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FROM THE PRINCIPAL'S DESK

In the last five years, *The Law Review* has acted as an academic platform for students to enable them to explore the labyrinthine maze of law and to contribute to the vast body of knowledge in their own small way. The fourth edition of *The Law Review* was sent to all the Hon'ble Judges of the Supreme Court and the Bombay High Court, all reputed law firms of Mumbai, law schools all over India and was appreciated greatly.

This year, the Law Review Committee had organised an orientation program for its prospective student authors and newly inducted committee members to enable them to develop their legal research and writing skills. The program dealt exhaustively with aspects right from choosing the topic of the article and researching on it, to specifications and minute details that must be adhered to while publishing it.

In the year 2006, the Law Review Committee received nearly twenty-five abstracts, of which eight articles have been chosen for publication on the basis of their content, relevance and coherence in the style of writing. Apart from the student editors, the committee ensured that every article was also edited by experts in the area of law dealt with by the article. With this intention, the Committee identified eminent practitioners of the legal arena, who undertook the tedious task of editing the articles.

The present edition of *The Law Review* carries a rich blend of a variety of legal topics. The articles, present not only an analysis of existing legislations and a detailed insight into the impact of proposed legislations on the existing law, but also submit detailed academic discussions on questions of law that have intrigued lawyers and academicians alike.

Over the years, the Government Law College has been fortunate to have received unconditional and wholehearted support in all its endeavours from judges and lawyers, amongst others. I thank the Editor-in-Chief, Mr. Justice YV Chandrachud, former Chief Justice of India, as well as the members of the Editorial Board, whose invaluable inputs have made a qualitative contribution to *The Law Review*. This publication would have not been possible without the generous financial support of some of the most prominent law firms of the country and I thank the contributors for the same.

It is indeed heartening to see that with every passing year, *The Law Review* has evolved into a fostering ground not only for the student authors but also for its readers. I sincerely hope that in the years to come, *The Law Review* not only achieves but also sustains its vision to contribute to the development of law and to initiate legal debate and reform.



Mrs. P. R. Rao
Principal, Government Law College

FOREWORD

It is with a great sense of pleasure that I pen these few words of editorial message. Any reader who has time and interest in perusing the performance of young and budding scholars will be struck by the depth and diversity of views expressed in these Articles. For example:

1. In the Article on “A Brave New World: Ethical And Legal Implications of Genomics And Genetic Research”, the author says:
“The mapping of the human genome is an astounding scientific leap. Being the basic genetic material of an organism, a genome holds many secrets that scientists are now unraveling.”
2. In “2(c) Or Not 2(c): Redefining Minorities Under The Indian Constitution”, the author says:
“In a democracy of myriad people, our Constitution has provided various rights, liabilities and safeguards both to individuals and to groups in an attempt to harmonise this diversity of our country with peace, progress, prosperity and other like concepts.”
3. In “Convergence And Competition : Reconciling Differences”, the author says:
“Rigid classifications of voice in radio, text in newspapers, data in microchips and images in video no longer exist. With the emergence of new technologies, such classifications are mere relics, rapidly giving way to digital highways where media and technologies congregate.”
4. In “Corporate- University Tie –Ups – Should India Go The Bay-Dole Way?”, the author says:
“India finally met its international patent obligations in 2006 and is at the threshold of the trans-national intellectual property arena. Legal developments in this field will chart the course that India takes, and with business and trade at an all time high (in India), it would not be hyperbolic to expect an intellectual property explosion over the next decade.”
5. In “Clinical Trials In India”, the author says:
“The past few years have witnessed an incredible rise in outsourcing of clinical trials from the developed countries to the developing countries by multinational pharmaceutical companies.”

6. In “Gender Wars: An Identity Crisis”, the author says :

“The object of the article is to highlight the legal hassles faced by transsexuals and the subsequent need for legislations that would safeguard their basic rights. It is imperative that the law recognizes the gender assertions they have made through seeking reassignment.”

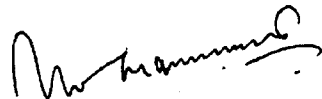
7. In “Liability For Copyright Infringement On The Internet”, the author says:

“The pervasive intrusion of the internet in our routine lives, easy and free access to copyrighted software, files and music and the evolution of advanced concepts like peer-to-peer file sharing and masked IP addresses, have made the protection from copyright violation a joke.”

8. In “Tap, Tap, Who’s Listening? Prying Into Privacy?”, the author says:

“The debate on the validity of the State to intrude in the realm of private life of citizens to prevent and preempt crime has assumed even greater significance in view of atrocities committed by way of terrorism.”

These are but a brief indication of the creativeness of the writers of these illustrious articles, their craving desire for originality and their deep study of the subject under consideration. I strongly and, albeit, objectively commend that the discerning reader may find time to enter into a new vista of this juristic canvas by careful perusal of these Articles, in the writing of which the authors have evidently burnt midnight oil. It will be difficult to make a comparative assessment of the articles on their merits. Each article has a merit of its own. I therefore recommend that the articles should be published in alphabetical order, according to the names of the writers.



Mr. Justice Y. V. Chandrachud
Former Chief Justice of India

GENOMICS—A BRAVE NEW WORLD†

*Aakanksha Joshi**

‘It’s a history book—a narrative of the journey of our species through time. It’s a shop manual, with an incredibly detailed blueprint for building every human cell. And it’s a transformative textbook of medicine, with insights that will give health care providers immense new powers to treat, prevent and cure disease.’

Francis Collins¹

I. INTRODUCTION

The mapping of the human genome² is an astounding scientific leap. Being the basic genetic material of an organism, a genome holds many secrets that scientists are now unravelling. The Human Genome Project (HGP), a collaborative effort between scientists from across the world, was initiated in the mid 1980s as an effort to characterise the human genome, culminating in a complete DNA sequence. The chief aims of the HGP at the time of its inception were creating and developing genetic maps and determining the complete human DNA sequence.³ Although the HGP succeeded in its primary objectives of decoding the DNA sequence of the entire human genome in 2003, many challenges still remain. These include refining the sequence information and identifying

† This article reflects the position of law as on 5 March 2006.

* The author is a student of Government Law College, Mumbai and is presently studying in the Second Year of the Three Year Law Course. She can be contacted at aakankshajoshi@gmail.com.

¹ The Director of the National Human Genome Research Institute noting that the genome could be thought of in terms of a book with multiple uses upon the publication of the majority of the genome in February 2001. ‘What was the Human Genome Project?’, *National Human Genome Research Institute*, available at <http://www.genome.gov/12011238> (last visited 5 March 2006).

² The genome of an organism is the whole hereditary information of an organism that is encoded in the DNA.

³ Dennis L Kasper et al, *Harrison’s Principles of Internal Medicine* (16th edn Macgraw-Hill New York 2005) 366.

genes that hold significant roles in the development of genetic disorders.⁴ It is believed by many that in discovering all there is to know about the human genome, it would be possible to create a panacea for all ills. A significant expansion in the global pool of scientific and medical knowledge has been achieved by successfully decoding the human genome, and genomics is expected to revolutionise health care.⁵

The advantages of genomics are manifold. It has made pre-diagnosis of latent illnesses possible. The HGP was initiated with the hope that the identification of disease causing genes would lead to progress in diagnosis, prognosis and treatment.⁶ The efficacy of treatment vis-à-vis a person's genetic predisposition can also be evaluated. In the future excision of malfunctioning genes may be achieved.

However, this science has not been without its detractors. Serious ethical and legal concerns need to be addressed so that the development of genetic research proceeds in the right direction. Issues such as privacy of genetic information, consent of participants of research, discrimination, commercialisation of research as well as ethical use of this technology are of grave significance. A suitable regulatory framework must be in place to adequately mitigate if not completely eliminate these concerns.

