[8]

When it comes to inventions in the field of biotechnology, naturally occurring substances, micro organisms or other biological materials face special problems. An analysis of the specific problems of patentability of naturally occurring substances, micro organisms etc., is included under a separate heading.

(ii) Inventive Step

For an invention to be patentable it should demonstrate the inventive faculty of the inventor. This implies the employment of the independent thought, ingenuity and skill of the inventor.[9] The question of the demonstration of inventive faculty as a necessary prerequisite of patentability came up for consideration before the Indian Supreme Court in *Biswanath*

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7 See *Harris v. Rothwell*, 35 Ch.D. 416. *Pickard v. Presscott*, 9 RPC 195

8 See N.S. Gopalakrishnan, *Intellectual Property and Criminal Law* (NLSIU, 1994), p.204.

9 *Ibid*, p.200.

Prasad Radhey Shyam.[10] The Court accepted the principle of *inventive faculty* and held that inventive faculty must be demonstrated for a claim to be patentable.[11]

(iii) Commercial Application

The extent of utility required for grant of patents is explained by Lindley L.J. in *Lane Fox v. Kensington and Knightsbridge Electric Company*[12]. The Law Lord was of the opinion that utiliy requirement should be understood in terms of the end results of the claim. If the object sought to be attained by the patentee can be attained, it is practically useful.[13]

Now-a-days patent laws expressed provide for utility as a condition for patentability. The India Patent Act expressly states that an invention to be patentable must be useful.[14]

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10 *Biswanath Prasad Radhey Shyam v. M/s Hindustan Metal Industries*, AIR 1982 S.C. 1444.

11 *Ibid*, p.1448.

12 (1892) 3 Ch.424.

13 *Ibid*, p.431.

14 See Sec.2(1)(j) of Patents Act, 1970.

An invention is considered useful if it is susceptible of industrial application. Industrial application implies the possibility of making use of the invention in any kind of industry. Industrial applicability is a very sensitive patentability requirement for science based inventions.

D. Intellectual Property Protection for Biotechnological Inventions: Products of Nature Problem and the Discovery Conundrum

Intellectual property rights in the field of biotechnology raises some novel issues as this whole area is connected with living forms. One such basic theoretical issue relates to the concept of invention and discovery. In identifying what is an invention and what is not, for the purpose of providing intellectual property protection, it is usual to distinguish an invention and a discovery. The patent laws of most of the countries exclude discoveries from patent protection. The patent laws of some countries use the terms *inventions* and *discovery* synonymously.[15] Now the issue in respect of biotechnological inventions is the extent to which the traditional concept of 'invention' covers inventions in the field of biotechnology for the purpose of intellectual property protection.

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15 The US patent law, for example, says that the term *inventions* means invention or discovery. 35 USC Para 100(a). Also in Art. 47(1) of the Spanish Act Scientific discoveries are treated as technical inventions.

Inventions in the field of biotechnology can be grouped into the following categories:

- plants, animals, micro organisms and other biological material and parts thereof;
- biological processes for the creation and production of plants, animals, micro organisms or other biological material, including those of isolation, purification, cultivation and multiplication.
- uses of plants, animals, micro organisms or other biological materials and parts thereof.[16]

The common definition of *discovery* includes the *products* of nature.[17] Invention in the field of biotechnology either directly or indirectly relate to living forms, which are products of nature. Therefore, the distinction between inventions for which protection is available and discoveries which cannot be protected seems a problem for biotechnological products.

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16 This classification seems to have been made scientifically based on the differences between the products and processes. See *OTA Report* 1981, p.42.

17 See *supra* n.19, p.44.

In India the expression *invention* was defined in the Inventions and Designs Act, 1888 to mean any manner or manufacture including an improvement thereof.[18] It was in the Statute of Monopoly of 1623, *any manner of new manufacture* was first time recognised as a patentability criterion.[19] In *Elgin Mills Co. v. Muir Mills Co.*[20], the Allahabad High Court explained the meaning of the expression *invention*. The Court held that for an invention to be patentable, there must be a certain amount of inventive faculty displayed.[21] This principle was followed in a number of other cases.[22]

The issue of *inventiveness of discovery* gets a new dimension when it comes to patenting living subject matter. Since most of the biotech

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18 See Sec.4(1) of the Inventions and Designs Act, 1888.

19 See Sec.6 of the Statute of Monopolies, 1623.

20 (1895) I.L.R 17 All.490.

21 *Ibid*, p.496.

22 See *Vidya Prakash v. Messrs Shahcharan Singh*, AIR (1943) Lah. 247. *Ganendro Nath Banerji v. Dhanpal Das Gupta*, AIR (1945) Oudh.6. *M/s Shining Industries v. M/s Shrikrishna Industries*, AIR (1975) All.231. *Press Metal Corporation Ltd. v. Noshir Sorabi Pochkhaswala*, AIR (1983) Bom. 144.

inventions amount to the identification of naturally occurring living materials, can they be called inventions at all?

The National Institute of Health (NIH) filed a patent application for partial human gene sequences (*expressed sequence bags* or *ESTs*) in 1991.[23] Since then the patentability of gene sequences remains as a debatable subject matter.[24] The Supreme Court of Canada in *Continental Soya Company Ltd v. J.R.Shart Milling Co (Canada) Ltd.*[25] considered whether claims to a naturally occurring enzymes were valid. the Court held that there exists a difference between discovery and invention. The Court observed:

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23 Patent Application dated June 20, 1991 of NIH (1992). See 11 *Biotech.L.R.* 1324.

24 See generally, K.G.Calia, "Patentabilikty of Expressed Sequence Tags; A Study of Venter Application" (1992), *Biotech. L.R.* 540. S.Best, "Misplaced Concerns Surrounding Venter/NIH Application Covering Human Genes" (1992) 11 *Biotech. L.R.* 145.

Helen Gavaghan, "NIH Wins Patent on Basic Technique Covering all *ex vivo* Gene Therapy", *Nature*. Vo.374, 30 March, 1995, p.393.

Malcolm Gladwell, "Are Scientists Wrong to Patent Genes?", *SPAN*, April/May 1996, p.52.

25 (1943), 3 CPR 1 (S.C.C).

"The difference between discovery and invention has been frequently emphasized and it has been laid down that a patent cannot be obtained for a discovery in the strict sense. If, however, the patented article or process has not actively been anticipated, so that the effect of the claims is not to prevent anything being done which has been done or proposed previously, the discovery which led to the patentee devising a process of apparatus may well supply the necessary element of invention required to support a patent. This is certainly the case if it can be shown that, apart from the discovery, there would have been no apparent reason for making any variation in the former practice."[26]

Holding the view that there exists an *inventiveness* in these discoveries the Canadian Supreme court allowed the patent claims.

In *Genentech Inc's Patent*,[27] the Court of Appeal in England considered the validity of claims for products and processes of *rDNA*

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26 *Ibid*, p.4.

27 (1989) R.P.C. 147.

technology used to produce pure *human tissue plasminogen activator (t-PA)*. The Court considered the patentability of DNA sequences which the researchers had discovered. The judges unanimously rejected the patent claims by adhering to a literal interpretation of para (a) of Sub.Sec. 1(2) of the English Patent Act 1972 which states that a discovery in itself is not to be regarded as an invention.

Scientific progress has to co-exist with legal norms. But the standards set by law fail to address certain complex situations. One such peculiar situation arises when law is required to objetively understand the notion of life. Life is commonly understood in terms of its attributes like growth, reproduction and internal reorganisation. An object which exhibits these attributtes is generally called a living being. At this outset there arises two issues. Firstly it is not always necessary for a living subject matter to exhibit all these qualities of life. As for instance in the case of a virus, it seems dead if you keep aloof but becomes active when gets into a living being. The same is the case of certain seeds which broods for years but sprouts in ideal conditions.

If the components of a living subject matter can be separated by genetic engineering, it must reach a stage where it requies some minimum components to be alive. This means a complex living being is reduced to a

minimal arrangements of components which exhibits life. Here arises a tricky question i.e., what is the differentiating line between being alive and not.

The second issue relates to the criteria of understanding different kinds of living beings. It is true that there exists some apparent differences between animals and plants. But when it comes to the animal kingdom a number of characteristics make the lower forms different from the higher ones. For e.g., the mammalian - non-mammalian difference. At this juncture we contract with the issue of getting objective legal standards to understand the notion of life for the purposes of patent protection. Can the patent laws use the same criteria equally in cases of patenting microorganisms and transgenic sheep? Why the U.S. patent office was compelled to explain that patent protection is available only for *non-human mammals*?

One has to look at the legal development on patenting of life form in the light of these issues. A detailed analysis of the law and practice of patenting life forms is attempted in the following pages.

E. Patenting Life Forms: The Legal Developments

1. The United States Experiment:

The US Constitution grants power to the Congress to make laws on patent grants for the purpose of encouraging scientific progress.[28] Section 101(iv) the main statutory provision dealing patentable subject matter under the US patent law.[29] The question of what is patentable under the U.S. patent laws come up from consideration before the courts on various grounds. But the U.S. Supreme Court in the famous *Chaktraborty case*[30] liberal interrupted

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28 Art.1 para 8 cl.8. of the U.S. Constitution says that the Congress shall have power to "legislate to promote the progress of science and useful Art, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries".

29 35 USCS S.101 reads: "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, or any new and useful improvement thereof, may obtain a patent therefore subject to the conditions and requirements of this title. The term process is also defined in 35 USCS S.100(6) as "process, art or method and include a new use of known process, machine, manufacture, composition of matter or material".

30 *Sidney A. Diamond v. Ananda M. Chaktraborty* (1980) Supreme Court 447 US 303. Anand Chaktraborty, an Indian scientist while working at the Genera Electric Co., USA has developed a bacterious of the pseudomonas species. This bacterium contains two stable energy-

the provisions contained in 35 USC Sec.101 so as to include within its provision a microorganism as patentable.[31] In this case Chaktraborty's claim for a patennt on the bacteria was rejected by the patent examiner on two grounds:

1. Microorganisms are products of nature
2. As living things they are patentable subject matter under 35 USC Sec.101.

On appeal by *Chaktraborty* the patent Office Board of Appeals affirmed the decision of the patent examiner on the second ground.

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generating plasmids which provide separate hydrocarbon degrading pathways which could *chew* hydrocarbon sludge from refineries. This is of high industrial use primarily to clean up petroleum slices in the sea. Anand Chakraborty filed a patent application for his invention. He claimed that the bacterium which he has invented in a genetically engineered, no-naturally occurring microorganism capable of breaking down crude oil. Chakraborty's claims were of three types: First, process claims for the method of producing the bacteria; second, claims for carrier material floating on water and the third, claims to the product. The patent examiner allowed the first two claims but rejected the claim on the bacteria themselves.

31 *Ibid.*

After a long voyage of appeals and further appeals[32] finally the case came up before the U.S. Supreme Court for consideration. The question before the court was one relating to the interpretation of 35 USC Sec.101. The Court considered whether a microorganism constitutes a *manufacture* or *composition of matter* within the meaning of the statute. The Court in a 5:4 majority judgment very liberally interpreted the above *expressions* and held the microorganism patentable. The reasons behind the judgment are very clear. The Court went against the legislation intent behind the provision dealing with patentable subject matter. As Brennan J., said in his dissenting

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[32] The court of Customs and Patent Appeals reversed the decision of the patent office Board of Appeal, by a divided vote, on the authority of its earlier decision in 563 F 2d. 1031 (1977), the Court held that "the fact that microorganisms are alive ... is without legal significance" for the purpose of patent law. The case involved a patent application for a pure culture of the microorganism streptomyces found to be useful in the production of lincomycin, as antibiotic. Subsequently the U.S. Supreme Court granted a petition for *Certiorari* in *Bergy* filed by the acting Commissioner of Patents and Trademarks. The Court vacated the judgment and remanded the case for further consideration in the light of *Parker v. Flook*, 437 US 584. In *Parker v. Flook*, the Court held that the laws of nature, physical phenomena and abstract ideas are not patentable. The Court of Customs and Patent Appeals vacated its judgment in *Chakraborty* and consolidated it with *Bergy* for reconsideration. In reexamination the Court reaffirmed its earlier judgments. The Commissioner for Patents and Trademarks for the second time prayed for a *Certiorari* and apex court granted the writ. Hence the case.

judgment[33], the Court has misred the applicable legislation. The minority view reflects the concern of the judges in going against the legislative direction because the legislative language has chosen carefully to limit patent protection to inanimate objects. On the hand it is evident from the majority view that the decision is thoroughly influenced by a number of socio-economic factors. But the Court observed that the grant or denial of patents on microorganisms do not affect in any way the pace of the genetic research. The Court, though mentioned, did not venture to make a value judgment on the relative merits and demerits of genetic engineering.[34] But the decision made a tempest in the intellectual circles resulting in a heated debates about the various ramifications of providing patent protection for life forms. The debate still goes on.[35]

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33 With whom White, Marshall and Powell, JJ. joined in the dissenting judgment.

34 The Court observed: "what is more important is that we are without competence to entertain these arguments - either to brush them aside as fantasies generated by fear of the unknown or to act on them". See *supra* n.7 at para 8.

