



M

MYSORE UNIVERSITY LAW JOURNAL

Volume 1

March 2008

Annual

U

L

J

DEPARTMENT OF STUDIES IN LAW
University of Mysore
Manasagangotri, Mysore- 570 006.
Karnataka INDIA

CONTENTS

1. Research in Law : A Socio-Relational Critique 1 - 12
Prof. H.K. Nagaraja
2. Balancing of the Competing Interests in Identifying
Infringement of Copyright 13 - 26
Prof. P. Ishwara Bhat
3. Criminal Liability of Doctors- An Analysis 27 - 33
Prof. C. Basavaraju
4. The Emergence of Tort Law in Indian in the post
Bhopal Era- An Assessment 34 - 44
Prof. T.R. Subramanya
5. Good Governance and Accountability to the Parliament
and State Legislatures 45 - 52
Prof. K.R. Aithal
6. Human Rights and Human Genomics 53 - 61
Prof. T.S.N. Sastry
7. Judges Inquiry Bill 2006: An Appraisal 62 - 69
Dr. Ramesh
8. Rule of Law and Democracy 70 - 80
Dr. M.D. Krishna
9. Indian and Australian Experience in the Resolution
of Industrial Disputes 81 - 93
Dr. V. Sudesh
10. Right to education and the fishing community in Kerala 94 - 107
Dr. Sheeba Pillai
11. Role of International Tribunals and Courts in Enforcing
International Criminal Law-A Critique 108 - 119
Dr. Maruthi T.R.
12. Medical Confidentiality : Decisions and the Law 120 - 133
M.S. Benjamin & Dr. C.B. Raju
13. Child Rights: Challenges for the Legal system 134 - 154
Dr. Sairam Bhat
14. Biotechnology as a Means of Controlling Environment
Pollution: an Analysis 155 - 170
Vishwanath .M.

HUMAN RIGHTS AND HUMAN GENOMICS

Prof. T.S.N.Sastry**

"The Day man believes he can conquer nature, it is asking for Danger."

Prof. Rajesh Parikh¹

Introduction

In 1997 when Dr. Ian Wilmut and Keith Campbell of the Rosalyn Institute of Scotland announced the successful creation of a cloned sheep, "Dolly", the attention of the whole world was attracted towards the changing niceties of Biotechnology. This in turn led for the creation of "Polly", "Millie" etc. The birth of "Polly" signaled the first step in the application of cloning technology for the production of useful products for therapeutic purposes. Polly had a human gene in every cell of its body. This had led the researchers/Scientists to use the technology of cloning closer to human beings by twinning rhesus monkey and embryos.²

The success of cloning the animals led the scientists to establish a massive Human Genome Project in 1990 under the chairmanship of Dr. Watson. In the year 2000 when scientists announced the successful identification of blue print of life by identifying 30,000 different genes common to mankind, genomics had taken a new ground for genetic archaeology. The results of Human Genome drew the attention of the people all around the world with a grappling of issues such as, Are we going to create super eugenics? Are we going to have a super racial problem? Who should have access to genetic technology? Is genetics posing a threat to moral, social, ethical and cultural values? Are we going to have a cultural diversity? Is there going to be plural civilians? How to regulate the scientific research? What would the role of law at the international and national levels? How to tackle the socio, economic impact of the Human Genome Project? Can we legally permit such high altitude research studies? So forth and so on.³

** Prof & Head, Dept of IPR, Tamil Nadu Dr. Ambedkar Law University, Chennai 28.
Email: tsnsastry@india.com

1. Dr. Rajesh Parikh, *The Week*, Sept 16, 2000, pp42-46
2. www.google.com/history_of_cloning/cloning.htm, visited on 25.8.2007
3. for a detailed discussion on the Impact of genetic revolution and the relationships of human rights Justine Burley (ed). *The Genetic Revolution and Human Rights*, 1999 Oxford, London.