This article seeks to explore the scope of the science, as well as examine and address the concerns pertaining to it. It is imperative that there is an emphasis on the value of human life while formulating the necessary regulatory framework for genomics. Human value must weave through a sound ethical analysis of life science research.⁷

II. ETHICAL CONCERNS

Genetic research has already contributed greatly to the development of medicine and health care. Identification of genetic variations 'shared

⁴ *Ibid*, 367.

⁵ Remigius N Nwabueze, 'What can Genomics and Health Biotechnology Do for Developing Countries?' (2005) 15 *Albany Law Journal of Science and Technology* 369, 370.

⁶ Kasper et al, *supra* n. 3, 367.

⁷ Gerard Magill, 'The Ethics Weave in Human Genomics, Embryonic Stem Cell Research and Therapeutic Cloning: Promoting and Protecting Society's Interest' (2002) 65 *Albany Law Review* 701.

among individuals, families and forbears' has 'the potential to disrupt disease taxonomies, dissolve fixed notions of the family, race and ethnicity, and enable new medical and pharmaceutical treatments for illness'.⁸ That a complete understanding of the human gene would aid in better diagnosis, treatment and prevention of disease is indubitable. Genomic research today is aimed towards understanding the structure of the mapped gene and the function of its various components. The detection of genetic predispositions towards certain diseases would greatly aid in treating them. It would be possible to determine the effects of medication on people depending upon their genetic information. As stated by RD Lele, '[G]enetic variations also effect drug absorption, distribution, metabolism and excretion.'⁹ Ascertaining that people possessing certain genes are susceptible to particular diseases, leaves open the prospect of modifying the gene so as to eliminate the risk of contracting the disease. The decoding of the human genome may have repercussions on social sciences such as anthropology by shedding light on concepts such as ethnicity and race. It may influence behavioural psychology by identifying the genetic reasons influencing a person's behaviour.

However, there are many serious ethical and legal concerns due to the unpredictable course the science may take. As stated by Derek Morgan, 'As it is for society, so it is for individual; the consequences of knowing so much about oneself, about others and about all humans are unforeseeable.'¹⁰ Nevertheless, in spite of the fears relating to the potential dangers, moves towards restricting genetic research have not met with much success. In 2001, the European Parliament rejected a report drafted by one of its committees that recommended more stringent restrictions on genetics and biotechnology.¹¹

⁸ Robin Mackenzie, 'Reprogenetics and Pharmacogenetics: In Whose Best Interests?' (2005) 24 *Medicine and Law* 343.

⁹ RD Lele, 'The Human Genome Project: Its Implications in Clinical Medicine' (2003) 51 *JAPI* 373.

¹⁰ Derek Morgan, *Issues in Medical Law and Ethics* (1st edn Cavendish Publishing Limited UK 2001) 156.

¹¹ Quirin Schiermeier, 'European Parliament Rejects Move to Restrict Genetics' (2001) 414 *Nature* 572.

In order to address the mounting concerns arising out of the developments—in the field of genomics, in 1993 the Director General of UNESCO was asked by the General Conference to draft an international instrument. Pursuant to this, the Universal Declaration of the Human Genome and Human Rights (Declaration) was drafted by the Legal Commission headed by Mr Héctor Gros Espiell and adopted by the General Conference of UNESCO ‘unanimously and by acclamation’,¹² on 11 November 1997. The resolution was then accorded assent by the General Assembly of the United Nations in the following year. Guidelines were laid down by UNESCO in 1999 to facilitate implementation of the Declaration.

The Declaration seeks to balance fundamental freedoms and human rights with freedom of research, which it recognises as a ‘part of freedom of thought’ as stated in article 12(b) of the Declaration. The basic rights of the human subjects of genetic research are enumerated,¹³ confidentiality of genetic information is sought to be protected and genetic discrimination and practices contrary to human dignity, including cloning, have been expressly prohibited.

¹² ‘The Universal Declaration on the Human Genome and Human Rights’ (1997) [portal.unesco.org](http://portal.unesco.org/shs/en/ev.php?URL_ID=1881&URL_DO=DO_TOPIC&URL_SECTION=201.html), at http://portal.unesco.org/shs/en/ev.php?URL_ID=1881&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited 5 March 2006).

¹³ Article 5 of the *Universal Declaration on the Human Genome and Human Rights*, 1997 states:

- (a) Research, treatment or diagnosis affecting an individual’s genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.
- (b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person’s best interest.
- (c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.
- (d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.
- (e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual’s human rights.’

At the 32nd General Conference of UNESCO held on 16 October 2003 the International Declaration on Human Genetic Data was adopted. The instrument aims to address the fear many people hold, that human genetic data will be used for purposes contrary to human rights and freedom.¹⁴ It contains provisions in respect of informed consent and sets out that the collection, storage and use of human genetic data must be in such a manner, so as to protect privacy.

In India, the National Bioethics Committee (NBC) was constituted with the approval of the Minister of Science and Transport, Government of India in 1999 to formulate policies for human genetic research and services, in consonance with the Declaration. The policies and were framed to be in consonance with the 'Ethical Guidelines for Biomedical Research on Human Subjects, 2000' developed by the Indian Council of Medical Research. They have been laid down in 'Ethical Policies on the Human Genome, Genetic Research & Services',¹⁵ and provide guidance to researchers, institutions, ethics committees and the public on the conduct of genetic research on ethical principles.

The Indian policies were framed in 2000 and no amendment has been made consequent to the mapping of the entire human genome in 2003 and the formulation of the International Declaration of Human Genetic Data. These policies need to be reviewed as ethical issues relating to confidentiality, consent and genetic discrimination have gained momentum since then. An adequate regulatory mechanism is urgently needed to tackle these issues. In addition, the employment of this new technology in the administration of criminal justice would need to be addressed due to the ethical and legal concerns this entails. These issues are discussed below with reference to existing regulatory framework in foreign countries, the potential dangers and the best possible way that they may be tackled.

¹⁴ *Supra* n. 12.

¹⁵ 'Ethical Policies on the Human Genome, Genetic Research & Services' www.dbtindia.nic.in, available at <http://www.dbtindia.nic.in/policy/polimain.html> (last visited 5 March 2006).

III. OWNERSHIP AND PRIVACY

Genomics may raise serious concerns about the privacy of genetic information. Genetic research may cause 'intrusion into three forms of individual privacy: bodily privacy in cases where the sample is taken from a person's body; genetic privacy, where predictive health and other information about the person is obtained from the sample; and behavioural privacy where the information is used to determine where a person has been and what he has done.'¹⁶

The misuse of genetic data would gravely compromise an individual's right to privacy. In India, the right to privacy flows from the right to life, and is, therefore, considered a fundamental right, as held in *People's Union for Civil Liberties (PUCL) v. Union of India*,¹⁷ by the Supreme Court. However, for the sake of public interest, jealously guarding the confidentiality of such vital information may prove detrimental and hamper scientific progress.

The concept of 'genetic privacy has two dimensions: protection from the intrusions of others and protection from one's own, hitherto unknown, secrets.'¹⁸

A. Ownership Of Genetic Information

The basic question that underlies the issue of privacy and consent is who owns genetic information. Ownership comprises a bundle of rights a person has over certain subject matter including possession, the right of use and enjoyment and the right of consumption, destruction and alienation. It is a right *in rem* and it is not necessary that the owner exercise or hold all these rights.¹⁹

The Supreme Court of California in the United States dealt with the question of the ownership of human body parts in the case of *John Moore*

¹⁶ Justice RK Abichandani, 'The Gene Age - A Legal Perspective' [2003] *High Court of Gujarat*, available at <http://gujarathighcourt.nic.in/Articles/legalpers.htm> (last visited 5 March 2006).

¹⁷ (1997) 1 SCC 301.