35 Vandana Shiva, "Parents on Life Forms: Playing god", *Third World Resurgence*, NO.57, (1996), p.4; Sumar Sahai, "International Property Rights over Life Forms: What should Guide India's Position", *EPW*, Jan.15, (1994), p.87; Malcolm Gladwell, "Are Scientists Wrong to Patent Genes?", *SPAN*, April/May (1966), p.52; Suman Sahai, "Patenting of Life Forms: What it implies", *EPW, April* 25, (1992), p.878; Europe Rejents Patents on Life, a note on the defeat of EC

There was an argument in the beginning that *Chakraborty* decision is concerned only with patenting of microorganism and it does not pave the way for patenting of higher life forms. In *Ex parte Allen*[36] the PTO Board of Patent Appeals and Interferences held that certain polyploid oysters are patentable because they were non-naturally occurring *manufacture* or *composition of matter* within the scope of S.101. It was in the light of the *Chakraborty's case making everything under the sun made by man patentable*[37] the Court in *Ex parte Allen* extended patent protection to multicellular organisms.

A few days after the decision in *Allen* the POT sued statement which read as follows:

> "The Patent and Trademark Office now considers non-naturally occurring non-human multicellular organisms, including animals to be patentable subject matter within the scope of 35 USC 101".[38]

Directive onBiotechnology by the European Parliament. See *Third World Resurgence*, NO.57 (1966), p.10.

36 (1987), 3 USPQ 2d 1425.

37 See *supra*, p.447.

38 See *U.S. Official Gazette*, April 21, 1987.

The Commissioner added that claims to human will not be considered for patent protection because granting property rights in humans would be unconstitutional. This statement is now reflected as policy in the Manual of Patentr Examining procedure.[39]

Based on their policy the US patent office granted the first patent on an animal, the *Harvard Onco-Mouse*.[40] The patent was for a ***transgenic non-human mammal***. The mouse disclosed in this patent was bearing activated *oncogenes* in its genome and as a result had an increased susceptibility to cancer.[41]

It is interesting to note that although the patent is generally referred as *the Harvard Onco-Mouse Patent*, the claims allowed under the patent were of considerable breadth not limited to the mice alone.[42] After the *Harvard*

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39 Harward T.Markey, "Patentability of Animals in the United States", 20 *IIC* 372 (1989), p.376.

40 U.S. Patent No.4,736, 866.

41 Patricia A.Rac, "Patentability of Living Subject Matter", 10 *CIPR* 41 (1993).

42 Claim I of the *Harvard Onco-Mouse* patent was as follows: "A transgenic non-human mammal all of whose germ cells and somatic

Oncomouse patent, no patents were issued till 1992 and in December 1992 further patent on transgenic mice were granted.[43] Patenting of living subject matter therefore is no more now confined to microorganisms. In 1995 the scientists at the University of Utah succeeded in finding BRCA 1, the breast cancer gene. They got it patented in U.S. and the small biotech company they have found to commercially make use of their invention started using it for diagnostic tests.[44] W.French Anderson of the National Institute of Health (NIH), U.S. obtained a broad patent as human gene therapy in 1995.[45] Mammals, human genes, cell lines; nothing is left out now. Virtually a patent for a human clone seems not far behind. Mammals a species to which human being also belong are now patented is U.S.

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cells contains a recombinant activated *oncogene* sequence introduced into said mammal or an ancestor of said mammal at an embryonic stage, *ibid*, p.43.

43 See *infra* n.52.

44 Malcolm Gladwell, "Are Scientists Wrong to Patent Genes?", *SPAN*, April/May (1996), p.52.

45 Hellen Gavaghen, "NIH Wins Patent on Basic Technique Covering all *exz-vivo* Gene Therapy". *Nature*, Vol.1, 374, March (1995), p.393.

2. The Experiments in Europe:

Article 52 and 53 of the European Patent Convention (EPC) deal with patentable subject matter.[46] The European Patent Office, along the same lines

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[46] Art.52 patentable inventions:

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(2) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products in particular substances or compositions for use in any of these methods.

Art.53 Exceptions to Patentability:

European patent shall not be granted in respect of:

(a) Inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all the contracting states.

(b) Plant or animal varieties or essentially biological processes for the productionof plants or animals: this provision does not apply to microbiological processes or products thereof.

as the US PTO, has granted numerous patents on all sorts of biological material.[47] Though not explicitly mentioned, it is generally accepted that EPC allows patent protection for microorganisms.[48]

The exclusion of plant and animal varieties was very narrowly interpreted by the Technical Board of Appeals of the European Patent Office (EPO) in many cases. Granting patent claim on plants and seeds, the Technical Bord of Appeal of the EPO concluded in *Re Ciba-Geigy AG*[49] that:

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[47] See for e.g.:

i) T.162//86. "Plasmid PSGZ/HOECHST AG", OJEPO 1988, 452.
ii) T 281/86, "Preprothasmatin/UNILEVER", OJEPOo 1989, 202-209.
iii) T 283/86, "Bovine Growth Hormone/The Regents of the University of California", unpublished.
iv) T 81/87, "Preprorennin/Collaborative", OJEPO 1980, 250-259.
v) T 118/87, "Amylotytic Enzymes/CPC", OJEPO 1991, 74-479.
vi) T 239/87, "Microorganisms/NABISCO", unpublished.
vii) T 39/88, "Microorganismss/CPC", OJEPO 1989, 499-502.
viii) T 157/90, "Human Calitonin Structural Gene" CELLE\TECH, Unpublished.

[48] Art.53(b) says that the exclusionof plants or animal varieties or essentially biological processes does not apply to products of microbiological processes. See *supra*, n.58.

[49] *Re Ciba-Geigy AG*. 7 49/83, OJ EPO 3/1984112 (EPO Tech. Bd. of App.)

"plant varieties ... are all cultivated varieties, clones, lines, strains and hybrids which can be grown in such a way that they are clearly distinguishable from other varieties, sufficiently homogenous and stable in their essential characteristics."

The claims were relating to herbicide resistant propagating materials, including plants and seeds.[50] The narrow and restricted interpretation of the EPC provisions on patentability was again upheld by the EPO's Technical Board of Appeal in *Re Lubrizol Genetic Inc.*[51] wherein claims to hybrid plants and seeds were granted.

The question of patenting an animal came up for consideration before the EPO Examining Division as well as the EPO Technical Board of Appeals in the *Harvard Oncomouse* patent claims.[52] The Examining Division of the

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50 See *supra* n.52, p.44.

51 *Re Lubrizol Genetics Inc.* T 320/87 OJ EPO 3/1990 71 (EPO Tech.Bd. of App.)

52 *Onco-Mouse/harvard,* OJ EPO 1989, 451 (EPO Exam.Div). The tests applied for determining the patentability of the 'harvard Mouse' was based on claims 1, 17 and 18 of the patent application. The claims were as follows:

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an activated

EPO did not accept the claims and held the subject matter not patentable under Art.53(b) of EPC.[53] This decision was subsequently set aside by the Technical Board of Appeal. The Board held that "the exception to patentability under Art.53(b) EPC applies to certain categories of animals but not to animals as such."[54]

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axogene sequence into a non-human mammalian animal at a stage no later than the 8-cell stage.

17. A transgenic non-human mammalian animal whose germ cells and somatic cell contain an activated oxogene sequence introduced into said animal, at a stage no later than the 8-cell stage, said oncogene optionally being further defined according to any one of the claims 3 to 10.

18. An animal as claimed in claim 17 which is a rodent.

53 Head Note 1 of the Examining Division's decision reads as follows:
"1. Article 53(B) EPC excludes patent protection for animals *per se* in general and not only if a particular variety is claimed.

54 See T 19/96, *Oncomouse Harvard* Headnote 1. The Board's reasonings were the following:

4.5 Firstly, the Examining Division did not take duly into account that Art.53(b) EPC is an exception for certain kinds of inventions, to the general rule under Art.52(1) EPC that European Patents *shall be* granted for all inventions which are susceptible of industrial application, which are new and which involve an inventive step. Any such exception must as repeatedly pointed out by the Blard of Appeal be narrowly construed (of. in particular 7 329/87, point 6, OJEPO 1990, 76).

This decision of the Board really reflects the political considerations involved in this issue. The attempt of the Board to analyse the confliting

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The Examining Division has given no convincing reasons for deviating in this particular case from this principle of interpretation, nor are any such reasons apparent to the board.

4.6 The possibility that the reference to ceratin categories of animals rather than to animals as such was simply a mistake by the legislation can be ruled out.

4.7 In contrast to the exclusion of 'plant varieties' from patentability under Art.53(b) EPC (of T.320/87-See above) the preparatory documents to their provision are completely silent as to the purpose of excluding *animal varieties* from patentability. However, the purpose of a law (*ratio legis*) is not merely a matter of the actual intention of the legislators at the time when the law was adopted, but also of their presumed intention in the light of changes in circumstances which have taken place since then. It is now the task of he European Patent Office to find a solution to the problem of the interpretation of Art.53(b) EPC with regard to the concept of *animal varieties*, providing a proper balance between the interest of the inventors in this field in obtaining reasonable protection for their efforts and society's interests in excluding certain categories of animals from patent protection. In this context it should, inter alia, be borne in mind that for animals, unlike plant varieties - no other industrial property right is available for the time being.

4.8 To sum up,the Board concludes that the Examining Division was wrong in refusing the present application on the ground that Art.53(b) EPC excludes the patenting of animals as such. The proper issue to be considered is therefore, whether or not the subject matter of the application is an *animal variety* within the meaning of Art.53 (b) EPC.

interests makes the politics of the issue explicit. The Board finds the probable environmental risks and the sufferings of the animals on one side and the usefulness of the invention on the other side as two competing rationale. But the Board did not venture to make a value judgement on the issue. Instead it left out the matter for Examining Division to act upon.

The EPO Technical Board of Appeal again confronted with this issue in the *Greenpeace decision*.[55] The Technical Board of Appeal of the EPO in

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55 *Greenpeace Ltd v. Plant Genetic Systems*, T 0356/93 - 3.3.4 21 Feb. 1995.

The Greenpeace filed opposition against the European patent No.0242236 granted on 10 October 1990 with forty four claims which included claims on plant cells and plants. Revocation of the patents was sought on the grounds including the one that the grant of a patent on plant life form and the exploitation of the patent was contrary to morality and/ordre public. The Opposition Division on 15 December 1992 rejected the opposition mainly on the ground that the Opposition Division of the EPO is not the proper forms to make a value judgment on the relative merits and demerits of the genetic engineering. The Greenpeace lodged an appeal against the decision of the Opposition Division. The arguments of the appellants, in short were the following:

a) Since plant genetic resources are the common heritage of mankind they had to be preserved intact for the future generations.

this case held that claims on genetically engineered plants are not acceptable. Following this decision now it will not be possible to obtain a European patent on genetically engineered plants or seeds because these will include plant varieties which come under the purview of the exclusion provision

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b) Surveys reflect that public opinion is against patenting of genetically engineered inventions.

c) The European Patent office is qualified to make value judgments on the relative merits and demerits of a given technology.

d) The claim No.7 related to biological process not micro biological process and hence is excluded from patentability under the terms of Art.58(b) EPC.

The arguments advanced by the respondents were precisely the following:

a) The evidence for public opinion put forward by the Appellants was defective because it is a general response and not particularly concerned with an invention.

b) The environmental hazards are not adequately proved. Risk assessment is to be done by agencies other than EPO.

c) The exclusion from patentability under Art.53(b) EPC is limited to plant varieties.

d) The legislative intent behind the EPC provisions is not to exclude technical inventions from patentability.

under Art.53(b) EPC. The EPO's Technical Board of Appeal considered two questions:

1. whether any of the claimed subject matter constitutes an exception to patentability under the provision of Art.53(a) EPC.

2. Whether any of the claimed subject matter constitutes an exception to patentability under the provision of Art.53(b) EPC.

The Board in detail analysed the implication of public order and morality in the context of patenting of life forms. The observations of the Board in this regard are critically analysed in the next part.

3. EC's Proposed Biotechnology Directive: The First Attempt of its Kind

The main purpose of the proposed European Council Directive on the Legal Protection of Biotechnological Inventions[56] was to lay down a clear set of rules on the basis of which biotechnological inventions could enjoy a equal level of patent protection in all member states of the Union. The proposal addresses essential issues such as: patentability of living matter, the effects of the exclusion from patentability of plant and animal varieties and

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56 Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, 17 October 1988.

essentially biological processes for the production of plants or animals as provided under Art.53(b) EPC and respective national laws of the member states.

The directive was first put forward in 1988 but did not get the assent of the EU institutions. Finally another proposal was drafted in 1996 almost on the same lines of the 1988 proposal. But on March 1, 1995 the European Parliament rejected the proposed directive on the legal protection of biotechnological inventions. It was argued that the proposed directive was highly necessary in the light of advancements in genetic research. Though the European Patent Office started giving patent protection for biotechnological inventions even for human genes since long time, the European Parliament did not give green signal to the proposal, purely on ethical grounds.[57] During the debate on the proposed EC Directive, the

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57 For eg:

1) *human lymphoblastoid cell lines* EP No.0113, 769 B1.

2) a DNA molecule capable of inducing the expression in unicellular hosts of a polypeptide displaying immunological or biological activity of *human beta-interferon* EP.No. 0041.313 B1.

3) a *human hepatocyte culture process* EP No.9143, 809 B1.

European Parliament's main concerns were the non-patentability of the parts of the human body, the so called *germ line* therapy, the protection of animals and the farmer's privilege.[58] Finally the European Parliament took a firm step not to pass the directive purely on moral and ethical considerations. But on 16th July, 1997 the European Parliament passed the *Biotech Patent Directive*.[59] In all, 510 Parliamentarians voted; 378 for the Directive with 113 against and 19 abstentions. The adoption of the Directive by the European Parliament has come in for scathing criticisms by NGO's and environmentalists. They have called it as a clear demonstration of a deplorable lack of democratic responsibility by the European Parliament.[60] But the EP's Council of Ministers has not yet ratified the Directive and the Council of Ministers is empowered to bring in amendments to the Directive.[61]

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4) the molecular closing and characterisation of a gene sequence coding for human relaxine. EP No.0101.301 B1.