It may not be possible to provide key control mechanism to genetic scientific studies altogether, human rights provides a potential tool to a government to the policy makers to address some of the problems raised by human genome. It can at least channel a debate within a society over what, when and how genetic techniques are to be developed and implemented. Taking into consideration the important role played by human rights to a maximum extent in regulating the genomics research, this paper makes an attempt to address the new developments in the field of biotechnology in brief, the steps to be taken by the policy makers around the world in the light of the attempts made by the UN and its agencies to address the new scientific developments in bioethics.

Benefits of Human Genomics

The Human Genetics Programme (HGP) is a welcome research in the field of science and technology to a certain extent, since it will increase the ability of medicine to diagnose, treat and prevent genetic disorders. It can rectify faulty genetic disorders. A wide variety of therapies can be developed to cover a variety of approaches for the treatment of disease by altering the genetic makeup of cells or organs of individuals. Gene therapies such as Germ line and Somatic may be employed to insert new genes directly into cells to provide the missing cellular structures or metabolic activities. The HGP may allow scientists to produce human bio-chemical substances for therapeutic use in people. The research on human pathogen and vector genome projects clearly suggests that the study of molecules and cells may likely to have major benefit for medical research. HGP in the long run does offer the possibilities of providing new approaches to the protection and management of many intractable diseases. It is also helpful to cure common diseases like Malaria, Cancer, T.B., etc.⁵

Problems of HGP

The evolution of genome projects and functional genomics will involve increasingly complex and expensive technology. Its role in health sector is far from clear. There are several misrepresentations and misinformation is coupled with it. The knowledge and therapies produced by HGP will cause a concern and conflict between various stakeholders such as individuals, employers and insurers, researchers and scientists, business corporations and governments. It may look like a potential technology to overcome the disabilities created by nature, but it may create a

4. Alastair T. Ittes, "The Human Genome Project: A challenge to the Human Rights Framework" Vol.9, *Harvard Human Rights Journal*, 1996 pp.27-102; also see Ram.C. Mehotra: *Human Rights and Genetic Revolution in Conflict Resolution: Human Rights and Democracy*, 2003, D.D. Khanna & Gert. W. Kueck (eds), Shipra Publications, New Delhi, pp.272-294.
5. See the Report of the WHO on *Genomics and World Health*, 2002, pp22-50.

potential danger especially in the vulnerable groups such as women, children, disabled and minorities etc. The knowledge may be misused by scientists to create super eugenics of the past and also may overtake the ethical, moral legal and social issues. At the same time liberalism will facilitate for the progressive promotion of HGP in future. To strike the balance between the advancement of knowledge in biotechnology can be regulated to a certain extent only by using the legal framework of human rights mechanism.

Human Rights Mechanism:

To protect the interests of all the stakeholders or affected parties specified above, human rights can only provide the mechanism to regulate the impact of HGP to a great extent because the control techniques of human rights are based upon the rights asserted by individuals against all societal institutions that may infringe upon them. They may not provide sustainable answers to all the potential issues raised by social problems. They stimulate discussion which will ultimately able to provide solutions to enact legislations by individual states in their national sphere.

In order to address the various societal issues since 1948 till date more than one hundred Declarations, Covenants and Conventions have been adopted by the international community on human rights under the auspices of the United Nations. Among them the Universal Declaration of Human Rights, 1948, (UDHR), the International Covenant on Economic, Social and Cultural Rights, 1966, (ICESCR), the International Covenant on Civil and Political Rights, 1966, (ICCPR), the Convention on Biological Diversity 1992, and the UNESCO's Universal Declaration on the Human Genome and Human Rights 1997, Universal Declaration on Bioethics and Human Rights, 2005 provide a variety of binding norms to regulate the scientific and technological progress at national and international and regional levels. Though the UDHR, ICESCR and ICCPR have various provisions to regulate the abnormalities of scientific progress, the Convention on Biological Diversity and the UNESCO's Universal Declaration are more specific to regulate the advancements and aberrations in the field of biotechnology, especially dealing with human genomics.