¹⁸ Morgan *supra* n. 10, 103.

¹⁹ PJ Fitzgerald, *Salmond on Jurisprudence* (12th edn Sweet and Maxwell London 1966) 246-247.

v. *Regents University of California*.²⁰ In this case, Moore, who had hairy cell leukaemia, consented to a splenectomy and for this purpose permitted samples of his blood, skin and bone marrow to be taken. These samples were then employed in research and were used to develop a cell-line that proved to be commercially successful. Moore contended that he had the right to the direct use of his own cells and that he was entitled to any profits made therefrom. The Supreme Court, rejecting this contention, held that he retained no right in respect of the cells removed from his body. However, it laid down that the doctrine of informed consent applied to such cases and that there was a fiduciary duty to disclose all relevant information to the patient.

B. Privacy

1. Genetic Information And Individualism

Genetic Information is unique to every individual; however, genetic traits are shared by groups having familial ties or larger groups belonging to the same ethnicity.²¹ Janet L Dolgin while examining the concept of individualism and genetic grouping states, 'Genetic groups (such as the genetic family) represent a peculiar involution of individualism. They displace the interests of the individual in favour of the interests of the whole, while defining the whole through the metaphor of the individual.'²² There is a conflict between the right to privacy of the individual over his or her genetic information and the potential advantages that might be available to others.

The question that then may arise is whether a person may be compelled to donate any of his own human tissue for a linkage test, ie a test to determine the extent to which individuals may be genetically, related, to be performed on a relative²³ or whether a person other than the donor

²⁰ 793 P 2d 479 (1990).

²¹ Janet L Dolgin, 'The Evolution of the "Patient": Shifts in Attitude about Consent, Genetic Information, and Commercialisation in Health Care' (2005) 34 *Hofstra Law Review* 137, 166.

²² *Ibid*, 174.

²³ Morgan *supra* n. 10, 102.

can have the right to access information gathered from the donor's genetic data.

In *Safer v. Estate of Pack*,²⁴ a woman initiated proceedings against the physician who had treated her father during his illness and who had failed to inform her about the risk to her own health. The New Jersey Appellate Court found for the Plaintiff and stated that there was a duty to issue a warning about genetic predispositions to health risks.

This would imply that in some situations a physician would be duty bound to inform third parties of certain genetic information. In India, the issue of the duty of disclosure by a physician of information to a third party was dealt with in *Mr X v. Hospital Z*,²⁵ wherein the Appellant contended that his right to privacy was violated when his fiancée was apprised of the fact that his blood sample had tested HIV positive. The Supreme Court held that the right to privacy is not an absolute right and that it could be restricted for prevention of crime, disorder or protection of health or morals or protection of rights and freedom of others. However, it is unclear how far such duty is to be extended and to what degree genetic privacy may be compromised.

The policy that may be followed in such cases is to encourage the patient to disclose such information. If such encouragement is to no avail, discretion may be exercised, dependant on certain conditions, to make third parties belonging to the same genetic group privy to genetic information where serious harm is likely to occur.

2. Misuse of Genetic Information and Statutory Protection

Due to the mapping of the human genome, it may soon be possible to foretell and prevent diseases. According to Derek Morgan:

‘This also gives rise to questions as to how this information is should be used, and the necessary background laws and norms that will either be applied or will become more clearly perceived

²⁴ 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996).

²⁵ (1998) 8 SCC 296.

to direct and control, to regulate the use of this information, either by individuals or societies generally.²⁶

In Australia, the *Privacy Act, 1988* (Privacy Act) has comprehensive provisions regarding the protection of the privacy of individuals. The Privacy Act provides information relating to privacy principles ie principles that govern the privacy of information, in relation to collection, solicitation, storage, recording and access to personal information.²⁷ It contains detailed provisions about personal information and what constitutes an interference with the privacy of such information. The provisions regarding sensitive information²⁸ are more stringent. Genetic information may be protected under the Privacy Act as it may fall under the purview of sensitive information. In addition, guidelines for protection of information collected during medical research have been issued by the Australian National Health and Medical Research Council (NHMRC).

In the United States, the approaches taken by different States regarding how genetic information is treated differ. The protection afforded to genetic information in some States is property based ie consent is necessary for its use and punitive damages are payable and criminal sanction may be faced for violating privacy. In others, it is liability based ie where on contravention of any obligation to maintain privacy, damages are payable.

²⁶ Morgan *supra* n. 10, 160.

²⁷ The *Privacy Act, 1988* defines personal information as ‘information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.’

²⁸ The *Privacy Act, 1988* defines sensitive information as:

- ‘(a) information or an opinion about an individual’s:
- (i) racial or ethnic origin; or
 - (ii) political opinions; or
 - (iii) membership of a political association; or
 - (iv) religious beliefs or affiliations; or
 - (v) philosophical beliefs; or
 - (vi) membership of a professional or trade association; or
 - (vii) membership of a trade union; or
 - (viii) sexual preferences or practices; or
 - (ix) criminal record;
- that is also personal information; or
- (b) health information about an individual.’

In some States; the right may be enforced by private action and in other States; means for public enforcement are provided.²⁹

In India, the ethical policies laid down by the NBC state that 'Identifiable information (clinical, genetic, etc) of individuals or groups is confidential and should be protected.' There is no legislative protection that has been afforded to genetic information in India. In the author's view, it is imperative that this be remedied to counter the possible misuse of genetic information.

C. Biobanks

Genetic information may be stored in Biobanks, organisations that accumulate human tissue samples and genetic information for research and therapeutic purposes. Biobanks have been set up by researchers, universities and corporations in foreign countries. The UK Biobank seeks to study the impact of lifestyle, environment and genes on the health of people from all around the UK.³⁰ Biobanks contain genetic databases that may prove of great value for the purpose of research. Therefore, the questions that then arise are when a person consents to having his or her genetic information collected for therapeutic purposes, can that information then be used as a part of research for other purposes? Further, if a person consents to having his genetic information used for research, could the information be provided to third parties? As per the ethical policies formulated by the NBC, such secondary use of information cannot be made without prior consent of the participant.³¹

²⁹ Edward J Janger, 'Genetic Information, Privacy and Insolvency' (2005) 33 *Journal of Law, Medicine and Ethics* 79, 81.

³⁰ 'UK Biobank: Improving the Health of Future Generations', available at <http://www.ukbiobank.ac.uk/> (last visited 1 July 2006).

³¹ The policies state: 'Consent is valid only for the research for which it is given by the participant (primary use). If the information or samples for primary use are to be used for other purposes or for sharing with other investigators (secondary use), clear mention of such secondary uses must be made during the process of obtaining informed consent. New consent must be taken for any use for which consent was not explicitly obtained. However, this will not be required if the sample is used as an "Unidentified" or "Unlinked" sample.'

In light of the upheavals in the corporate world caused by mergers and acquisitions, the protection available to data in a corporate biobank is unclear. In the author's view, if the relationship between the donor of genetic information and the biobank is treated as purely contractual, then the protection of the data may not be adequate. However, if the donor is treated as the owner of the information, the protection afforded is stronger.³² In India, any unauthorised use of genetic information is prohibited as per the ethical policies of the NBC. In view of these policies, the protection afforded would be property based and therefore, not put to any use contrary to the donor's wishes.

IV. CONSENT

The doctrine of informed consent is that the donor of any genetic material used for genetic or genomic research or any therapeutic purpose must give consent³³ to the procedure after being fully apprised of all relevant facts regarding the method of collection of the information and the end use of such data. When informed consent is sought, the distinction between medical therapy and medical research is clearly drawn and both the donor and the researcher comprehend the purpose for which the genetic material is collected.