5) *interferones* like alpha type EP.No.032 134 B1.

58 Willi Rothley, "European Parliament must Think Again about Biotechnological Protection", 26 *IIC* 668 (1995) at 669.

59 See *A Price on the Living*, News Report, *Down to Earth* (Vol.6, No.6, Aug.15, 1997), p.19.

60 *Ibid.*

61 *Ibid*, p.16.

4. The International Legal Scenario:

(i) The WIPO Efforts

The World Intellectual Property Organisation has made remarkable achievements in resolving certain basic issues on the patenting of biotechnological inventions. WIPO commissioned a number of studies taking into account the views and opinions of governments and non-governmental institutions.[62] These studies provided an improved understanding of the patent law problems especially in the key issues like life patenting.

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62 For eg:

1. WIPO,Industrial Property Protection of Biotechnological Inventions, paper prepared by Dr.Joseph Straus, BIG/281/July 1985.

2. Report of the Committee of Exports on Biotechnological Inventions and Industrial Property Bio T/CE/IV/2 - June 24, 1988.

3. Protection of Inventions in the Field of Biotechnology, paper prepared by Dr.Ludwig Baeumer for the Industrial Property Division of WIPO.

4. Intellectual Property Law and Biotechnology WIPO/IP/KVC/90/2 Oct.1990.

(ii) The TRIPs

The Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPs) forms part of the Final Act of the WTO signed in Marrakesh on 15.4.1994. One of the most controversial provisions in the TRIPs Agreement is the one relating to patenting of micro-organisms and micro-biological processes.[63] The lack of consenses on the issue resulted in

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63 Art.27 of the TRIPS Agreement (1994) deals with patentable subject matter. The Article reads as follows:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health to avoid serious prejudice to the environment, provided that such exlcusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

incorporating a temporary position in Art.27(3) which is subjected to review by the year 1999.

The TRIPs Agreement provides a 5-10 year transition period for developing country nations.[64] The developing country members are required to introduce basic policy changes during his period so as to structurally adjust their economies making it compatible to the global market. For those countries where there is no product patent protection available at the time of entering into TRIPs, the Agreement gives a transitional time of 10 years to introduce product patenting.

TRIPs in Art.27(1) gives the general mandate to provide patent protection for all inventions irrespective of products or processes. This

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(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

(b) plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

64 See Art.65(4) of TRIPS.

mandate covers all fields of technology and the general patentability norms are identified as,

- novelty,
- inventive step, and
- industrial applicability

The patentability criteria in Art.27 specifically states that patent shall be available for all products irrespective of any discrimination as to whether imported or locally produced. The central point of the economic dimensions of Patents is their particular clause which facilitates import monopoly.

Art.27(2) of TRIPs provides that the member countries can exclude from patentability such inventions, the prevention of the commercial exploitation of which is necessary to protect:

- *Ordre public*,
- Morality,
- Human Life,
- Animal Life,
- Plant life,
- Health, and
- Environment

The purpose behind these general exclusions is to make the operation of the general mandate slightly limited thereby to strike a balance between the competing interests involved in patents generally. But the provisions in Art.27(2) are drafted very carefully so as to avoid the members finding shelter under this provision by way of making certain inventions not patentable through their domestic laws.

In Art.27(3) TRIPs Agreement excludes plants and animals from the general patentability mandate. But the provision clearly says that microorganisms cannot be excluded. As regards plant variety protection the Article suggests three ways. The members can provide patent protection or a *sui generis* protection or a combination of both. Art.27(3) provides for a review of the provision contained in that sub-paragraph in the year 1999.

(iii) The Budapest Treaty

Deposit of microorganisms is now internationally accepted as supplement or replacement of written disclosure requirement for patenting an invention in this area. In fact it is difficult to describe sufficiently an individual microorganism. This difficulty can be overcome by the deposition of the microorganisms at a culture collection from which samples of the

microorganisms will be made available to the public. This deposition procedure is facilitated internationally by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms.[65] The basic purpose of deposition of microorganism is to overcome the problems of effectively disclosing it. The Treaty envisages the constitution of depository institutions located on the territory of a contracting state. A depository institution attain the status of an International Depository Authority when the Director Geneal of the World Intellectual Property Organisation accepts a communication from the institution to that effect.[66] The detailed procedure for original and new deposits of microorganisms, its storage, seereey etc., are given in the Rules annexed to the Treaty.[67]

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65 The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure is done at Budapest on April 28, 1977. Under the Treaty on International Depositary Authority is constituted for the purpose of patent procedure.

66 See Arts. 6 & 7 of the Treaty.

67 The Regulations annexed to the Treaty include Rule 1 to Rule 15. Rule 6 provides for making the deposits. Rule 9 speaks of storage of microorganisms and Rule 11 provides for furnishng of samples (release) etc.

F. India and Patenting Life Forms

The issue of patenting of life forms becomes controversial in the Indian socio-legal context, in the light of the TRIPs provisions for microorganism and micro biological process patenting. India under the present situation is required to provide product patent protection for microorganisms before January 1, 2005.[68] Indian Patent Act does not address at all the issue of patenting living beings. The Patent Act in its true spirit seems to exclude all forms of living subject matter from patentability.[69] The various

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68 Being a developing country member not having product patents for microorganisms at the time of entering into WTO a ten year transitional period is available under Art.65(4) of TRIPS.

69 Sec.3 of the Patents Act, 1970 deals with non-patentable inventions. The expression invention is defined in Sec.2(j) of the Act. An invention means "any new and useful -

(i) art, process,method or manner of manufacture.

(ii) machine, apparatus or other article.

iii) substance produced by manufacture and includes any new and useful improvement of any of them and an alleged invention.

Sec.3 says what are not inventions -

(a) an invention which is frivolous or which claims anything obvious contrary to well established natural laws.

ramifications of the *legality, morality, public health* clauses in the Act and its social, legal, ethical and environmental implications as regards the issue of life patenting are addressed in Chapter IV and V.

G. Conclusion

The legal developments on life patenting which we have seen in the foregoing pages is not far from criticisms. We will find a fundamental difference between *Chakraborty*[70] and *Greenpeace*[71] in their approach towards the larger questions involved in patenting life forms. *Chakraborty*

(b) an invention the primary or intended use of which would be contrary to law or morality or injurious to public health.

(c) the mere discovery of a scientific principle or the formulation of an abstract theory

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.....

(h) a method of agriculture or horticulture

(i) any process for the medicinal, surgical, curative, prophylactic or other treatment of humanbeings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

70 See *supra*, n.41

71 See *supra*, n.67

was in fact a beginning.[72] But *Greenpeace* seems to be a reflection of the serious concerns raised from various corners about the ethical and environmental consequences of patenting living beings.[73] In *Chakraborty* the US Supreme Court restricted the whole issue to the case of a statutory construction. The Court observed:

> "the question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 USC Sec.101".[74]

Relying on the historical decision of *Marbury v. Madison*[75] the Court held that once the Congress has spoken, it is the "province and duty of the judicial department to say what the law is".[76] The intention of the Court was to restrict the case so as not to address the various ramifications of the issue involved in it. But Brennan, J. speaking for himself and on behalf of his three other brother Judges expressed serious concerns about the probable consequences of a liberal statutory interpretation on this point. Suggesting

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72 The case was decided on 16 June 1980.

73 The case is decided on 21 February 1995. By the time the arguments for and against life patenting had acquired a concrete shape.

74 See *supra*, n.41, p.149.

75 *Marbury v. Madison* 1 Cranch 137, 2L Ed. 60 (1803).

76 *Ibid*, p.177

that there is an absence of legislative direction in this context the Judges preferred to leave the matter to the Congress to decide. Brennan J. bluntly brought out his dissent in the following lines:

> "I believe the Court has misread the applicable legislation. I dissent".[77]

At one occasion the Court addressed the arguments based on the demerits and disadvantages of genetic engineering. The Court observes:

> We are told that genetic research and related technological developments may spread pollution and disease that it may result in a loss of genetic diversity, and its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately presented; they reminded us that,at times, human ingenuity seems unable to control fully the forces it creates - that with Hamlet, it is sometimes better "to bear those ills we have than fly to others that are know not of".[78]

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77 *Supra*, n.41, p.156

78 *Ibid.*

The Court based its findings on two grounds to reject the arguments against patent grants on a living being.

1. The grant or denial of patents on living beings (in this case microorganisms) do not affect research on genetic engineering.

2. The court is without competence to entertain these arguments.[79]

It seems that the Court was trying to structure these arguments so as to arrive at a predetermined conclusion. But the value-neutrality of this decision has not been challenged so far. The U.S. Congress has not thus far taken any legislative step in this regard. Does it mean that the US Congress ratifies the decision in *Chakraborty*? The Court did not say that there has to be free permit for patenting life forms. Instead the Court expressed its inefficiency to weigh the strength of the competing rationales and left it for the legislature to act upon. That means the Court found both the arguments; for and against life patenting equally strong.

The recognition of the importance of the arguments against patenting life forms becomes more explicit when it comes to *Greenpeace*. Though the judicial forum was different the issue in question was identical. In *Greenpeace* the Technical Board of Appeal of the European Patent Office

79 *Ibid.*

was called upon to explain the concepts of *ordre public* and morality occurring in Art.53(a) of the European Patent Convention.[80] The Board held:

> "it is generally accepted that the concept of *ordre public* covers the protection of public security and the physical integrity of individuals as part of the society. This concept encompasses also the protection of the environment. Accordingly under Article 53(a) EPC inventions the exploitation of which is likely to breach public peace or social order or to seriously prejudice the environment are to be excluded from patentability as being contrary to *ordre public*.[81]

Explaining the concept of morality the Board held that it is related to "the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture."[82] Therefore, the Board opined that an invention which does not conform to the

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80 See *supra*, n.67

81 *Ibid*, p.14

82 See Chapter V for a detailed discussion.5

conventionally accepted standards of conduct are to be excluded from patentability as being contrary to morality.

The approach of the Board was very practical. In order to appreciate the desirability of patenting living subject matter, the Board weighed the sufferings of animals and possible risks to the environment on the one hand and the invention's usefulness on the other. This seems to be a very pragmatic approach. The observations of the Board seem to address the issues with the right sense of appreciation.

Since the TRIPs is forcing its member nations to move towards a global patent regime, the law and legal institutions are to be understood and analysed in a global context. Therefore, the Indian statutory provisions cannot be seen in isolation. The *public order, morality, natural law principles* clauses in the Patents Act are to be analysed and understood in the light of the above mentioned development of law.[83] The question here is: do the *public order, morality, natural law principles* exempt from patentability inventions relating to life forms? The Indian Courts have not so far interpreted these clauses. But the concept of *public interest* was explained by the Government of India in a different context. The issue was relating to the revocation of a patent granted to a U.S. based biomedical and plant

83 See Sec.3 (a) and (b) of the Patents Act, 1970.

product corporation.[84] The public interest notion was explained to include the economic interest of the nation, the interests of the farmers and public health.[85] Since the public order morality clauses are closely related to the concept of public interest this issue becomes relevant in this context. That means the public interest notions have an overall predominance in the working of the Indian patent system.

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84 On 24 October, 1994, the Government of India revoked Indian Patent No.168950 entitled "Methods of Producing Transformed Cotton Cells by tissue Culture". Agracetus, the patentee was given a show cause notice. The notice contained the following facts to support the public interest ground on which the revocation was proceeded (The provision attracted was Sec.66 of the Patents Act 1970 which empowers the Government of India to revoke a patent on public interests).

a) cotton being an important national crop vital to the export economy should not be the subject matter of a patent;

b) the interest of farmers would be prejudiced; and

c) the effect of the patent when used was not known and it was believed that cotton seed oil extracted from the cotton so produced or garments made therefrom might be harmful when used.

After a few hearings an order was passed revoking the patents on the ground of public interest. See *RAFI Communique*, July-August, (1993). *The New Scientist*, (Vol.141, No.1913, Feb. 19, 1994). *Biotechnology and Development Monitor* (No.21, Dec. 1994).

85 See *supra* n.30 and 55.

Another interesting issue relates to the varying degrees of patentability among life forms themselves. At present the TRIPs mandate is only for patenting microorganisms and microbiological processes. But U.S. and EU have already given patents on transgenic mammals.[86] If life is understood in terms of its attributes like growth, reproduction and internal reorganisation, it is common to all living beings like microorganism, plants, animals etc. Now the question is if one life form can be patented why cannot the others? The policy declaration of the US Patent Office tried to answer this issue by making the patentability requirements of living subject matters very explicit.[87]

But the extent of human unnatural interference in the natural biological processes is common in all these cases and the risk elements in releasing microbes has not proved to be less than that of releasing a transgenic sheep.[88] Therefore it becomes difficult to set legal standards to distinguish various forms of life for the purpose of patent protection.

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86 See *supra*, n.49.

87 See *supra*, n.38.

88 See generally the discussion in Chapter IV.

The challenge before us is to articulate whether *public order*, *morality* and *well established principles of natural law* provisions in the Patents Act go against the TRIPs mandate for patenting microorganisms and microbiological processes? In order to appreciate this question one has to look into the various dimensions of these clauses. That is what the precedence in *Greenpeace* tells us. Do these provisions encompass environmental protection? Can the ethical issues raised in the context of patenting life be linked to these clauses? These questions can be answered only after critically analysing the ethical and environmental issues relating to patenting of life forms.