Human Genomic Programme and Biological Diversity Convention 1992

Taking into consideration of the advances in science and technology, the Convention imposes obligations on the states parties to regulate the socio, economic, scientific, educational, cultural and recreational and aesthetic intrinsic value of biological diversity which includes genetic research. According to the provisions of the Convention, all the States parties to the Convention should establish monitoring mechanism to regulate Biological diversity including that of Genomes and genes which are important in the social, economic, and scientific context.⁶

6. Arts 8-10 of the Convention.

The Convention on the one hand recognizes the sovereign equality of states and supremacy of national legislation,⁷ on the other hand imposes obligations on the states to share the transfer of information and technology⁸ and minimizing the adverse impact of such research activities which are harmful to human cloning.⁹

With respect to research in the area of biotechnology and distribution of its benefits, the states parties are expected to regulate the Genomic research and information and its transfer and benefits through appropriate legislative, administrative or policy measures so as not to be inconsistent with the philosophy of international law of human rights.¹⁰

UNESCO's Universal Declaration on the Human Genome and Human Rights, 1997.

Taking into consideration of the fundamental principles of dignity, equality and mutual respect of men as proclaimed by the Charter of the United Nations and the catena of Conventions, Covenants and Declarations on human rights, the UNESCO on 11 November 1997, adopted the above declaration. This was later adopted by the General Assembly of the United Nations on 9 December, 1998. This is the first direct declaration on human genome in the field of human rights. The Declaration contains 25 articles divided into seven parts. They are as follows:

- Part I Deals with human dignity and human genome (Arts 1-4)
- Part II deals with Rights of the persons whom gene therapy is going to be used and confers rights on the people for any systematic violation of national and international law (Arts. 5-9)
- Part III deals with research on human genome. This part prohibits the abnormal usage of the knowledge of genomics and reminds the scientists their duty to use the knowledge without degrading the human dignity in any manner. Reproductive Cloning of humans has been completely banned. (Arts 10-12)
- Part IV imposes conditions the manner in which the exercise of scientific activity need to be carried out (Arts. 13-16)
- Part V requires the states to extend their solidarity and international cooperation in particular with respect to individuals, families and vulnerable groups to or affected by disease or disability of a genetic character. It further imposes an obligation on the member to share advance knowledge of genetics to foster scientific and cultural cooperation especially between the developed and developing states (Arts 17-19)

7. Art. 17

8. Art 16 of the Convention

9. Arts 14 &15 of the Convention

10. Art. 19 of the Convention.

- Part VI expects the States to take necessary steps to promote the ideals set forth in the Declaration through education and other relevant means (Arts 20-21)
- Part VII imposes an obligation on the states parties to take cognizance of the principles and implement them by appropriate means to the fullest extent possible with the cooperation of UNESCO's Bioethics Committee (Arts 22-25).

Considering, the claims and counter claims in scientific circles especially in the industrialized world about the creation of cloned human being, the UN quickly reacted by adopting a resolution banning any further attempts in that direction. The resolution prohibits all forms of human cloning and reminds the scientific world about the moral, legal, social and cultural problems that are associated with such research studies. The resolution inter-alia requested the member states to take legislative, administrative and policy measures to prohibit such studies and research, as they being contrary to human dignity and the need to protect the natural human life.¹¹

Universal Declaration on Bioethics and Human Rights, 2005

The Universal Declaration on Bioethics and Human Rights was developed as part of the Bioethics Programme of the United Nations Educational, Scientific and Cultural Organization (UNESCO). The Declaration came into existence in the year 2005. The main objective of the Declaration is to regulate the ethical issues raised by medicine, Life Sciences, and other associated technologies which are applied to human beings. Further, the Declaration once again reiterates the significance of Bio-ethics in international human rights and by ensuring the life of human beings. It recognizes the potential in regulating the relationship between ethics and human rights and rejuvenates the need to regulate the concept of Bio-ethics.