However, there are certain concerns for which there are no clear answers. One is whether a person can be a party to the financial benefits that may accrue by the use of his or her genetic information in research. Another is the issue of volition. There arise situations where a person may consent to the collection of his genetic information for research purposes, as it may be the only way that he may be able to receive medical treatment.³⁴ Establishment of contact by the researcher with the donor and communicating the results of the research and the implications of such research is also an ambiguous area.

³² Janger *supra* n. 29, 82.

³³ As per the International Declaration on Human Genetic Data, 'Consent: Any freely given specific, informed and express agreement of an individual to his or her genetic data being collected, processed, used and stored.'

³⁴ Ellen Wright Clayton, 'Informed Consent and Biobanks' (2005) 33 (1) *Journal of Law, Medicine and Ethics* 15, 19.

A. *The Doctrine Of Informed Consent*

The doctrine of informed consent was developed in research settings 'in express response to the revelation of abuses of human subjects by researchers. The deliberation that followed led to the construction of the informed consent doctrine and to the institutionalisation of "bioethics" as an area of study and practice.'³⁵

The ethical principles laid down by the Nuremberg Court while trying Nazi doctors and researchers, who had conducted horrific research on human subjects during the Second World War, established concepts such as consent to participate in research and avoiding harm to human research subjects.³⁶ The concepts are elucidated in the Nuremberg Code,³⁷ the first principle of which states:

'The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.'

The concept of informed consent is now accepted as a part of medical treatment and research.

In the United States, the Common Rule of the Food and Drug Administration contains provisions relating to informed consent, which are applicable to the recipient of federal research funds. There is, however, a qualification and the Common Rule would not be applicable to research where the subjects of research cannot be identified and it specifies circumstances where the requirement of informed consent may be waived.

³⁵ Dolgin *supra* n. 21, 146.

³⁶ Dolgin *supra* n. 21, 147.

³⁷ Available at <http://ohsr.od.nih.gov/guidelines/nuremberg.html> (last visited 5 March 2006).

Apart from this, many States have enacted laws in which the doctrine of informed consent has been included.

The ethical policies of the NBC contain detailed provisions regarding consent. No use of genetic material may be made without the consent of the donor. Any new use of genetic material already collected also requires the donor's consent. The policies recognise the fact that group consent would be necessary where the research pertains to a certain ethnic group. However, consent is not contemplated for unidentified samples of genetic data. This would make it impossible for the unidentified donor to share in the commercial gains that may arise from significant developments in research to which his genetic sample may have made an important contribution.

The lack of the requirement of informed consent in legislation in India is a grave cause of concern. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2000 provide for obtaining of consent only at the time prior to an operation. There are no provisions relating to obtaining consent for use of genetic data collected through biological samples for the purpose of research.

B. Concerns Relating To Informed Consent

The effectiveness of this doctrine in India leaves a lot to be desired. Donors are, at times compelled to waive this requirement in exchange for monetary benefit or to avail of medical care. In most cases, consent is acquired by keeping the donors in the dark regarding the details of the research and its purpose. Exploitation of the poor by unprincipled researchers is quite possible and they could be subjected to substantially harmful experimentation. There should be strict prohibitions on such unscrupulous practices. Article 8 of the International Declaration on Human Genetic Data expressly states that 'Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples.' This principle should be integrated into the regulatory framework applicable to any medical research.

On the whole it seems that property based protection has been offered to genetic information. However, it is cautioned that, 'A strict property regime, limiting any use of information without consent, might deprive society of important benefits.'³⁸ In *Govind v. State of Madhya Pradesh and another*,³⁹ the Supreme Court stated, 'Assuming that the fundamental rights explicitly guaranteed to a citizen have penumbral zones and that the right to privacy itself is a fundamental right, that fundamental right must be subject to restriction on the basis of compelling public interest.'

Too many restrictions on the flow of genetic information may hinder research that may be significant to public interest. A policy that may be applied in such cases is that transfer of genetic information may be made only to organisations specified by the government engaged in medical research beneficial to public interest. For transfer of genetic information to any person, institution or organisation other than those specified by the government in this behalf, the donor's express informed consent should be required. The organisations specified by the government must be bound by stringent rules that would ensure that genetic data is used in an ethical manner.

C. *Re-contact*

Communication of the results of research by the researchers to their human subjects is also a problematic issue. Unexpected and unwanted re-contact by researchers should not be permitted unless during the process of obtaining the informed consent, the donor of genetic material is intimated that he may receive such communication.⁴⁰ Even where the donor has given prior consent to receiving communication relating the

³⁸ Janger *supra* n. 29, 84.

³⁹ AIR 1975 SC 1378.

⁴⁰ Article 10 of the International Declaration of Human Genetic Data states: 'When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results.'

results of the research, re-contact may be undesirable if their implications are ambiguous. Contact by researchers may be initiated only if the results are scientifically validated, the results hold significance for the donor's health and the necessary treatment for the donor's illness is available.⁴¹ Where the research results may have significant implications for persons other than the donor who are genetically linked to the donor, the question of whether the researchers may contact them to disclose such results is uncertain. On applying the principle enunciated in *Safer v. Estate of Pack*,⁴² one may argue that the researcher may be bound by such duty.

V. DISCRIMINATION

Every individual's genome is unique. In that sense, it is the very basis for individuality. The information contained within a genome relates to the distinctive traits of the person to whom the genome belongs. The genome also contains information relating to a person's genetic history. Those sharing the same genetic history share common characteristics. The identification of traits held in common by a particular genetic group may result in discrimination. On a societal level, this may create or fortify prejudices against certain genetic groups. This would have an implication on criminal justice as genetic profiling may be targeted at certain communities.⁴³ A more immediate concern is that of genetic discrimination by insurance companies and potential employers.

A. *Breeding Prejudice*

Most countries around the world are trying to escape their pasts in which atrocities were committed against certain ethnic groups based on racial and ethnic prejudices. History is rife with stories of ethnic cleansing and unfortunately, we hear of such things even today. Hitler's pogrom against

⁴¹ Clayton *supra* n. 34, 20.

⁴² 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996).

⁴³ The Pardi community of Maharashtra are often identified as perpetrators of certain crimes. For a discussion on the modus operandi and the nature of crimes undertaken by this community, see Seetarami Reddy, 'Pardhi Gangs of Ganga Khed, Parbhani Districts of Maharashtra State', at <http://www.cidap.gov.in/documents/Pardhis.pdf> (last visited 5 March 2006).

the Jews was based on the unsubstantiated belief that the Jews belonged to an inferior race and that only the Aryans had the right to exist. Such actions are almost uniformly condemned in today's world, since it is not possible or ethically desirable to determine the superiority or inferiority of any single race.

However, this may be achieved by genomics. What if people are presented with scientific data that proves that certain genetic groups are more prone to violence or that people belonging to a particular ethnicity are more likely to lie? The rational aura that science possesses would tend to make such information more credible. This in turn would reinforce prejudices or create new ones that people may feel justified in holding, as they are founded on science. Based on such prejudices, certain groups may face a great deal of discrimination. People may be less likely to champion the cause of a race that has been proved to be genetically undesirable and prefer the marginalisation or elimination of such race. The implications of this on human rights and morality will be far reaching.

B. The Immediate Concerns

It is now possible to ascertain a person's susceptibility to certain diseases and the treatments to which he may respond. However, the fallout would be the misuse of such information by insurers. For example, if by access to genetic information an insurance company discovers that a person is predisposed towards developing a certain disease, it may refuse to insure that person due to the risk involved. This would make it difficult for that person to receive any medical treatment for his ailment because he or she does not have any health insurance. This might in turn hamper genetic research. People may not agree to participate in research for the fear that their genetic information may be provided to an insurance company and that would be against their interests in making it difficult for them to get insurance coverage.⁴⁴ Genetic discrimination may also come into play during the employment process. Applicants may be rejected based on

⁴⁴ 'Genetic Discrimination in Health Insurance', National Human Genome Research Institute, available at <http://www.genome.gov/10002328> (last visited 5 March 2006).

their genetic makeup. This too would make a person hesitate before participating in genetic research.