CHAPTER IV

THE MORALITY OF LIFE PATENTING

A. Introduction

Conundrums start proliferating when the discussion is all about life. The present day understanding of the notion of life is an outcome of centuries old thought processes. Philosophers of all the time have confronted with the question, what is life? The following enquiry relates to the notion of life and its intrinsic values. The enquiry is made with the purpose of analysing the ethics of patenting living beings.

The questions central to this analysis are:

i) Are there certain values inherent in life according to the well established principles of natural law?

ii) Do patents on living beings violate inherent values of life?

The following analysis is made in three different but interrelated planes. First of all an attempt is made to conduct a jurisprudential enquiry into the concept of life. The purpose of this enquiry is to see whether the notion of life as having some intrinsic values is justified by the established principles of natural laws. In the second plane the notion of private property

is analysed in brief with the purpose of answering the question: Should there be a limitation on the extension of private property rights over living beings. This question is answered in the light of the findings arrived at in the first analysis. The last issue addressed relates to 'the convergences and divergences of science and spirituality'.[1] The enquiry in this context centres around a core issue i.e., can the value judgments of the human beings be replaced by those that are originated in scientific investigations?[2] It should be noted here that these value judgments, at all times in human history, were subjected to stringent rationalisations.

B. The Natural Right to Life:

The modern legal systems recognize the notion of life in terms of rights.[3] The concept of life within the parameters of a right under the Indian

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1 This is the title of a paper prepared by Dr. Raja Ramanna, NIAS, IISc, Bangalore, for a seminar held in honour of the Dalai Lama.

2 A question identical to this is raised by James, B. Conant. See S.Radhakrishnan and P.T. Raju (eds.), *The Concept of Man, A Study in Comparative Philosophy* (Harper Collins, 1995) at p.16.

3 Most of the modern constitutions guarantee the right to life of individuals. See for example:
Art.21 of the Constitution of India
Art.12 of the Constitution of Japan
Art.16 of the Constitution of Canada

constitution was the subject matter of creative decisional jurisprudence from the Supreme Court.[4] The court liberally interpreted the meaning and content of he expression *life* occurring in Art. 21 of the constitution giving it very many dimensions. This judicial process is a reflection of the awareness of the need for a better and more qualitative human existence. The underlying notions which the judiciary was trying to reflect upon was the supremacy of the constitutional protection of human life.

Centuries before modern constitutions came into force the concept of life in terms of individual rights was very well recognised by legal documents. As early as in 1215 Magna Certa documented the basic principle that there are fundamental individual rights that the state may not violate.[5] The Charter declared:

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4 See generally, *Bandhua Mukti Morcha v. Union of India*, (1984) 3 S.C.C 161. *Olga Tellis v. Bombay Municipal Corporation*, (1985) 3 S.C.C 545. *Mohini Jain v. State of Karnataka*, (1992) 3 S.C.C 666. *Unnikrishnan J.P. v. State of Andhra Pradesh*, AIR 1993 S.C 2178. All these decisions directly relate to the interpretation of life.

5 For a discussion on the politics and history of the Charter see Bernard Schwartz, *The Great Rights of Mankind*, (Oxford University Press, 1977), pp.2-7.

"No free man shall be captured or imprisoned or deceased or outlawed or exiled or in any way destroyed... except by the lawful judgment of his peers and by the law of the land."[6]

The American Bill of Rights (1689) which was the culmination of what has been termed as the Glorious Revolution further elaborated the basic rights of the individuals.[7] Finally, the self-evidence of the right to life finds recognition in a universally acclaimed legal document, the United Nations International Covenant on Civil and Political Rights (1966). Art. 6 of the convention reads as follows:

"Every human being has an inherent right to life."[8]

At the roof of the notion of *self-evident right to life* lies the concept of life as something inherently valuable. These notions are constructed upon strong foundations of natural law principles. The theoretical justifications for the natural right to life recognised in the legal documents mentioned

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6 *Magna Carta* (1215), ch.12, See Brownlie, *Basic Documents on Human Rights* as quoted in L.J. Macfarlane, *The Theory and Practice of Human Rights*, (Mourice Temple Smith, London, 1985), p.18.

7 *Ibid*, p.130.

8 See Art.6 of *The Covenant on Civil and Political Rights*, (UNICCPR, 1966).

above stem from the fundamentals of natural law. Therefore irrespective of the fact that there exists the expression life in positive legal documents, an enquiry into the conceptual foundations of life, enters the realm of natural law. The same is the case in the context of patenting life forms also.

C. Natural Law and the Concept of Life:

Natural law postulates the existence of objective moral principles which depend upon the nature of the universe and which can be discovered by reason.[9] The truth conditions of these principles are not questioned because they are valid of necessity.[10] In strict philosophical sense the fundamental propositions of natural law are *a priori* synthetic in nature.[11] The validity of the basic postulates of natural law are accepted because the basic rules governing correct human conduct are logically connected with immanent truths concerning human nature. These immanent truths

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9 See MDA Freeman, (ed.), *Lloyd's Introduction to Jurisprudence*, (Sweet and Maxwell, 6th edn., 1994), p.80.

10 *Ibid.*

11 The manner in which the distinction between *a priori* and *a posterori* or analytic and synthetic are presently made can be traced back to the German Idealism. For an authoritative disquisition see Immanuel Kant, *Critique of Pure Reason*, (Everyman, 1969), pp.25-37; see also Lewis White Beck, *A Commentary on Kant's Critique of Practical Reason*, (University of Chicago Press, 1960).

rationalise the quest for survival within human beings there by making self-preservation an accepted fundamental fact. Self-preservation has its foundation in human reason and it is the great lesson of natural law.[12]

The notion of self-preservation is therefore closely related to the concept of life. The understanding that there are some basic values inherent in life seems to have its origin in the initial understanding of self-preservation. At this juncture a complex question arises: Why do you need to preserve yourself?

Resorting to a Darwinian frame H.L.A. Hart starts his discussion on laws and morals (especially the one relating to the minimum content of natural law) with certain truisms about human nature; human vulnerability; approximate equality.[13] Hart's '*Minimum Content of Natural Law*' theory is premised on biology and psychology.[14] Human values can have biological origins.[15] But Hart did not venture to analyse the scientific reasons behind

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12 *Supra* n.9, p.81.

13 H.L.A Hart, *The Concept of Law*, (Oxford University Press, 1992), pp.189-191.

14 *Supra* n.13, p.188.

15 See Michael Hechter, Lynn Nadel and Richard E. Michod (eds.), *The Origin of Values*, (Aldine De Gruyter, New York, 1993), pp.261-270.

the basic moral propositions. Instead he takes it for granted that human beings are committed to survival as a necessary aim of human life. Hart says:

> "our concern is with social arrangements for continued existence, not with those of a suicide club".[16]

But Hart resorts to such a simpler, less philosophical justification after a detailed discussion on the teleological justifications for the basic principles of natural law as expounded by the classical natural law philosophers.[17]

According to this philosophical stand point[18] there are immanent norms and values in the nature of things. Aristotle and his followers believe that natural processes tend towards predetermined ends.[19] Aristotle gives the example that *acorns grew into oaks, etc.*[20] In doing this they fulfill their

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16 *Supra* n.13, p.188.

17 *Ibid*, pp.184-188.

18 Teleology in ordinary parlance is a doctrine that ends are immanent in nature. According to this natural processes and nature are directed towards an end. They are shaped by a purpose. *Webster's Encyclopedic Unabridged Dictionary of the English Language*, (Random House, 1989), p.1460.

19 Aristotle, *Politics*, 2 (translation by Jowell, Basic Books), p.28.

20 *Ibid.*

natural function. Man also has his own function which could be discovered by reason and thought. The teleological understanding gives us an idea of a *good* which a species pursue. The good for a species is the end it will reach if its progress is not impeded. That means each being is to be understood in terms of a natural process having continuity. Man is to be understood as a part of a properly functioning social whole. Therefore, the teleological view considers man as having ends which can be ascertained by reflecting on his nature and his needs.[21]

The classical natural law principles and their justifications find a different interpretation in the medieval biblical philosophy. Acquinas developed a synthesis of Aristotelian philosophy and catholic faith and identified three domains of law, the *lex aeterna*, the *lex divina* and the *lex naturalis*.[22] The *goods* disclosed by nature belonged to the realm of *lex aeterna*.[23] In a recent restatement of natural law[24] John Finnis adopts an

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21 These observations are based on Aristotle's justifications, *ibid.*

22 See A.H. Chroust, *An Introduction to Acquinas*, (1974) 19 Am.J of Jurisprudence 1.

23 *Ibid.*

24 John Finnis, *Natural Law and Natural Rights*, (Clarendon Press, Oxford, 1980).

altogether different strategy to defend the basic premises of natural law and natural rights.[25] Finnis identifies certain basic goods for human beings. For him natural law is the seat of principles of practical reasonableness is ordering human life and human community.[26] The basic principles of natural law are premoral.[27] Finnis describes the basic human goods as aspects essentially immeasurable and incommensurable. These basic goods are objective values. This implies that every reasonable person must assert to their value as objects of human striving. Finnis identifies seven basic goods, life, knowledge, play, aesthetic experience, sociability or friendship, practical reasonableness and religion.[28] For the purpose of the present enquiry we will confine to the first basic good of Finnis i.e., *life*.

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25 Finnis's work is widely acclaimed in the philosophical circles. While Hart finds '*very great merit*' in Finnis's account, Neil Mac Cormick says that, '*it requires us to abandon our carricature version of what a natural law theory is*'. See H.L.A. Hart, *Essays in Jurisprudence and Philosophy*, (Clarendon Press, Oxford, 1983), p.11, Neil Mac Cormick, "Natural Law Reconsidered", (1981), O.J.L.S. 99, p.109.

26 See *supra* n.23, p.280.

27 See J.Finnis and G.Grisez, "The Basic Principles of Natural Law" (1981) 26 Am.J. of Jurisprudence 21, p.28.

28 *Supra* n.23, p.90.

The value of life is a basic value which corresponds to the drive for self-preservation.[29] The expression life signifies every aspect of the vitality which puts a human being in good shape for self-determination.[30] For Finnis:

> "life here includes bodily (including cerebral) health and freedom from the pain that betokens organic malfunctioning or injury. And the recognition, pursuit, and realisation of this basic human purpose (or internally related group of purposes) are as various as the crafty struggle and prayer of a man overboard seeking to stay afloat until his ship turns back for him...."[31]

Finnis's attempt here is to provide a rational justification for the fundamentals of natural law which consider the notion of life as something sacrosanct. He acknowledges that the value of life is a basic value. For him life is the first human good.

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29 *Ibid*, p.86.

30 *Ibid.*

31 *Ibid.*

From the above discussions it becomes clear that the early western thought, the biblical interpretation, the analytical positivism of Hart and the natural revivalism of Finnis accept in common that there are some values inherent in life. The differences in their approaches were only in the ways in which they tried to rationalize the notion of life as having intrinsic values.

D. *Life* in the Indian Thought:

In a move which is unparallel, the Indian philosophy has attempted to exhaustive enquiries into the notion of life. The Indian thought gives an altogether different teleological dimension in this regard.[32] The Indian Thought gives the teleological perspective of *prakriti*[33] which is designed to arrive at desired ends. The classical Indian Thought looks at the notion of life in two different ways. While the vedic and vedantic philosophy adopt a

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32 All philosophical disquisitions in the Indian Thought centre around the concepts of man, life and nature. The *Upanishad* vision is based on the postulate *atmanam vidhi* i.e., know themself. *Atman* here does not mean merely the metaphysical self but also reason, mind, the life and the body. See generally S. Radhakrishnan, *Indian Philosophy*, (Oxford University Press, 1989), For an elaborate account of the original texts and treatises see P.V. Kane, *History of Hindu Dharmasastra*, (Government oriental series, 1977).

33 *Prakriti* means nature. See *infra* n.95.

spiritual approach towards the problems of life and existence, the systemic thoughts in *Nyaya, Vysesika*, etc., adopt a purely materialistic approach.[34]

The nature and natural processes are designed according to the classical thought to meet predetermined ends.[35] There exists a holistic vision of nature in the oriental thought.[36] Nature comprises both animate and inanimate objects.[37] The living components of the nature and human beings

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34 See for a critical appraisal of the ancient Indian religious and political thought Debi Prasad Chattopadhyaya, *Science and Society in Ancient India*, (Research India, Calcutta, 1977). See also *Uddalaka and Yajnavalkya, Materialism and Idealism, Studies in the History of Indian Philosophy*, (K.P. Bagchis Co., Calcutta, Vol.1, 1978).

35 *Rigveda* speaks about the notion of *rta* as a form of physical existence, p.IV, 23, 8 and 9.

36 See S. Radhakrishnan, *Indian Philosophy*, (Oxford University Press, Delhi, Vol.1., 1989), pp.36, 82, 102, 105, 1259-60 and 540-1. See also Debiprasad Chattopadhyaya, *Indian Philosophy, A popular Introduction*, (People's Publishing House, 1986), pp.114-115.

37 See Debiprasad Chattopadhyaya, *ibid*, pp.106-117. See also N.S. Junankar, *Goutama, the Nyaya Philosophy*, (Motilal Benarsidas, 1978).

are treated alike.[38] In many occasions plants are considered as sensible organisms.[39]

Creation is considered as the handiwork of a creator.[40] The existence of an omnipotent transcendental entity called *Brahman* and the presence of its elements equally in all living beings resulted in the integrated philosophy of life, man and the nature.[41]

This holistic vision is closely identified to an ecocentric understanding of nature. The belief that there exists a transcendented entity called *paramatma* and that it manifest in equal proportion in all living beings in the

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38 The *Mahabharata*, highly eulogizes plant life and divides plants into six kinds and says that he who plants trees is saved by them just as sons do and that they should so tended like sons. See *Mahabharata, Anusanaparva*, 58, 23-32 for a detailed account of the importance accorded on plant life. See P.V. Kane, *supra* n.31, Vol.11, Part II, 894-6.