The Universal Declaration on Bioethics and Human Rights has been divided into five parts consisting of 28 Articles. They are:

Part one of the Declaration deals with the General Principles which deals with the Scope of the Declaration and the aims of it. The various aims are to promote universal framework to regulate the aspects of bio ethics; to promote respect for human beings of the present and future generations and their rights; to promote multiparty dialogue on various issues relations and to highlight the significance of biodiversity and its conservation as a common concern of mankind etc. (Arts. 1 & 2)

Part two of the Declaration lays down the principles to be respected while conducting research in Human Genomics. These principles are; (a) Human Dignity

11. UNGA/A/RES/59/280, dated 8.3.2005

and Human rights which need to be respected (Art. 3); (b) the advances in medicine and any scientific knowledge relating to humans need to extend the benefits to the entire mankind and minimize the harms (Art.4); (c) the autonomy and the individuality of the individuals need to be respected (Art.5); (d) any experiment, test or research is conducted on any individual, such research need to be carried out on such person only with his/her prior consent and the possible affects need to be informed (Art.6); (e) In case if any person is not in a position to give consent for such scientific investigations, provisions need to be made in the domestic law of each country extending protection to such persons (Art.7); (f) Any scientific research or advances need to take into consideration of human vulnerability and personal integrity of the individuals and groups (Art.8); (g) the aspect of privacy and confidentiality need to be taken into consideration in conducting research according to the standards of international law and human rights (Art.9); (h) the concept of equality, justice and equity need to be maintained and such human beings who consent of such experiments need to be treated equally (art10); (i) under no circumstances no individual or group need to be discriminated and stigmatized (art.11); (j) cultural diversity and respect of cultural pluralism need to be respected at all times (art.12); (k) solidarity and cooperation among individuals internationally to be achieved (art.13); any advances in science need to promote the concept of social responsibility and health which are primary for the existence of human beings and try to eliminate poverty, hungry, right to health, quality medicines, access to nutrition, water, reduction of poverty, illiteracy, promotion and protection of the right and health of vulnerable groups; any exclusion of persons; and promote the concept of sustainable development (art.14); (l) any benefits of scientific research need to be shared among the individuals of the international community without any discrimination (art15); (m) the protection of future generations need to be borne in mind always in the advancement of any scientific and technological developments (art.16); (n) the protection of environment, biosphere and biodiversity need to be augmented (art.17).

Part three deals with the application of the Principles concerning decision-making and addresses the of bioethical issues (art18); (b) the significance of the establishment of the ethical committees and their role in promoting the advancement of such scientific development and the need for education of bioethics (art19); (c) and deals with the issue of risk assessment and management (art.20); (d) transnational practices and the responsibility of the states parties to regulate such research agreements with in the sphere of the human rights and ethical practices(art.21).

Part four deals with the responsibility of the states parties(art.22); and the UNESCO(art.25); in promoting the declaration through bioethics education, training and information (art.23); and highlights the need for international cooperation in achieving the objects of the declaration (art.24).

Part five is the final provisions deals with the interrelation and complementarity of the principles relevant to all circumstances (art.26); the application of the principles

of the declaration may be limited by law on the grounds such as public safety, for the investigation and prosecution of investigations of criminal offences, and protection of the rights of others. However, such laws need to be in conformity with the principles of international human rights law. (art.27); and no state or any group of persons or any organization should interpret the provisions in any manner that are inconsistent with the provisions stated therein and no derogation is permissible. (art. 28).

Apart from the declaration, the UNESCO has adopted a resolution requesting all the states parties to take all the necessary steps to promote the Declaration and to see that the principles stated there in need to be widely disseminated across the globe.