These concerns have proved to be well founded. In the United States, numerous reports in the news media and from expert groups have already uncovered instances where people were denied health insurance or coverage for particular conditions based on genetic information.⁴⁵

C. Regulatory Protection

The repercussions of genetic discrimination have received some attention in a few countries across the world. In the United States, the *Health Insurance Portability and Accountability Act, 1996*, (HIPAA) first tackled the problem of use of genetic information by insurance companies. The provisions of the HIPAA prohibit the exclusion of persons from insurance coverage as a result of past or present medical problems, including genetic predisposition to certain diseases. The HIPAA, however, does not address the problem of insurers charging higher rates of premium from the insured based on higher risks to their health. A number of bills have since been introduced in the Congress regarding these issues. Forty-one States have passed legislation regarding genetic discrimination in relation to health insurance.⁴⁶

In the United Kingdom, the Government established a Genetics and Insurance Committee in 1999 for the supervision of the use of genetic information by the life insurance sector.⁴⁷ Since 1 November 2001, insurers have observed a five-year moratorium on the use of genetic test results.⁴⁸ The coverage of the moratorium is conditional upon the value of the insurance coverage. It covers all types of insurance policies, the sum insured of which is £300,000 or less. However, life insurance for which the ceiling limit is £500,000 is not covered. Apart from this, genetic tests

⁴⁵ *Ibid.*

⁴⁶ *Supra* n. 44.

⁴⁷ Morgan *supra* n. 10, 181.

⁴⁸ Jane Burgmeister, 'Switzerland Has Opened Door to Genetic Discrimination, Say Ethicists' (2004) *bmj.com*, at <http://bmj.bmjournals.com/cgi/content/full/329/7457/70-a> (last visited 5 March 2006).

are only permitted if they are approved by the Genetics and Insurance Committee for setting the premium. After three years of the moratorium, the financial limits may be reviewed.⁴⁹

As far as the issue of employment is concerned, President Bill Clinton passed an Executive Order in the year 2000, prohibiting agencies of the federal government from acquiring genetic information about their employees or job applicants and from using genetic information in hiring and promotion decisions. Since the aforesaid Executive Order, 31 States have enacted laws that relate to discrimination in the workplace.⁵⁰ In February 2005, the Senate passed the *Genetic Information Non-Discrimination Act, 2005*.⁵¹

Under Indian law, these issues are yet to be addressed. Genetic discrimination for health insurance is one area that needs regulation in the lines of the HIPAA, however with the provision that the rate of premium charged for all insured persons would be the same. Similarly, provisions must be introduced in employment laws that prohibit discrimination based on a person's genetic information. The protection afforded under Article 15⁵² and Article 16⁵³ of the Constitution of India should be expanded to include genetic discrimination.

VI. AN UNCERTAIN FUTURE

Mounting concerns regarding the direction that genetic research might take and the impact of mapping the human genome have been receiving a great deal of consideration. The moral validity of the science of genomics

⁴⁹ *Ibid.*

⁵⁰ *Supra* n. 44.

⁵¹ 'Genetic Discrimination', *National Human Genome Research Institute*, available at <http://www.genome.gov/10002077> (last visited 5 March 2006).

⁵² Article 15(1) of the Constitution states, 'The State shall not discriminate against any citizen on grounds only of religion, race, caste, sex, place of birth or any of them.'

⁵³ Article 16 of the Constitution states inter alia,
(1) There shall be equality of opportunity for all citizens in matters relating to employment or appointment to any office under the State.
(2) No citizen shall, on grounds only of religion, race, caste, sex, descent, place of birth, residence or any of them, be ineligible for, or discriminated against in respect of, any employment or office under the State.'

itself has been questioned. It is contended that genomics may be responsible for the erosion of the basic value of human life and thus would be detrimental to human rights. Nora O'Callaghan makes a vociferous argument against the 'serious risk created by an anthropology infected by biological reductionism, driven in no small part by the extraordinarily scientific method, which seeks to break all systems into their smallest parts in order to determine and control their mechanism.'⁵⁴ Due to the strides made in genetic research, comparisons between the genomes of human beings and that of other species have become a part of the research carried out by scientists. Nora O'Callaghan shows concern that such data might be interpreted in a manner endangering the sanctity and dignity of human life. She decries the scientific approach of reducing even human beings to the most basic unit.⁵⁵ We must never lose sight of the fact that a human being is more than a sum of all his parts. Although the science of genomics moves towards reducing an organism to its smallest part, we must preserve the inviolability of human life and human dignity. In light of this, we must make ethical decisions on the manner of utilising this science.

Some of the ethical and legal perspectives of the potential uses of genetic research are discussed in this section of the article.

A. *Scientific Developments*

The probable uses of genetic research have been the subject of many arguments. Issues such as cloning, patenting of human genetic material⁵⁶ and the possibility of eugenics, have drawn attention to the moral and consequently the legal implications of scientific development.

⁵⁴ Nora O'Callaghan, 'Human Origins and Human Rights in the Genome Age' (2005) 3 *Ave Maria Law Review* 123,130–131.

⁵⁵ *Ibid*, 137.

⁵⁶ However in the *Relaxin case*, a method by which a substance named Relaxin, which is a naturally occurring substance used for relaxing the uterus during childbirth, and its DNA sequence could be obtained was an invention and had a use and thus were patentable (1996) 27 *IIC* 704.

1. Disturbing The Social Cycle

The present approach to medicine is curative in nature. With genomics, a preventive approach may be possible. Genomics offers medicine the ability to 'vastly speed up the rate at which important disease-causing genes can be found.'⁵⁷ The likelihood of a person developing a disease may be discovered and the disease would thus be prevented from being contracted.

A probable outcome of this would be the increase in life expectancy. This could have serious repercussions, as the problem of overpopulation would become even more acute. There would be more pressure on the limited resources available. Such a situation would have the potential of creating a great deal of conflict.

2. Cloning

Cloning of animals has already taken place and scientists are now perfecting the technique. Several countries have passed bans on human reproductive cloning.⁵⁸ Many religious groups across the world have denounced cloning⁵⁹ while some sects have encouraged it. The Raelian movement, a sect that was founded in France, established a company known as Cloneaid, which claimed to have produced the world's first cloned baby.⁶⁰ However, the subject of reproductive human cloning has been condemned almost universally. The grey area regarding this issue is that of human therapeutic cloning ie stem cell research. The attitude towards this is not uniform across the world and misuse of such technology is feared. Within the United States itself, the States are divided on this issue. Those supporting stem cell research believe that a strict regulatory

⁵⁷ James Watson, 'Genome Ethics' (2004) 11 (3) *The Nonprofit Quarterly* 64.

⁵⁸ The Universal Declaration on the Human Genome and Human Rights as well as the ethical policies of the NBC in India prohibit human cloning.

⁵⁹ Adrienne N Calhoun Cash, 'Invasion of the Clones: Animal Cloning and the potential implications on the Future of Human Cloning and Cloning Legislation in the United States, the United Kingdom, and internationally' (2005) 82 *University of Detroit Mercy Law Review* 349, 350.

⁶⁰ David Chazan, 'Who are the Raelians?' (2002) *BBC News*, at <http://news.bbc.co.uk/1/hi/health/2610795.stm> (last visited 5 March 2006).

framework can overcome the concerns pertaining to such research by establishing a neutral governmental agency to supervise the regulation of stem cell research.⁶¹

3. Eugenics

The term eugenics originated in 1883 and was first used to refer to the 'science' of heredity and good breeding. It comes from the Greek roots for 'good' and 'generation' or 'origin'.⁶² The concept of eugenics flourished in the United States after the First World War. In Germany, Dr Alfred Ploetz founded the Archives of Race-Theory and Social Biology in 1904 and the German Society of Racial Hygiene in 1905. Thereafter, the interest in eugenics increased. The idea of breeding a super race was the basis for the extermination of the Jews and physically and mentally challenged in Nazi Germany.