39 *Ibid.*

40 See *supra* n.35, p. 102.

41 See *Yajnavalkya - Janaka Samvada* in the first *Brahmana*, fourth *adhyaya* of *Brihadaranyakopanishad*, The Thirteen *Principal Upanishads*, translated by R.E. Hume, (Oxford University Press, Delhi, 1992) pp.127-30. See generally S. Radha Krishnan, *the Principal Upanishads*, (Oxford University Press, Delhi, 1989).

forms of *pran* resulted in the sanctification of the notion of life. Therefore any intereference with the existence of a living object matter was considered to be a wrong action or "*adharma*".[42]

E. Marx and the *Species Being*:

Before summing up the discussion on the concept of life it will be ideal to have a look at the species being (*Gattungswesen*) concept of Karl Marx.[43] For Marx the notion of *species being* involves two things.

i) man theoretically and practically makes his own species as well as that of other things his objects.

ii) as present and living species he considers himself to be a universal and consequently free being.[44]

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42 *Adharma* is the antonym of *dharma*. *Dharma* means right action. For a discussion on Dharma See S.D.Sharma, *Administration of Justice in Ancient India*, (Harman Publishing House, New Delhi, 1988), pp.35-63.

43 Karl Marx, *Economic and Philosophic Manuscripts*, (1844) translated by Lloyds D. Easton and Kurt H. Guddat, (Anchor Books, New York, 1967).

44 *Ibid.*

The life in man is physical and he lives by the inorganic nature. Since the realm of the inorganic nature he lives in, comprises plants, animals, minerals, air, light etc., they form part of his consciousness. Since man depends his organic nature for his physical as well as spiritual life, the components of nature form part of human life and life activity.[45] Nature is the inorganic body of man. Man lives by nature. That the physical and spiritual life of man is tied up with nature in another way of saying that nature is linked to itself, for man is a part of nature.[46]

Even the above Marxian analysis views human life in its relation with the nature. This analysis takes us to the realm of an *'organic commune'* where the components of nature exists in proximity because of certain organic bandages. This is quiet close to the realm of a communal life. The concept of life there acquires a sanctity. [47]

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45 *Ibid.*

46 The concept of man in his relationship with nature is explained by Karl Marx in the context of explaining his principle of alienation. For an exhaustive account of Marxian writing in this regard see *Karl Marx and Frederick Engles, Selected Works,* (Progress Publishers, Moscow, 1970).

47 For an argument in these lines see Roberto Unger, *Knowledge and Politics* as cited in *Lloyd's Introduction to Jurisprudence, supra* n.9, pp.595-97.

F. The Intrinsic Values of Life

It seems that there are two reasons for considering life as something intrinsically valuable.

i) the inability to explain its origin and therefore the mysteries involved in it.

ii) the understanding that life is the essence of existence.

The Central tenets of natural law were reasserted by the recent revivalists.[48] Even these recent restatements accept that there are some values inherent in life.[49] The basic premise of natural law thinking seems to have accepted the second tenet that life is essential for existence therefore has certain inherent values.

From this premise we will now proceed to address the next question. Is granting patents against the intrinsic values of life? This question involves the issues of morality of patenting life forms. In order to understand the morality of life patenting we need to look at the extension of private property rights over the living beings. The attempt here is not to analyse the morality

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48 See *supra* n.234.

49 *Ibid.*

or justness of private property but to confine it the morality of *private propertising* living beings.

H. Private Property, Patents and Living Beings:

Private property denotes a complex of rights.[50] These rights are rights in *rem*[51]: The ownership of a property takes with it the rights to possess, enjoy and even dispose of the property in possession.[52] A right in *rem* amounts to the exclusion of all other persons from interfering with the owner's rights over the things in his/her possession. A patent confers a private property rights on the patentee.[53] Patenting a living subject matter therefore implies the confirment of an exclusive right to the patentee over that living subject matter. Since a living being reproduces, the right extends to its progenies also. Patent necssarily implies the commercial use of the

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50 Salmond, *Jurisprudence*, (Sweet & Maxwell, London, 12 ed., 1966), p.264.

51 A right in *rem* implies a right against the rest of the world. It is generally used in contradistinction with a right *in personam* which means a right against a particular person, *ibid.*

52 *Ibid*, p.247.

53 See Chapter.I, n.1.

invention.[54] If the subject matter of the invention is a living being, its commercial use makes it a tradable commodity. Therefore living being and their progenies become mere commodities over which individual possess absolute monopoly rights.

Extension of commodification is an accepted basic premise of capitalism.[55] The transition of capitalism into modern market economy is backed by liberal theories and most recently (presently libertarianism).[56] The liberal justification of market economy have their fundamental conceptual basis in Lockean Social contract.[57] Locke's *labour theory* affords strong theoretical justifications for private property. Does locke envision the extension of private property rights over living beings? A scientist who alters

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54 For patentability norms see Art.27 of the TRIPs.

55 See generally Karl Marx, *Capital*, Vol.1 (Foreign Languages Publishing House, Moscow, 1958) See also Bottomore, *Capitalism* as cited in Manjula Bose "Capitalism", in K.Roy and C.Gupta, eds., *Essays in Social and Political Philosophy*, (ICPR, New Delhi, 1989), pp.385-414.

56 The recent theoretical assertions can be seen in Robert Nozick, *State Anarchy and Utopia*, (Oxford University Press, Oxford, 1974). Nozick advocates libertarianism and for that matter a minimal state. See also John Rawls, *Theory of Justice*, (Oxford University Press, 1988), Rawls' attempt is to arrive at a higher level of theoretical abstraction based primarily on Lockean Social Contract.

57 See Rawls, *op. cit.*, p.11.

the genetic constitution of a living being is putting his labour in doing that. Does it mean that he can claim private property rights over that living beings and its progenies according to the Lockean theory?

Locke's *social contract* stem from the fundamentals of natural law.[58] The consent theory has at its root, the notion of the necessity of a compact for self-preservation. Locke's attempt is to construct a theory of natural rights through the social contract doctrine.[59] Many of his ideas reiterate the central assumptions of 16th century thomist thought.[60] Locke himself says that the knowledge of natural law was compulsive and "*writ in the hearts of all mankind*".[61]

Creating a new form of life and establishing a domain of private rights over the whole species of the new life form amount to a distortion of the intrinsic values of life. As seen earlier natural law principles postulate the

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58 See *Lloyd's Introduction to Jurisprudence*, *supra* n.9, p.103.

59 For an introduction to the thoughts of Locke, see J.Dunn, *Locke*, (1984) as cited in *Lloyd's Introduction to Jurisprudence*, *supra* n.9, p.103.

60 *Ibid.*

61 Quoted by J.Dunn, *supra*, n.58, p.30.

intrinsic values of life. The *creation* of a new form of life is an outcome of an unnatural human intervention, therefore against the order of nature. Subsequently the procreation, growth, etc., of the *created life form* will be regulated by the monopoly holder for his/her own ends. This results in private holdings of animal and plant varieties. This amounts to a distortion of the values inherent in life, therefore a violation of the fundamentals of natural law. If this is the case Locke's theory being premised on natural law does not permit the granting of private property rights over living subject matters. Therefore neither Locke nor Lockean interpretations afford to justify patenting living beings. That means even in liberal theories patenting of life forms do not have valid justifications.

In the light of the above analysis now we will address the last issue raised in the beginning of this discussion. The question is, can the value judgments of the human beings be replaced by those that are originated in scientific investigations?

I. Science and Spirituality:

Scientific and analytic thought has dispelled many superstitions. But the growing scientific and analytic spirit should not destroy the values of life which are of lasting importance.[62] Many basic issues raised by human reason still (even at wake of this scientific revolution) remain unresolved.[63] While life sciences fail to give us a convincing answer to the question what is life, physical sciences still struggle with time, space and casuality.[64] Conant says:

> "...there is nothing to be gained by asserting that is principle all our common sense ideas about the universe and human behaviours, all our ethical principles, and our moral convictions could be replaced by 'concepts growing out of experiment and observation'. Even in the restricted area of the physical sciences there are huge spots where empricism alone is the guide for the conduct of scientists as scientists."[65]

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62 *Supra* n.2, p.17.

63 James B. Conant, *Modern Science and Modern Man*, (Columbia University Press, New York, 1953), pp.97-8, as quoted in S. Radhakrishnan and P.T. Raju, *supra* n.2, p.16.

64 See Raja Ramanna, *Scientific Philosophy with Reference to Buddhist Thought*, (Tibet House, New Delhi, 1996).

65 See *supra* n.2.

Our understanding of life, existence, etc., stem from a broad base of morals, religious values and traditions. These believes have been conceptualised through age long thought processes. They do have very strong social basis. Therefore any attempt for a complete replacement of these values goes against human civilization.

J. TRIPs and the Morality of Life Patenting:

The question relating to the morality of life patenting are to be answered in the light of the finding arrived at in the foregoing discussions. As mentioned earlier, principles of natural law are premoral. Therefore morality forms the essence of these principles. But the morality issues relating to life patenting bring us back to the realm of positivist discourses because there exist, in the TRIPs Agreement and in the Patent Act, 1970, express provisions relating to morality.[66] TRIPs in Art. 27(3) permits the member nations to exclude from patentability, subject matters like plants and animals but not microorganisms. By permitting certain exclusions on the ground of morality and public order is TRIPs trying to strike a balance between the divergent interests in the case of life patenting? This question is to be answered in the light of the analysis of the TRIPs provisions on patenting which we have seen in the proceeding chapter.

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[66] See Art.27(2) of the TRIPs Agreement and Sec.3 of the *Patents Act*, 1970.

Let us take the case of India. The Patents Act says that inventions which are contrary to well established natural laws[67] and which are contrary to morality[68] are not patentable. Since micro organisms patenting is a case of life form patenting[69] these expressions are to be interpreted to decide its patentability.

The fundamental principles of natural law are universal in character. But within the broad parameters of these universal principles different communities develop different value choices. These values vary from communities to communities.[70] Therefore morality acquires a territorial

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67 See sec.3 (a) of the *Patents Act*, 1970.

68 *Ibid*, sec.3(b).

69 Microorganisms are living subject matters which exhibits all attributes of life, see n.23 in Chapter.I.

70 *Mahabharata* says:

अवस्थधर्मो धर्मो हि धर्मोऽधर्मश्च आपदि ।
कारणाद्देशकालस्य देशकालः स तादृशः ॥

Meaning thereby: Values differ from time to time and place to place, *Santhiparva*: 6: 1.

character. The notion of territorial morality as enunciated by various judicial fora in different occasions is addressed in short in the following passage.

Brennan, J. in *Mabo v. Queensland* (No.2)[71] held that the Australian community has its own community values. The judge said:

> "Whatever the justification advanced in earlier days for refusing to recognize the rights and interests of the indigenous inhabitants of settled colonies, an unjust and discriminatory doctrine of the international community accord in this respect with the contemporary values of the Australian people."[72]

Subsequent to this decision, in *Dietrich v. The Queen*[73] the court held that the Australian community has its own permanent social values distinct from others.[74]

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71 (1992) 175 CLR 1.

72 *Ibid*, p.42. The Judge was making the point that unjust descrimination in the enjoyment of civil and political rights was inconsistent with the contemporary Australian values.

73 (1992) 177 CLR 292.

74 The court was explaining the right to free trail in relation with Art. 15 of the International Covenant on Civil and Political Rights, *ibid*.

In the *Green Peace* decision[75] the Technical Board of Appeal of the European Patent office held

> "the concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is *the culture inherent in European society and civilization*. Accordingly, under Act 53(a) EPC, inventions, the exploitation of which is not in confirmity with the conventionally accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality."[76]

The recognition of the *European morality* is an express assertion of the fact that patentability norms are to be set according to the territorial morality of a given community.

The Supreme Court of India whenever required to interpret expressions of the sort of morality resorted to the distinct traditions and culture of the country. Supreme Court's interpretation of notions like

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75 See Chapter III, n.55.

76 *Ibid*, para.6.

secularism,[77] Hindutva,[78] life,[79] education,[80] etc., were largely based on a territorial understanding of values.

Contemporary social theory gives a strong theoretical footing to the concept of distinct territorial morality of nations.[81] The contemporary social theory enunciates the concept of an "*abstract-concrete*" space which the nations inhibit.[82] The nation-space is abstract being a metaphysical construct. But it is concrete being geographical and hence physical. The space

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77 See *S.R. Bommai v. Union of India*, (1994) 3 S.C.C 1.

78 See for elaborate discussion of the Hindutva judgments in these lines, Soli. J. Sorabjee, "Indian Supreme Court on Hindutva", *Religion and Law Review*, (Vol.1.5; 1996, Institute of Objective Studies, New Delhi).

79 See *Gian Kaur v. State of Punjab* (1996) 2 S.C.C 648, pp.656-657.

80 *Unnikrishnan J.P. v. State of Andhra Pradesh*, AIR 1993 S.C 2178, p.2230.

81 See generally Benodict Anderson, *Imagined Communities*, (Verso, London, 2nd ed. 1991). See also Frederik Barth, *Ethnic Groups and Boundaries: The Social Organisation of Cultural Differences*, (George Alles and Unwis, London, 1969).