Ethical, Legal and Social Implications (ELSI) of the Human Genome

Taking into consideration of the claims and counter claims in the advancement of human cloning by the scientific world, the Director General of the World Health Organization (WHO) in 2002 December, asked the Advisory Committee on Health Research (ACHR) to prepare a report examining the implications of advances in genomics and other critical areas of biotechnology. Recognizing the important role played by ethical, legal and social issues raised by developments in human genomics, the Committee prepared an exhaust report titled as "Genomics and World Health" and prepared a set of recommendations to be adopted by member states of WHO with respect to projects concerning human genomics.¹² The Important recommendations are as follows:

- Member States should develop ethical frameworks to guide the conduct of human genomic research taking into consideration of the international and national legal aspects, especially that of the social, cultural, economic, and, religious aspects.
- Member states should coordinate with each other in human genomic research and should transfer and share the knowledge with each other.
- Member states need to establish regulatory mechanism to monitor and control the commercial and medical application of genomic research activities to prevent possible threat to public environment.
- Member States are requested to come forward to encourage collaborate approaches in developing human genomics in order to enrich the potential of all the states to prevent misuses in the field.
- WHO has been asked to play a vital role to assist the member states in their ethical policy frameworks in this area by imparting training in bioethics.

12. see www.who/human-genome/ELSI, visited on 27.7.2007.

These recommendations have been incorporated by the Human Genetics Programme (HGP) of the WHO. The HGN is also taking into consideration of the ELSI after a considerable debate and discussion with experts identified four priority areas where in research need to be progressed and permitted. They are Genetic Testing and screening; Genetic Patents; Data Banks and Pharmacogenomics.¹³ The HGN is working in cooperation with partners towards socially just and equitable health solutions and outcomes. Working through its ELSI programme, the HGN aims to achieve the following aspects.

- ❖ Promote just and equitable affordable access to genetic tests, diagnostics and other technologies.
- ❖ Promote the development and safe applications of new technology in vulnerable groups, especially to women, children and disadvantaged groups.
- ❖ Try to reduce health risks in new technological fields, especially in the four identified priority areas.
- ❖ To empower vulnerable people through propagation in the fields of human genomics, health research. Further it is the responsibility of the HGP to oversee that research products are accessible in an affordable manner.
- ❖ To develop tools for genomics capacity building including educational modules and mechanisms for accessing bioinformatics, especially in the developing world.
- ❖ To regulate genomics abased technologies and genetic service delivery to promote health through ethical regulation of the research in the area of human genomics.

Conclusion

No doubt, with the revolutionary progress made in the fields of biotechnology and gene therapy man has marched nearer to the nature to reveal its mysteries. Yet we have to remember that we know little bit about the evolution of man. May be in the longer run the genomic research may offer considerable possibilities for the improvement in health sector. At the same time, it is yet to fully explore all the aspects with respect to the controversies that are surrounded with human genomics research. Even if one assumes that the researchers may find all the technical information to answer the plaguing issues surrounded with genomics, there is every possibility for its potential misuse by researchers, private enterprises, insurers etc. The best solution is that if the researchers could able to answer all the potential problems of genomics, therapeutic cloning may be permitted with the permissible

13. For details see the WHO's comprehensive report on *Genomics and World Health 2002*. available at the Web site of the WHO.

limits of the ethical, social and legal concerns. At any cost, human cloning has to be banned. Whatever we may achieve with the help of science and technology, we may not be able to create a super human being that cent percent matches with that of the qualities of a natural human being. Human dignity, equality and mutual respect for men cannot be degraded by scientific creations. The strides cannot take precedence against human well being. Human cloning as already banned by some of the countries, (like USA, India, etc.) all the states of the international community should come forward to introduce deterrent laws for any invention that leads to degrade the human rights of the human beings.

Even in therapeutic cloning, nation-states, researchers, scientists all over the world should have a focused approach to reach the right path that matches with the moral, ethical, social and legal standards according to the needs of the particular societies. Further, before introducing therapeutic cloning, the nation-states should take steps to educate the people about the advantages and disadvantages of such health prescriptions. Further more, all the scientists should always bear in mind that as a cultural aspect of human rights, science and technology should serve the socio economic, legal and moral necessities of the society (be that international or national) but should not try to over ride the ethical and legal considerations. If any attempt is made in that direction, as the popular saying of the Hindu philosophy that rapid growth in any field will only result in for its own destruction than constructive purposes will be applicable to research in human genomics too. Hence in the best interest of preserving the dignity of mankind any such attempts need to be stopped.