The issue relating to eugenics arises due to the new science of rerogenetics. Reprogenetics, the method of ensuring or preventing the inheritance of certain genes in a child by the use of genetic technology, has become an acceptable part of reproductive planning to ensure that a child is born healthy.⁶³ On identification of genes and the constituents of the genome and determining their structure and function, it may be possible to alter them in such a manner that the child may be born with certain desired characteristics. Apart from eliminating the likelihood of diseases, the possibility of designing a child to conform to particular standards arises. The morality of designer babies is questioned. Qualms about a future akin to the dystopian world imagined in Aldous Huxley's famous novel 'A Brave New World' are prevalent. As stated by Nora O'Callaghan, 'If it should happen that they are successful in altering and "enhancing" the human genome of those who can afford this technology, then the biological basis for respecting equality and human rights will be seriously undermined.'⁶⁴

⁶¹ Christopher L Logan, 'To Clone or Not to Clone: Should Missouri Allow Cloning for Biomedical Research?' (2005) 73 *UMKC Law Review*.

⁶² 'Eugenics Movement reaches its height in 1923', at <http://www.pbs.org/wgbh/aso/databank/entries/dh23eu.html> (last visited 5 March 2006).

⁶³ Mackenzie *supra* n. 8, 347.

⁶⁴ O'Callaghan *supra* n. 54, 134.

4. Controlling Genetic Destiny

With the advancement of genetic science, it is possible to detect genetically impaired fetuses. Such knowledge can create a dilemma in the mind of the expecting parents on whether to terminate the pregnancy. There are those who think that if we attempt to control the genetic destiny of children, 'we are following in the dreadful footsteps of the Nazis'.⁶⁵ However, would it be moral to let a child be born into the world with severe genetic defects, knowing full well that he would live a life of acute physical and emotional suffering? Such a child may have legal recourse against the parents who have done nothing to prevent the birth and thereby ensuring its painful existence.

5. Gene Splicing

Other worrying developments include gene splicing. Gene splicing 'involves cutting out part of the DNA in a gene and adding new DNA in its place.'⁶⁶ This process has a therapeutic value since it can be used to repair genes so that 'the new gene will begin functioning correctly, producing the appropriate enzymes for its type.'⁶⁷ However, scientists have been experimenting with splicing animal genes by adding human genes. The ethical difficulties this creates are manifold. Nora O'Callaghan states:

'Given that the human neural cells in the brains of these mice, as well as the liver cells in the sheep, or the human embryos in the mouse womb would apparently each contain within themselves the entire human genome, the foundation of our human dignity according to the United Nations, one could suggest that the real threat presented by these experiments is to our understanding of the basis of human dignity.'⁶⁸

These troubling questions haunt the subject of genetic research and scientific advancement. The manner in which this may be addressed is to allow only the therapeutic use of these technologies.

⁶⁵ *Supra* n. 56, 63.

⁶⁶ 'Gene Splicing', *Gene Therapy Solution*, at <http://www.genesolutions.com/page8.html> (last visited 5 March 2006).

⁶⁷ *Ibid.*

⁶⁸ O'Callaghan *supra* n. 54, 141.

B. *The Administration Of Justice*

*The growth of the study of genetics has given birth to the science of behavioural genetics. Genes do contribute to behavioural and personality traits of an individual. However, it may be cautioned that, 'No single gene determines a particular behaviour. Behaviours are complex traits involving multiple genes that are affected by a variety of other factors.'*⁶⁹ *There are mixed reactions to the understanding of how genetics influences behaviour.*

'For some people, the idea that they might not be entirely at fault for some of their less desirable qualities is liberation, conferring a scientifically backed reprieve from guilt and self-doubt. Others feel doomed by their own DNA, which seems less changeable than the more traditional culprits for personal failings, like a lack of discipline or bad childhoods. And many find it simply depressing to think that their accomplishments might not be the result of their own efforts.'⁷⁰

The development of the science of behavioural genetics gives rise to the question of whether the genetic traits of a person could be a mitigating factor while determining his guilt.

Genetic information is being used as evidence in judicial proceedings in India.⁷¹ In fact, a prisoner is compelled to undergo a medical test as soon as he is incarcerated and a register of his health is required to be maintained.⁷² Genetic material found at a crime scene may also be adduced as evidence.⁷³ If it can be determined that the accused was predisposed to committing a particular act due to his genetic structure, could this be used as a criminal defence?

⁶⁹ 'Behavioural Genetics', *Human Genome Project Information*, [genomics.energy.gov](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/behavior.shtml), at http://www.ornl.gov/sci/techresources/Human_Genome/elsi/behavior.shtml (last visited 5 March 2006).

⁷⁰ Amy Harmon, '“My Genes Made Me Do It,” Say More People', *The New York Times* (articles selected for the Asian Age) (New York USA 24 June 2006).

⁷¹ AIR 2003 SC 3450.

⁷² As per the provisions of the *Prisons Act, 1894*.

⁷³ Although Article 20 of the Constitution of India provides that no man can be compelled to be a witness against himself, using human tissue found at a particular place as evidence would not amount to being a witness since the article only prohibits compelling a person to furnish self incriminating evidence that is in form of a communication.

An approach that may be adopted is that where the accused introduces such a defence, he should also prove that there was a direct link between the action and the genetic disability ie there should be a causal relationship between the two.⁷⁴

However, 'behavioural genetics does not determine who will commit a crime, only that a person has a predilection or increased likelihood of exhibiting antisocial behaviour when combined with multiple other factors like environment and upbringing.'⁷⁵ Although genetic predispositions may be employed as a defence in a criminal proceeding, it would not be desirable to completely absolve an offender of all liability. A person may be found liable in spite of his having proved his genetic predilection towards criminal behaviour, if he fails to take sufficient precautions to prevent any criminal action, even though he is aware of his genetic predispositions.⁷⁶

The genetic structure of a person may also play a part during the sentencing of a person for a crime. The quantum and the type of punishment could depend on the genetic make up of a person. The type and length of punishment may be determined having regard to his genes. Lately there has been a great deal of stress on the reformatory theory of punishment. Indeed, 'too much attention has been paid to the crime, and too little to the criminal.'⁷⁷ Criminals genetically predisposed towards violence who serve a long sentence in jail are hindered from learning how to control their aggression due to the hostile environs of a prison and this intensifies their predilection for violence.⁷⁸ Their aggressive behaviour could be treated by knowing the genetic cause of their behaviour.

Treatment of genetic impairments of criminals by prescription drugs as well as psychotherapy, after identifying their genetic structure may prove to be an effective curb on crime. Rehabilitation of criminals could be

⁷⁴ Lisa Schriener Lewis, 'The role genetic information plays in the criminal justice system' (2005) 47 *Arizona Law Review* 519, 542.

⁷⁵ *Ibid*, 541.

⁷⁶ Lewis *supra* n. 74, 548.

⁷⁷ Fitzgerald *supra* n. 19, 96.

⁷⁸ Lewis *supra* n. 74, 545.

more successful if one could discover the genetic triggers underlying their behaviour. However, such treatment should be voluntary and completely regulated so that prisoners do not become subject to dangerous experimental procedures.