82 See generally Anthony D. Smith, *The Ethnic Origins of Nations*, (Blackwell, Oxford, 1986).

exist in the social realm of a nation.[83] Nations are emergent phenomena. They become visible only when an ideological terrain and an identifable territory can be cross-mapped onto each other to produce a sense of nationness shared by large members in society.[84]

This ideological construct of a nation space stands for territorially delimiting the social space of a nation. The social space emerges out of a historic process of collective existence and therefore represents morality of a given community within that territory. This cannot be discorded by positivist intervention, that too of international dimension.

K. The Conclusion:

The above analysis shows that any attempt to interpret the expression morality occurring in the Indian Patent Act, in the context of patenting living beings, has to be made in the light of the distinct values of Indian community. As has said earlier the Indian understanding of the concept of life is based strongly on a broad base of customs, traditions and other

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83 See Anderson, *supra* n.80.

84 *Ibid.*

religious principles.[85] The central questions addressed in the classical Upanishads, which form the core of Indian philosophy, were all about the notions of life and existence.[86] The intrinsic values of life as understood by the Indians were strongly justified by the rationalisation in the philosophical expositions. The *Ahimsa*, which was central to Buddhist thought stem from the understanding of the dignity of life.[87]

The morality of life patenting is to be seen in the light of the foregoing analysis. The following propositions can be drawn from the above analysis.

1. Principles of natural law postulate the intrinsic values of life.

2. The concept of morality and the principles of natural law are deep in human minds in such a way that a sudden replacement of these concepts with observations drawn from scientific experiments goes against human civilisation.

3. The Indian understanding of morality co-exists with the universal principles of natural law but acquires different dimensions based on its distinct community values.

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85 See *supra* n.33.

86 See *supra* n.31.

87 For an account on Buddhism, see S. Radhakrishnan, *Indian Philosophy*, Vol.1, (Oxford University Press, New Delhi, 1989).

4. India, having its own age-old social values and religious believes backed by different philosophical schools, has a territorial morality of its own.

A patent on a living being results in the following:

1. It gives private property rights (the right to possess, enjoy and even to destroy) to a patentee on that particular living being and its progenies.

2. The patentee's right is an exclusive right (All others except the patentee will be excluded from using those living beings. This means a single individual enjoys monopoly over a particular variety of plant or animals).

3. The patentee commercially uses his invention thereby making the living beings an object of trade and therefore commodities.

The consequences together with those mentioned earlier, when analysed in the light of the prinnciples enunciated above show that patenting of life forms in the distortion of the values inherent in life. TRIPs now mandates India to provide patents on microorganisms. As said earlier Indian Patents Act clearly speaks about morality and principles of natural law as grounds to determine patentability. It is felt that these provisions stand against patenting of life forms.

As mentioned above the mandate in TRIPs for patenting life forms has to be seen on the basis of the territorial understanding of morality. As far as India is concerned any interpretation of the "morality clause" in the Patents Act should encompass the Indian understanding of morality. As we have seen earlier the notion of morality in the Indian perspective is rooted deeply in the Indian vision of natural law. Hence any attempt to extent private property over living beings go against these morality notions. The recognition of the morality, public order clause in Art.27(2) of the TRIPs is a recognition of this reality with reference to different nations and their soveriegnity. If morality is to be viewed territorially, the provision in the Sec.3 of the Patents Act have an over riding effect on the TRIPs provisions contained in Art.27(2). Therefore India has a strong case against the TRIPs mandate for life form patenting under Art.27(3).

Sec.27(3) of the TRIPs explicitly gives room for a review of the patentability criteria. Accordingly the first revision is going to be held in the year 1999. This is to be considered as a built in cybernetics within the TRIPs paradigm and has to be effectively used to renegotiate the patentability norms.

In *Law, Liberty and Morality*[88] H.L.A. Hart asked the question, "Has the development of law been influenced by morals?". His unequivocal response to this question was "the answer to this question is plainly '*Yes*'".[89] If law has to be influenced my morals in its development, where from they springs up? In this context the observation of Cardozo is quite pertinent. Cardozo says:

> "Law is indeed, an historical growth for it is an expression of customary morality...."[90]

Justice Oliver Wendell Holmes asserts[91] these propositions by saying that:

> "the life of the law has not been logic, it has been experience. The felt necessities of the time, the prevalent moral and political theories, institutions of public policy... have had a good deal

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88 H.L.A. Hart, *Law, Liberty and Morality*, (Oxford University Press, Oxford, 1984).

89 *Ibid*, p.1.

90 B.N. Cardozo, *The Nature of Judicial Process*, (Yale University Press, New Haven, 1921), pp.104-105.

91 O.W. Holmes, *The Common Law*, (Dover, New York, 1991).

more to do than the syllogisms in determining the rules by which men should be governed...."[92]

Atharva Veda declares:[93]

समानी प्रपा सह वोऽन्नभाग :
समाने योक्त्रे सह वो युनज्मि
सम्यञ्चोऽग्निं सपर्यतारा नाभिमिवाभित :

"All have equal rights on articles of food and water. The yoke of the chariot of life is placed equally on the shoulders of all. All should live together with harmony supporting one another like the spokes of a wheel of the chariot connecting its rim and hub."

The vedic hymn postulates that all living beings have equal rights and it is immoral to be otherwise.

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92 *Ibid*, p.1.

93 *Atharva Veda* as cited in Rama Jois, *Seeds of Modern and Public Law*, (Eastern Book Co., Lucknow, 1990), p.49.

CHAPTER V

THE ENVIRONMENT

Introduction

The importance of biotechnology as a branch of science need not be emphasized. But the benefits of scientific progress has to be estimated in the light of the long-term socio-economic progress they result in. If the progress in a branch of science creates short-term benefits and if there exists a serious apprehension of a long-term social risk arising out of it, the case is to be dealt with care and caution. Genetic engineering raises such a challenge. The technocratic version of sustainable development promised by genetic engineering industry and a faction of scientific community is yet to be realized.[1]

Scientists have told us the tremendous socio-economic benefits genetic engineering create.[2] But now a part of the same scientific community tells us the serious environmental hazards of deploying biotechnological research.[3]

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1 See Vandana Shiva, "Why the Engineering Paradigm in Life Forms is Flawed", *Third World Resurgence*, Jan/Feb (1995), pp.53-54.

2 See Chapter I, n.39.

3 See Chapter I, n.34.

Therefore at a time when we are necessitated to provide patent protection for inventions in the field of biotechnology, which will foster the commercialisation of such inventions, the arguments on the environmental hazards are to be carefully analysed.

This chapter consists of four parts. Part I deals with the environmental risk issues. The arguments relating to the ecological hazards of the deployment of genetic engineering are analysed in this Part. Part II is an analysis of the biosafety mechanism especially in India which controls and regulate the genetic engineering research and development. In Part III certain specific issues relating to bioethics is highlighted with the purpose of having a theoretical perspective of the environment-based arguments against the harmful effects of genetic engineering. Part IV contains a critical appraisal of the whole issue.

Part I

A. The Environmental Risks of Genetic Engineering

Most of the environmental issues, raised in the context of genetic engineering and the commercial application of rDNA techniques, are yet to be resolved.[4] The global public concern over safety relating to genetic

4 For a detailed discussion of these issues see *infra* n.8.

engineering seems to have scientific grounds.[5] From 1975 itself the scientific community started warming the world about the probable risks involved in this field of research.[6] But the issue acquired a new form when the scientific community itself is divided into two groups, one group comprising mainly of geneticists and microbiologists speaking for genetic engineering and the other group, mainly ecologists speaking against it.[7] The arguments against the deployment of genetic engineering researches are mainly based on the following areas.

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5 See *infra*, n.7.

6 See *the Asilomar Declaration* (1975). The statement issued by the scientists comprising the Committee on *Recombinant DNA* of the U.S. National Academy of Sciences warned that 'there is a serious concern that some of these artificial *rDNA* molecules could prove biologically hazardous'. The Conference in Asilomar was chaired by Dr Poul Bars and the Committee included Dr James Watson himself. See *Third World Resurgence*, No.93154 (1995), p.17.

7 Richard Hindmarsh, "the Flawed Sustainable Promise of Genetic Engineering", *The Ecologist*, Vol.21, No.5 (1991), p.196. The author observes, "most of the scientists responsible for low-risk statements are either molecular biologists, geneticists, microbiologists or biochemists, who specialise in biology at the molecular and cellular levels. Often they are directly involved with the genetic engineering industry. By way of contrast many critics are ecologists who specialised in biology at the organism, eco-system - biosphere levels of interaction and who are independent of the industry.", p.201.

B. Herbicide - Resistence and Pest Resistence

The thrust area on which the agri-genetic engineering industry focus their commercial strategies are herbicide resistence and pest resistence. The highest priority is given to the development of herbicide tolerant plant varieties in the agenda of the agri-genetic engineering research and development. About 30-50 per cent of the industry's resources are directed at this product.[8]

A study conducted by the Ministry of Environment of the Government of Denmark reveals that the massive commercialization of the R & D efforts on herbicides tolerant plants results in serious environmental hazards.[9] The study was intended to assess the environmental risks of the use of herbicide resistent agricultural crops. The study revealed that the transfer resistant genes to weeds will cause a gradual spreading of resistence to an agent

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8 Mooney, P, "Beyond Biocides: People Linking for a Sustainable Future", *The Gene Exchange*, Vol.2 (1991), p.9.

9 The study was conducted on a number of selected agricultural crops. For a detailed discussion on the strategies adopted in the study, See Vandana Shiva, "Tripping Over Life", *Third World Resurgence*, No.57 (1955), p.7.

(which was a Basta Oil Seed Rape in this particular case) and is thus likely to result in an increased worldwide use of herbicides.[10]

This case study substantiates the arguments regarding natural gene transfer. Genes which are introduced into the crop variety get transferred to its wildrelatives through natural gene transfers.[11] This spontaneous hybridisation rate for *oil seed rape* and its wild relative *Brassica Compestris* is 0.3% to 8%. This suggests that cultivation of *oil seed rape* might result in spread of transgenes to related wild species by hibridisation.[12]

It is argued that genetic engineering research results in irreparable biological pollution. In the development of herbicide and pesticide tolerant varieties, it is cheaper to adapt a plant to a chemical than a chemical to the plant. This is the strategy generally followed by the agri-genetic engineering industry. The creation of genetically engineered herbicide resistant varieties can end up in the creation of weeds.[13]

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10 *Ibid*, p.8.

11 R. Jorgensen and B. Anderson, "Spontaneous Hybridization, the risk of Growing Genetically Modified Oil Seed Rape", *Am.J. of Botany*, 81 (12) 1994.

12 For more details, *ibid*, pp.81-85.

13 See *supra* n.7, p.8.

It is generally accepted that pesticides tolerance research can be limited to environmentally benign chemicals. But even the low-dose herbicides like *sulfonylurea, chlosulfuron* and *imidazole* also cause harms by way of persisting in the environment.[14] It is important to note that the U.S Environmental Protection Agency (EPA) cancelled and restricted various formulations containing *bromoxynil* on the grounds of potential birth defects in the children of persons handling the products as the induction of carcinogenic effects.[15]

Transgenic biopesticides furthers the ecological risks in many ways, though they are claimed to be environment friendly.[16] When a new form of

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14 See *supra* n.7, pp.197-199. The author cites the case of transgenic tobacco hybrid produced by the Plant Industry Division of the Industrial Research Organisation (CSIRO) of Australia. This tobacco hybrid survived spraying with dosages of phenoxy herbicide 2, 4-D. Though 2, 4-0 is claimed to be environmentally benign the U.S. Geologists found it to be more susceptible to insert infection and disease. Beneficial inspects like bees have been found to suffer adversely from 2, 4-0, usage.

15 See Richard Hindmarch, *op. cit.*, p.198.

16 See J. Doyle, "Potential Food Safety Problems relating to New Uses of Biotechnology". *Biotechnology and the Food Supply: Proceedings of a Symposium*, (National Academy Press, Washington DC, 1988). The author is of the opinion that, with the accelerating pace of

genetic resistence is introduced into a crop strain the resistence collapses after 5-15 years because of a newly evolved form of disease or pest. A serious health hazard which is a direct outcome of using biotoxin is the genesis of a new naturally occurring toxins.[17]

C. Environmental Releases

In the coming days the release of *genetically engineered organisms* into the nature is going to be of common place. It is very difficult to have a general standard for assessing the risks of releasing *Genetically Modified Organisms (GMOs)*. Therefore for risk assessment in *GMO* releases since the harms of releasing genetically engineered organisms can be assessed only after releasing those organisms. Some authors have even described the whole process as '*Opening Pandora's Box*'.[18]

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biotechnology development, new gene transfer technique may allow a more rapid change in toxin levels, the introduction of new toxins or the creation of secondary situation that invite the genesis of a new toxin.

17 *Ibid.*

18 Paul Hatchwell, "Opening Pandora's Box: The Risk of Releasing Genetically Engineered Organisms", *The Ecologist*, Vol.19, No.4, p.130. The author argues that the fullest adoption of genetic engineering would involve fundamental changes in the way we think about our place in the natural order, since human intervention shifts

Dr Martin Alexander, a Professor at Cornell University's Department of Agronomy and the then Chairman of the Environmental Protection Agency's (EPA's) Study Group on Biotechnology, has identified the following major risk components of the environmental release of genetically engineered organisms:[19]

1) the possibility that the organism will survive following its release.
2) the likelihood that the organism will multiply in some natural environment or in farmed areas.
3) the possibility that it will be dispersed and make contact.
4) the chance that it will be harmful.