For effective use of genetic materials for the administration of criminal justice, it is important that members of the judiciary are educated and made aware of the science underlying genetics and genomics. State and Federal court administrators in the United States have initiated programmes of scientific education as well as publication of manuals on scientific evidence.⁷⁹ In India, 'National and State Judicial Academies and the Bar Councils should develop and promote continuing legal educational programmes for judges and legal practitioners, respectively, in relation to the use of genetic information in the court proceedings.'⁸⁰

VII. CONCLUSION

The Human Genome Project is an astounding 'inward voyage of discovery rather than an outward exploration of the planet or the cosmos'.⁸¹ The advantages of mapping the human genome are manifold and may possibly lead to the elimination of many dreaded diseases and have many beneficial impacts on public health. However, we must not lose sight of the many concerns that have arisen. We need satisfactory laws to maintain a balance between individual rights and public interest.

To make a suitable regulatory framework, it is necessary to evaluate the potential areas in which the science can be used, the manner in which it is used and the ethical questions that arise therefrom. The difficulty that appears in connection with assessing the impact of genomics is that it is not possible to know how the science may develop and what its possible repercussions may be. The application of traditional legal principles to a newly evolving facet of science having far-reaching implications on humanity, may prove abortive. This has been realised even by the scientific

⁷⁹ *Supra* n. 69.

⁸⁰ Abichandani *supra* n. 16.

⁸¹ 'All About the Human Genome Project' *National Human Genome Research Institute*, at <http://www.genome.gov/10001772> (last visited 5 March 2006).

community. As early as 1975, at the Asilomar conference a group of molecular biologists recommended a moratorium on genetic manipulation and invited regulation for their activities.⁸² Since then the anxiety, stemming from the effects of genetic science has only increased. James Watson cautions 'even when appropriate satisfactory laws and regulations are in place, there will be many dilemmas that cannot easily be handled by these means.'⁸³

The world is in constant flux created by circumstances in which technology plays no small part. It is important to embrace technological advancement but not at the cost of human dignity. New principles of ethics and law must emerge retaining the value placed on humanism and the sanctity of human life. A brave new world lies before us, but before we fully venture forth, it is necessary for us to chart a clear path.

⁸² Morgan *supra* n. 10, 155.

⁸³ Watson *supra* n. 57, 63.

2(C) OR NOT 2(C): REDEFINING MINORITIES UNDER THE INDIAN CONSTITUTION.†

*Astad Randeria**

I. INTRODUCTION

In a democracy of myriad people, our Constitution has provided various rights, liabilities and safeguards both to individuals and to groups in an attempt to harmonise this diversity of our country with peace, progress, prosperity and other like concepts. In this vein, religious and linguistic minorities have been bestowed with the right to establish and administer educational institutions by Article 30¹ of the Constitution of India. In the context of these rights, the meaning of the term 'minority' assumes great importance.

The only available definition of the term 'minority' is to be found in Section 2(c) of the *National Commission for Minorities Act, 1992*, which defines the term (for the purposes of the Act only) as 'a community notified as such by the Central Government' (emphasis supplied). Given that the Constitution is silent on the definition of the term 'minority', should the definition of minority under Section 2(c) of the Act be applied to Article 30? Consequently, is the right of a minority community to establish and administer educational institutions under Article 30

† This article reflects the position of law as on 20 June 2006.

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¹ Article 30 of the Constitution states,

'Article 30-Right of minorities to establish and administer educational institutions

(1) All minorities, whether based on religion or language, shall have the right to establish and administer educational institutions of their choice.

(1A) In making any law providing for the compulsory acquisition of any property of an educational institution established and administered by a minority, referred to in clause (1), the State shall ensure that the amount fixed by or determined under such law for the acquisition of such property is such as would not restrict or abrogate the right guaranteed under that clause.

(2) The State shall not, in granting aid to educational institutions, discriminate against any educational institution on the ground that it is under the management of a minority, whether based on religion or language.'

contingent on such a notification by the Central Government? This article explores these and related issues that have a direct impact on the concept of 'minority' in the Constitutional context.

The crux of the right under Article 30 is the relative freedom that minorities enjoy from restrictions and governmental intervention in the administration of their educational institutions. The necessity or desirability of such a right has formed the subject matter of academic discussion since the days of the Constituent Assembly and will continue to do so till this right exists. However, the more important issue to be considered and understood in the present scenario is the full scope and ambit of the term 'minority' as contemplated by Article 30. The Apex Court has, through numerous judgments, clarified the law relating to minorities under Article 30 and the various facets of the rights accruing to minorities thereunder.

One important facet of Article 30 that remains entwined in controversy however is the eligibility criteria for enjoying the rights under Article 30, which any group claiming to be a religious or linguistic minority must satisfy. This issue has been considered in the case of *TMA Pai Foundation and Ors. v. State of Karnataka and Ors.*² (TMA Pai Case) where the court held that minorities ought to be determined on a state-wise basis. The reasoning was that since Article 30 of the Constitution deals with religious and linguistic minorities in the same breath, the unit or basis for determining a linguistic or religious minority must also be the same. Subsequent to the States being reorganised on a linguistic basis, the unit for determining a linguistic minority must be the State (in which the rights under Article 30 are sought to be exercised), and not the country as a whole. Religious minorities being placed on the same footing as linguistic minorities, the unit for determining a religious minority would, therefore, also be the concerned State.

Another aspect which had hitherto not been considered was the relationship between the definition of the term 'minority' given in the *National Commission for Minorities Act, 1992* (the Act) and Article 30.

² AIR 2003 SC 355.

Recently, the Supreme Court, in the case of *Bal Patil and Anr. v. Union of India and Ors.*,³ (*Bal Patil Case*) has touched upon the issue but, as this article will attempt to show, has not clarified its position adequately. The Supreme Court has discussed both the Act and Article 30 without clarifying the nature of the relationship between the two. Under the Act, the term 'minority' is defined (for the purposes of the Act) as one notified as such by the Central Government.⁴ Whether or not a notification under the said Act is a prerequisite for enjoying the protection and benefits guaranteed by Article 30 has not been dealt with, in the Act, nor in the *Bal Patil Case*. This article will, in Part II, attempt to analyse two possible relationships which the Act and Article 30 may share, and will stress the need for a decisive view of the Apex Court one way or another.

Part III of this article discusses the full scope and import of the term minority, both generally and *in specie* with regards to Article 30 of the Constitution. This part also deals with the judgment of the Supreme Court in the *Bal Patil Case* and its analysis of what constitutes a minority. The correctness and propriety of observations made in the *Bal Patil Case* that Jains are, in fact, Hindus is also questioned. In Part IV, this article deals specifically with the decision of the Apex Court in the *Bal Patil Case* and attempts to point out numerous inconsistencies in law and fact which necessitate a review of the decision in that case. The need for the Supreme Court to review the various areas of the law discussed and to clarify its position on them is stressed throughout this part.

II. NOTIFICATION: A SINE QUA NON FOR ARTICLE 30?

As stated above, it is, as yet, unclear whether or not a notification under the *National Commission for Minorities Act, 1992* is necessary for a minority community to enjoy the benefits conferred by Article 30. Section 2(c) of the *National Commission for Minorities Act, 1992* empowers⁵ the Central

³ (2005) 6 SCC 690.

⁴ *National Commission for Minorities Act, 1992*, section 2(c).

⁵ Although Section 2(c) is essentially a 'definition provision', defining a minority as one notified by the Central Government, it has been treated by the Central Government as an empowering provision. See, *Notification dated 23rd October, 1993, issued by the erstwhile Ministry of Welfare, now the Ministry of Social Justice and Empowerment*. The said notification begins by stating that it is being issued by the Central Government 'in exercise of the powers conferred by Clause (c) of Section 2 of the National Commission for Minorities Act, 1992 (19 of 1992)'.

Government to notify a particular community as a minority community. However, Section 2(c) expressly limits the power of the Central Government to notify minority communities *only for the purposes of the Act*.⁶ (emphasis supplied)

It therefore becomes necessary to understand what is meant by the phrase 'purposes of the Act'. The purposes of the Act may be gleaned from the Statement of Objects and Reasons of the Act and the functions of the National Commission for Minorities (the Commission) as listed in section 9 of the Act.