Of all these risks involved in the release of *GMO's* probably the most important and serious may be the risks of self propagation. This raises serious challenges to the safety measures of genetic research.[20]

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the environmental conditions in the favour of artificial threat to ecosystem *perse*.

19 *Planned Releases of Genetically-Altered Organisms: The Statutes of Government Regulation, Hearing Before the Sub-Committee on Investigations and Oversight of the House of Commons on Science and Technology*, 99th Cong. 1st Sess. 40 (1985) as cited in Mark W Lauroesch, "Genetic Engineering: Innovation and Risk Minimization", 57 *George Washington Law Review*, 100 (1988).

20 *Ibid.*

The compelling factors that prompt the scientists to speak against the unfettered commercial application of genetic engineering are many. In 1993 in a study namely *"Perils Amidst the Promise"*, the Union of Concerned Scientists in Washington DC addressed the question whether genetically engineered crops should be commercially released.[21] The findings were against giving an absolute permit for using genetic engineering techniques for all commercial purposes.[22] To highlight the harmful effects of microbe releases, ecologists cite the case of the 1992 epidemics of the disease *Eosinophelia - Myalgra Syndrome* (EMS). The death toll of the epidemic was 38 out of the 1512 reported cases.[23]

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21 "Neglect of Safety Concerns and the Need to Consider a Moratorium on Geo Releases," *The Third World Resurgence*, No.53/54, p.20.

22 *Ibid.*

23 An epidemic of the disease *Eosinophelia-Myalgia Syndrome* brokeout in U.S. in 1992, the symptoms of which include abnormally high counts of *WBC*. By June 1992 there were about 38 deaths reported. The victims had taken a particular batch of *Synthetic L. Esyptophas*, an amino acid found naturally in various foods. A genetically engineered strain of *bacillus amyloliquefaciens*, the organisms used to produce *tryptophan* has been introduced in December 1988. This is cited as a serious unpredicted health hazard of genetic manipulation. See for details, *Ibid.*, pp.19-20.

In scientific terms there exists little distinction between the release of a *novel organism* and an *exotic organism*.[24] Various case studies show that *exotic organisms* do potential harms to the ecosystems. An oft-quoted case is the field trials of *pseudomonas fluorescence bacterium*.[25]

D. GENETIC DIVERSITY

It is argued that genetic engineering raises serious threats to genetic diversity.[26] The major concern is that genetic engineering will induce farmers to use only the most efficient plant or animal of a species. This is now

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24 A novel organism can be an indigenous organism with atleast one modified or inserted gene. But an exotic organism may not be an indigenous one. *Supra*, n.3, p.201.

25 See *TIME*, No.9, 1987, pp.74-75, M.D.Lenosick reports the field trials carried out on the bacteria *psudomonas fluorescens* near Black Ville, South Carolina by researchers from Clemson University. These bacteria were genetically engineered to turn blue in the presence of a chemical known as *X-Gal*. They were resistent to the antibiotic *rifampsin* rendering them easily detectable in oil samples. MONSANTO the multinational biochemical corporation was expected to monitor the release. But no proper monitoring could be carried out.

26 The Testimony of Thomas Wagner, Director, Edison Animal Biotechnology Centre, Ohio University, *Patents and the Constitution: Transgenic Animals: Hearings Before the SubCommittee on Courts, Civil Liberties and the Administration of Justice of the House of Commons on the Judiciary*, 100th Cong. 1st Sess. 39-40, as cited in Mark W. Lauroesch, "Genetic Engineering", *supra*, n.15, p.119.

termed as spread of monoculture.[27] Monoculture means the spread of a single efficient variety of a breed of livestock or transgenic crop.[28] Monocultures are ecologically unstable and they invite diseases. In order to prove this argument Vandana Shiva cites the U.S *Corn Blight* Epidemic.[29]

The risks highlighted in the foregoing pages seem to be scientifically well founded. The reason behind this conclusion is that the above discussed arguments are not so far outrightedly rejected by the scientific community. The serious concerns over the risks of deploying genetic researches resulted in the emergence of biosafety mechanisms. In the next part an attempt is made to critically appreciate the role of the biosafety mechanisms in curbing environmental hazards of genetic engineering.

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27 See Vandana Shiva, *Captive Minds Captive Lives*, (Research Foundation for Science, Technology and Natural Resource Policy, 1995).

28 See *supra*, n.5, p.7.

29 The *Corn Leaf Blight* of 1970-71 laid waste 15% of America's crop produce during the period. See Richard Hindmarsh *op.cit.*, n.7.

Part II

Biosafety Policy and Regulation

A. Introduction

The significance of biosafety needs no elaboration in the light of the above discussion. A number of cases on the mismanagement of genetic engineering are reported from various parts of the world.[30] In India, a very

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30 Bruch *et al. Biotechnology Policy and Industry Regulation: Some Ecological, Social and Legal Considerations: Submission to the House of Representatives Standing Committee on Industry, Science and Technology: Inquiry into genetically modified organisms,* (Australia, September, 1990), *The Ecologist,* Vol.21, No.5, Sept/Oct. 1991. The list of incidents of the mismanagement of genetic engineering include:

a) In November, 1986, the Wistal Institute of Philadelphia in collaboration with the Pan American Health Organization conducted field tests of a genetically engineered viral vaccine on 20 cows in Azul, Argentina without the approval of Argentine or US officials. The viral vaccine was conveyed from the USA to Argentina in a diplomatic bag thus evading Argentina's import laws. Wistar maintained that it was not legally obliged to disclose anything because Argentina had no law on the subject and no regulatory mechanism for the field testing of potentially harmful bio-technology products.

b) In May 1987, a Researcher at the University of Bayreuth, West Germany, carried out a release of genetically manipulated *rhizobia* on to a pea field. In order to comply with the national regulations on genetic engineering any experiment involving the release of genetically

recent issue of a field trial conducted by the Indian Agricultural Research

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engineered organisms had to be approved by the Central Committee for Biological safety. But genetically engineered organisms were defined to include only those created *in Vitro* using *r-DNA techniques.* Much to the consternation of critics the *rhizobium* released did not fall under this subject and thus did not need official approval.

c) In 1987, an accidental release of *gaseous protein dust* from a factory near Leningrad caused widespread cases of *bronchial asthma* resulting nation wide environmental protests forced the closure of this Soviet Micro Biological Industry.

d) In 1988, over 50 transgenic pigs were taken to an abattoir in South Australia from facilities run by Metrotech a joint venture between Metro Meats and the University of Adelaide. The transferred pigs were slaughtered for human consumption. It appears that neither the University's Institutional Bio-safety Committee nor the National Genetic Manipulation Advisory Committee were notified. The Managing Director of Metrotech has asserted that Australia's voluntary code of conduct applied to the University but not to companies.

e) In 1990, the US Environmental Protection Agency granted Mycogen an experimental use permit for large scale field testing of a bio-pesticide containing gene altered bacteria. Mycogen was able to side step the laws because the bacteria were killed before they left the factory (prevailing laws pertain only to live releases). Yet there is still the possibility that live bacteria or viruses in the field can interact with the dead bacteria and so alter live organisms.

This is a part of a longer list which comprises a number of incidents of genetic mismanagement.

Institute, New Delhi, raised much public concern.[31] The IARI scientists introduced a *synthetic toxin gene [RY IA(b)]*, obtained from Japan into the native variety of an egg plant, *Solanum Melongena*. *Bacillus thuringesis (Bt)* which expresses gene *Solanum Melongena* was grown in a 60 square meters compound in the IARI campus in New Delhi. This was continued from August, 1996 till, December 1996. The experimental plot was not adequately protected and nets were the only protective covers. Since this unauthorised field trial started raising hue and cry the Government of India ordered IARI to burn down the experimental plot.[32]

These and a number of other incidents highlight the significance of an efficient biosafety mechanism. The necessity of having a safety mechanism was felt by the scientific community itself, which in the beginning forced the scientists to place a moratorium on certain *rDNA* experiments.[33] When the Moratorium was lifted the scientific community replaced it with voluntary guidelines.[34]

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31 Sachin Chaturvedi, "Biosafety Policy and Implications in India", *Biotechnology and Development Monitor*, No.30, March (1997), p.10.

32 *Ibid*, p.11.

33 *NAS Ban on Plasmid Engineering*, 250 *Nature*, 175, (1994).

34 See the *Declaration by the Asilomar Conference* on *Recombinant DNA Molcules* 1 *Science* 991, p.991-94 (1975).

B. Biosafety: The U.S. Experiment

In 1983 the U.S. Government issued a regulation on genetic engineering researches.[35] This *Recombinant DNA Research Guidelines* made it compulsory for all NIH supported *rDNA* researches to comply with guidelines formulated by NIH. These regulation were applicable only to NIH funded researches. But the chunk of the genetic engineering research is carried on by private corporations. They are not bound by the guidelines.

In 1983, the *Biotechnology Science Coordination Committee (BSCC)* was constituted by the Reagan Administration.[36] The purpose of establishing BSCC was the coordination of the regulation of the bio-industry.

BSCC consisted of seven members. The members represented the following agencies:

1. The Department of Agriculture (2 members)
2. The Department of Health and Human Services (1 member)
3. The Environmental Protection Agency (EPA) (2 members)
4. The Food and Drug Administration (FDA) (1 member)
5. The National Science Foundation (1 member).

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35 *Recombinant DNA Research Guidelines*, 41, Fed. Reg. 27.

36 51 Fed Reg. 23, 306 (1986).

Under this *Coordinated Framework* the jurisdiction of regulation was determined by product's use.[37] The Environmental Protection Agency had jurisdiction over pesticides, microorganisms in contained uses, and microorganisms not used for agricultural purposes. Food and food activities, animal and human organs, medical devices and biologics[38] came under the Food and Drug Administration. The United States Department of Agriculture was revewing animal biologics, plants, animals, microorganisms with agricultural uses and plant pulses.[39]

Eventhough this *Coordinated Framework* has certain advantages, it resulted in an overlapping of jurisdiction. Therefore, BSCC constituted a *lead* agency to coordinate its function.[40]

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37 See *Supra*, n.7, p.191.

38 Biologics are medicinal preparations made from living organisms and their products including serums, vaccines, antigens and antitoxis. *Dorland's Medical Dictionary*, p.169 (26 ed. 1985).

39 See Richard Hindmarch, *op. cit.*, p.200.

40 *Ibid.*

C. The Institutional Framework for Biosafety: The Indian Position

The Ministry of Environment and Forests under the Environmental (Protection) Act, 1986 issued a notification in the year 1989.[41] This Notification set certain Rules for Manufacture, use, import, export and storage of hazardous microorganisms or cells.

Five Committees were set up at various levels under the Notification.[42] The Committee were:

1. Recombinant DNA Advisory Committee (RDAC)
2. Review Committee on Genetic Manipulation (RCGM)
3. Institutional Bio-Safety Committee (IBSC)
4. Genetic Engineering Approval Committee (GEAC)
5. State and District Level Biotechnology Coordination Committees (SBCCs and DBCCs)

The first three Committees i.e., RDAC, RCGM and IBSC are presently functional under the Department of Biotechnology (DBT) and the GEAC is functional at the Ministry of Environment and Forests.[43]

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41 Notification No.1037 (E) dated 5.12.1989.

42 *Ibid*

43 See Biosafety Regulations, *The Annual Report of the Department of Biotechnology*, (1996-1997).

The Department of Biotechnology prepared the Recombinant Safety Guidelines in 1990 in accordance with the 1989 Regulations. The Department of Biotechnology Revised the Guidelines in 1994. This revision was carried out in the light of India's ratification of the Biodiversity convention.[44]

Since most of the researches using GMOS are considered as department projects the Institutional Biosafety Committees ensure that all the rDNA Biosafety Guidelines are followed and adhered to. The DBT has one representative each in all IBSCs. Presently 71 IBSCS are functional.[45]

Having seen the environmental risks involved in genetic research and the structure of the biosafety mechanism evolved to curb these environmental hazards, now we will attempt to have a look at the bioethical dimensions of the issue.

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44 *Ibid.*

45 *Ibid.*

Part III

The Bioethical Dimensions

The purpose of this brief enquiry here is to restate the fact that there are eqaully strong arguments in theoretical plane against excessive human interference with nature and its products. The following arguments are two representative lines of thinking in this regard.

A. Species Integrity:

Species integrity is the understanding that species should not be mixed.[46] This is based on the notion of *completeness* of a living being.[47] The *holistic* understanding of animate existence envisions the universe and the living nature in terms of interacting wholes.[48] In this perspective human being as well as microbes play somewhat equal roles in the process of biological evolution.[49] But modern biology rejects this *completeness* concept

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46 Daryl R.J. Macer, *Attitudes to Genetic Engineering*, (Eubios Ethics Institute, 1992), p.13.

47 *Ibid*, p.23.

48 *Ibid*.

49 Vandana Shiva, *Captive Minds and Captive Lives*, (Centre for Science, Technology and Resources Policy, 1995), p.20.

of living matter and considers species as reproductive communities.[50] Theoretically speaking, this is the reflection of the reductionalist paradigm of life sciences. Reductionism explains biological entities in terms of the laws of inanimate existence.[51] A living being is considered equal to a machine which can be dismantled and again reconstructed. It is argued that reductionalist biology devalues all forms of knowledge and ethical systems related to living organisms that are not reductionist.[52] In this context the observation of David Ehrenfeld is pertinent:

> "We are on the verge of losing our ability to tell one plant or animal from another, and of forgetting how the known species interact among themselves and with their environment."[53]

Therefore species integrity is to be preserved for human, animal and plant well being. But genetic engineering flows the reductionist paradigm and advocates for the engineering of living beings. Patents on life forms which encourages this therefore goes against the notion of species integrity.

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50 *Ibid*, p.2.

51 See *supra* n.1.

52 See generally, David Ehrenfeld, *The Forgetting*, (Oxford University Press, New York, 1993).

53 *Ibid*, p.6.

B. Intergenerational Equity:

Intergenerational equity is the basic equality of generations in the human family.[54] According to Edith Brown, the concept of intergenerational equity has the following dimensions.[55] It involves:

- Conservation of options: Each generation must conserve the natural and cultural resources base so that the options of future generations are not restricted.
- Conservation of quality: Each generations must maintain the quality of the planet so that it is passed on in worse condition that they found it. This is the minimum requirement.
- Conservation of access: Each generation must have an intergenerational equity to right of access to the legacy of past generations.

If we have an obligation towards the coming generations to keep the nature intact are we doing justice when we interfere with the natural evolution? The patentability norms for biotechnological inventions require *substantial changes* in the genetic constitution of a living subject matter as a

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54 Edith Brown, "Our Rights and Obligations About Future Generations", 84 *A.J.I.L,* 198 (1990).

55 *Ibid,* p.203.

basic criterion. That means an invention to be patentable must have made substantial changes in the nature and function of a living organism for meeting the novelty requirement. Instead of limiting non-natural interventions, this criteria require the human intervention to be extensive. Therefore our present day patentability norms further the extension of human intervention with the nature and its products *forgetting* our obligations towards the generations to come.

Part IV
A Critique

We have seen in Part I of this Chapter, the various risks involved in the development of genetic engineering. The veracity of the arguments against the uncontrolled application of genetic engineering is not so far refuted by the scientific community. Since these arguments are not outrightedly rejected, it can be understood of having some valid scientific grounds. Therefore the attempt is not to discard or approve these environmental risk issues instead an attempt is made to appreciate the desirability of patenting living beings in the light of the potential ecological threats it poses. The first issue here is, can restrictions on patent grants be effectively used to check the unfettered deployment of biotechnological inventions so as to curb its ecological hazards?

Though there are arguments claiming that broad biotechnology patents hamper innovation, it is generally accepted that patent stand as an effective tool in boosting the commercialisation of biotech inventions. Since biotechnological innovations are of high commercial viability, biotechnology has become the focal point of investments in the international trade scenario, the chunk of which is made by the MNCs.[56] Profit motivation drives the corporations towards massive commercialization of biotech inventions. On the other hand the R & D efforts on various biotechnology researches need huge investments which compel the scientific community to get associated with the Corporations. Therefore patents play an important role in bringing the biotechnological inventions from laboratories to the market. This shows the possibility of using patents as regulatory mechanism on the deployment of biotech innovations. If patents can effectively be used as an instrument to regulate genetic engineering industry, the next important question is; is a ban on life patenting a progressive step in this regard?

As stated earlier, the importance of biotechnology is to be estimated in the light of the long term social risks associated with it. The environmental risk arguments gets strengthened when it comes to "*living inventions*" i.e.,

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56 See K. Ravi Srinivas, "Private Investment in Biotechnology in Promoted in India", 11 *Biotechnology and Development Monitor*, 16, (1992). See also "Biotechnology: For whose Benefits?" *E.P.W*, Sept.7 (1991). For a general understanding of the issue see Mitchel B. Wellerstein *op. cit.* p.8.

microorganisms, plants and animals. If the extent of intervention in the natural evolution is greater, the more is the ecological hazards.

The trends in the field of patenting biotechnological inventions during the last fifteen years, if critically looked at, reveals certain fundamental facts. The patent claim in *Chakraborty case*[57] was for a microorganism. In the later cases the claims did not confine to microorganisms or micro biological process. In *Onco Mouse case*[58] the claim was for a transgenic mouse, a case on animal patent. In a development parallel to this patents were granted on plants also.[59] Now according to the present practice of EPO and American Patent Office cell lines (both human and non-human) can be patented.[60] Presently the concern is transgenic mammals,[61] and the recent reports centres around *human-clones*[62] It should be noted that mammals is the species to which human beings also belong.

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57 *Diamond v. Chakraborty* (SC) 447 U.S.305.

58 See Chapter III, n.40.

59 See for details Chapter III, n.36.

60 See Patricia A. Rae, *op.* cit., p.32.

61 See Chapter III, n.39.

62 See generally, *The Hindu Daily* dated 28 Feb., 1997, *The Asian Age Daily* dated 2 March, 1997.

From the above fact it can be understood that there exists a tendency to get patent protection for higher and higher forms of life. Since the issue central to the environment risk bared arguments in the varying degrees of non-natural intervention the above observations become important. If that is the case patenting of a microbiological process has to be seen differently from patenting of a cloned sheep. Here arises the question of setting legal norms as to what is petentable and what is not, on the basis of the extent of intervention and the resultant environmental hazards.

TRIPs is attempting to strike a balance by drawing a line in between microorganisms patenting and higher life-form patenting. But TRIPs does not prevent the member countries from providing a broader patent regime covering higher forms of life also. In order to strike this balance the grounds relied on were public order, morality, health and environmental protection. Is this a right approach towards the issue of patenting life-forms? It is not so far scientifically proved that the risk involved in releasing genetically engineered microbes into the nature will be lesser than the risks of releasing genetically engineered higher life-forms. Therefore on the basis of ecological standards, patentability norms cannot be set distinguishing microorganisms and microbiological processes from the case of ptenting higher form-supplies.

The same is the reasoning for distinguishing eco-friendly biotech researches from the ecologically hazards ones. In order to explain the expression injurious to *public health*, what all are the harmful researches and what are not are to be determined. This cannot be done on the basis of certain general standards. Therefore even in the institutionalized arrangements a case to case approach is generally adopted. Therefore, a general mandate for patenting of microorganisms makes it impossible to adopt a case to case approach. This vitiates the very essence of public health provision in the Patent Act.

The basic reason behind creating biosafety mechanism is to strike a balance between the relative merits and demerits of biotechnology research by putting *reasonable restrictions* upon it. Having seen the institutional arrangements in US and in India, now we are to ask the question, are biosafety mechanisms capable to curb the environmental hazards of making applicable biotechnological inventions. This question can be answered in two angles. The first and foremost criticism against all biosafety arrangements is that the risk of genetic engineering research cannot be measured in uantitative terms. All biosafety mechanism are targetted towards two goals:[63]

1. Risk Assessment, and
2. Monitoring

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63 See Mark W. Lauroesch, "Genetic Engineering: Innovation and risk minimization", *57 George Washington, Law Review*, 100 (1988).

The complexity of organisms, the fluid nature of genomes and the complexity of ecological interactions make both these goals near impossibilities.[64] Scientific strategies are yet to be evolved to objectively estimate the risk of *Geo Releases*. Therefore till such standards are evolved biosafety guidelines will not be able to provide objective criteria which in a way determine the patentability of biotechnological inventions.

Another criticism is the one relating to the inefficiency of the existing mechanism, especially that in India. As for example the institutional arrangement for biosafety in India is purely adhoc in nature. The industry's primary objective in this regard is the uncertainty of the DBT's approach towards a specific case. Another major criticism is the one relating to the non-transparency of the system. The absence of clear statutory provisions backed by strong policy, results in incidents like the IARI issue.

64 *Ibid.*

CHAPTER VI

THE CONCLUSION

Law in the area of life patenting has been in the course of development in the developed countries for the last two decades keeping pace with the developments in biotechnology. Biotechnology either directly or indirectly deals with living subject matters. The advancements in this area, proved possible that genetic constitutions of living beings can be altered. This resulted in the emergence of genetic engineering as a scientific revolution which promises even the *creation* of new forms of life. The subject matters of these inventions are microorganisms, hybrid plants, genetically engineeered animals, human genes and cell lines. The high commercial potentials of genetic researches made this branch of science a focal point of trade and investment. Consequently claims for patents on these living beings have started coming up. This led to a situation where law and legal systems were called upon to address the issue of granting patents on living beings particularly in the context of globalization of traditional investments. The various judicial bodies which were called upon to address the issue, did not venture to look at it objectively in the light of the moral, ethical and environmental dimensions. This is evident from the U.S. Supreme Court decision in *Chaktraborty* and the reletance on the part of the EU Patent

Appellate Board in *Green Peace* case accept the responsibility of Patent Office to decide on the question of environmental risk. The resultant judicial process therefore failed to reflect upon the competent rationale involved in it. This gave rise to the legal recognition of undesirable standards incompatible with the larger social needs thereby lacking universal acceptability. The attempt in the TRIPs Agreement to recognise patent protection for some life forms even lack sound jurisprudential backing. On the other hand the patentability norms under the Indian patent regime in this regard are set in tune with the social and political setting of India. The country is at cross roads today because TRIPs mandates for patenting living beings.

We have seen that our present day understanding of the notion of life has its roots in the well established principles of natural law. Even the concept of life in the constitutional legal domain stem from the notion of natural rights. This natural right to life is nothing but the principles of natural law brought to the realm of *rights* through the *consent theories*. Therefore the positivist understanding of life do not have an existence independent of the principles of natural law. Natural law principlees have been recognized in different way and in different form in different schools of thought. But it remains the same in its essence. The fundamentals of these natural law principles postulate the values inherent in life.

Our property jurisprudence also has to have its conceptual basis in the principles of natural law. But no school of thought so far has ventured to advocate the extention of property over '*life*', making it private property and an object of commerce. Even the liberal theoretical construct on property by Locke did not proceed in those lines. Any attempt to restate the jurisprudence of property has to have a conceptual bearing on the basic premises of natural law. But the extention of private property rights over life forms by patent grants is an attempt to contradict the fundamentals of natural law. It lacks a conceptual theoretical basis and any attempt to justify such a move need to restate and redefine the basis of natural law which seems to be a near impossibility. Therefore it is strongly felt that granting patents on life forms violate the intrinsic values of life.

At a time when India is required to provide patents on living organisms, the provisions of the Patents Act which set the norms for patentability need thorough examination. Such an examination is to be made in the light of an understanding of India's territorial morality. This Indian morality is also premised on the fundamental principles of natural law explained above and extents further so as to encompass the values of the Indian Society. We have noticed that these values of Indian community consider it to be immoral and unethical to interfere with life thereby distorting its inherent values.

The Indian Patents Act specifically says that an invention is not patentable if it is against the principles of morality and natural law. Here arises the conflict between the TRIPs and the Indian Patent Regime. The attempt in the TRIPs to strike a balance between the value conflicts on life patenting is evident from the incorporation of the *'morality-public ordre'* provisions in Art.27(2) so as to certain items from patenting and the obligation to grant patent for microorganism and microbiological processes under Art.27(3).

The operation of Art.27(2) is limited by a proviso which says that an exclusion cannot be made merely because the exploitation is prohibited by law. But Art.27(3), though allows the exclusion of plants and animals from patentability, brings micro organisms within its purview. This infact goes against the jurisprudential basis of Art.27 (2) resulting in an erosion of the balance aimed to strike by incorporating certain basic norms for excluding even living beings from patentability based on morality principles of sovereign states. But from the review provision in Art.27(3) it appears that the framers of the TRIPs were aware of these conflicts. Art.27(3) provides for a review of the patentability criteria, to be made four years after the date of entry into force of the WTO Agreement i.e., 1-1-1999. As far as India is

concerned the attempt should be to bring specifically inventions on life within the coverage of the general exclusion under Art.27(2).

As regards plant varieties are concerned the TRIPs mandate is to provide protection by patents or by *suigeneris* or by a combination of the both. Since patents on plants attract scathing criticisms in the above lines, the alternative is the *suigeneris* system. An effective *Suigeneris* system also diamond for a private property rights over plants through a statutory mechanism. Therefore all the arguments based on moral grounds equally apply to such a legal mechanism.

The provisions in Sec.3 of the Patents Act are to be analysed in the light of Art.27(2) of TRIPs. Since these provisions encompass the notion of morality in the Indian territorial context, the TRIPs objection for making certain inventions illegal by statutory measures does not have any bearing upon it. In fact Art.27(2) of TRIPs justifies the mandate in Sec.3 of the Patents Act. Any attempt to interpret the above mentioned provisions is to be made in the light of the jurisprudential enquiry can on the context of morality in the Indian context. This enquiry unequivocally declares that patenting of living beings is immoral and against the well established principles of natural law. Therefore Section 3 of the Indian patents Act denying patent protection for any form of life needs to be retained.

TRIPs is Art.27(2) expressly recognises the need to protect human, animal and plant lives, as well as health and environment. This reflects the concern regarding the long term social risks associated with the commercial exploitation of biotechnological inventions. Since trade motives foster the commercialisation of biotechnology, the environment risk arguments have a larger economic dimension. But granting private property rights stands central to all these different arguments. Therefore the morality issue has a direct bearing on the environment-based arguments against the deployment of biotechnological inventions.

This again attracts a joint reading of Art.27(2) of TRIPs and Sec.3 of the Indian Patents Act. The reasoning here is identical to the one which we have raised in the morality context. Sec.3 of Patents Act has to be read in consonance with Art.27(2) of TRIPs thereby reasserting the strength of '*the morality, public order, environmental protection*' arguments against life patenting. Any attempt to override or nullify these provisions violate the basic norms, which they stem from. Therefore Art.27(3) is to be restructured so as to receive universal acceptability. This becomes easy because Art.27(3) gives a room for renegotiating the patentability norms in the TRIPs.

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