The Statement of Objects and Reasons of the Act states, 'The Minorities Commission was set up in January, 1978 for providing an institutional arrangement for *evaluating* the safeguards provided in the Constitution for protection of the minorities and to make *recommendations* for ensuring implementation of the safeguards and the laws.' (emphasis supplied)

Moreover, the functions of the Commission also suggest that purposes of the Commission, and therefore of the Act, are limited and not all pervasive.⁷

⁶ Section 2(c) states, '(c) "Minority", *for the purposes of this Act*, means a community notified as such by the Central Government'. (emphasis supplied)

⁷ Section 9 contains an inclusive list of the various functions of the Commission. The functions are reproduced here for ease of reference,

- (a) evaluate the progress of the development of Minorities under the Union and States;
- (b) monitor the working of the safeguards provided in the Constitution and in laws enacted by Parliament and the State Legislatures;
- (c) make recommendations for the effective implementation of safeguards for the protection of the interests of Minorities by the Central Government or the State Governments;
- (d) look into specific complaints regarding deprivation of rights and safeguards of the Minorities and take up such matters with the appropriate authorities;
- (e) cause studies to be undertaken into problems arising out of any discrimination against Minorities and recommend measures for their removal;
- (f) conduct studies, research and analysis on the issues relating to socio-economic and educational development of Minorities;
- (g) suggest appropriate measures in respect of any Minority to be undertaken by the Central Government or the State Governments;
- (h) make periodical or special reports to the Central Government on any matter pertaining to Minorities and in particular the difficulties confronted by them; and
- (i) any other matter which may be referred to it by the Central Government.'

The above functions demonstrate that the Commission's purposes are supplemental and subordinate to the application of Article 30.

The functions of the commission are investigative, evaluative and recommendatory in nature. It is not the stated purpose of the Commission (and therefore of the Act) to determine minorities for the purposes of Article 30. The Act does not make it incumbent on a community to be notified as a minority for exercising the rights conferred by Article 30.

It is relevant to note that whereas the Legislature has specifically identified and mentioned the above purposes of the Act, it has remained silent on whether or not a notification under the Act is a *sine qua non* for enjoying the benefits of Article 30. In such a situation, to impute this intention to the Legislature may not be correct. When far less significant purposes of the Act are specifically mentioned, it is unreasonable to assume that such a monumental purpose would be left to implication. Therefore, on a plain reading of the Act, the logical conclusion is that the Act is, and was intended to be, supplemental to the rights guaranteed by Article 30 of the Constitution. The Supreme Court, however, in the *Bal Patil Case* seems to have held to the contrary.

The Supreme Court, in the *Bal Patil Case*, seems to have proceeded on the footing that notification under Section 2(c) of the Act and Article 30 are linked and need to be considered together. In the *Bal Patil Case*, the Supreme Court was concerned with minorities for the purposes of the Act, inasmuch as the relief sought was a notification for the Jain Community under the Act. The *Bal Patil Case* was adjourned on many occasions because the Court was waiting for the decision in the *TMA Pai Case*. However, as is reproduced in paragraph 6 of the *Bal Patil* judgment, the *TMA Pai Case* concerned itself with providing the basis for determination of minorities for the purposes of Article 30 only. In the *Bal Patil Case*, this basis for determination of minorities has been adopted for the determination of minorities for the purposes of the Act as well, thus linking the Act to Article 30.

Paragraphs 11 and 12 of the *Bal Patil* Judgment, reproduced below, elucidate the opinion of the Supreme Court on the relationship between the Act and Article 30.

‘11. The expression ‘minority’ has been used in Articles 29 and 30 of the Constitution but it has nowhere been defined. The

Preamble of the Constitution proclaims to guarantee every citizen "liberty of thought, expression, belief, faith & worship". Group of Articles 25 to 30 guarantee protection of religious, cultural and educational rights to both majority and minority communities. It appears that keeping in view the constitutional guarantees for protection of cultural, educational and religious rights of all citizens, it was not felt necessary to define 'minority'. Minority as understood from constitutional scheme signifies an identifiable group of people or community who were seen as deserving protection from likely deprivation of their religious, cultural and educational rights by other communities who happen to be in majority and likely to gain political power in a democratic form of Government based on election.

12. In the background of constitutional scheme, the provisions of the Act therefore instead of giving definition of 'minority' only provide for notifying certain communities as 'minorities' who might require special treatment and protection of their religious, cultural and educational rights. The definition of 'minority' given under the Act in section 2(c) is in fact not a definition as such but only a provision enabling the Central Government to identify a community as a 'minority' which in the considered opinion of the Central Government deserves to be notified for the purpose of protecting and monitoring its progress and development through the Commission.'

The Apex Court has highlighted the lack of a definition of 'minority' in the Constitution and attributed this as the reason for the power being given to the Central Government to notify minorities. In the circumstances, it may be reasonably concluded that the Supreme Court, in the *Bal Patil Case*, considered a notification by the Central Government to be necessary for the enjoyment of the rights under Article 30.

In this context, it is relevant to consider the provisions of the recent *National Commission for Minority Educational Institutions Act, 2004*. Section 2(f) of that Act also defines a minority as a community notified as such by the Central Government. This Act makes it mandatory for a person wishing

to establish and/or administer an educational institution to obtain a 'No-objection Certificate' from the competent authority set up under the Act.⁸ The competent authority is a body set up under the *National Commission for Minority Educational Institutions Act, 2004*, whose main function is to issue no-objection certificates to minorities.⁹ The competent authority, exercising powers under the *National Commission for Minority Educational Institutions Act, 2004* is bound by the definition of minority contained in that Act. Since the no-objection of this competent authority is required to set up a minority educational institution under Article 30, it is clear that for availing of the benefits of Article 30, a notification under the Act is necessary. Thus the opinion of the Supreme Court (expressed in the *Bal Patil Case*) appears to be in consonance with the opinion of the Legislature (expressed in the *National Commission for Minority Educational Institutions Act, 2004*).

The important question that arises as a necessary consequent of the above proposition is whether or not there is a *fundamental right* to be notified as a minority. If a notification is necessary for the enjoyment of the fundamental rights guaranteed by Article 30 to all religious and linguistic minorities, then surely there must also exist a right to be considered for such a notification. If this were not so, the fundamental rights accorded to minorities under Article 30 could be trampled upon by the Central Government, by it simply refusing to consider the claim of a particular religious or linguistic denomination for minority status. Since the Supreme Court seems to have proceeded on the footing that a notification under the Act is in fact an essential requirement to be entitled to the protection given to minorities under Article 30, a right to be considered for such notification assumes the character of a fundamental right, which must be read into Article 30.

However, the Supreme Court, in the *Bal Patil Case*, seems to have contradicted the basic premise of the argument that the right to obtain a notification is a fundamental right. This premise is that a notification is

⁸ *National Commission for Minority Educational Institutions Act, 2004*, section 10.

⁹ *Ibid*, section 2(ca).

necessary to enjoy the benefits of Article 30. The apparent contradiction arises inasmuch as the Court has not issued a writ of *mandamus* to the Central Government.

By refusing to issue the writ of *mandamus*, the judgment in the *Bal Patil Case* has the effect of confirming or accepting the contention of the Central Government in that case, that post the decision in the *TMA Pai Foundation Case*, the Central Government no longer possesses the power to notify minorities. Since minorities are to be determined on a state-wise basis, the power for such determination now vests in the respective State Governments.

If the Supreme Court was of the opinion that the Central Government retained the power to notify minorities, then by not issuing a writ of *mandamus* to the Central Government directing it to consider notifying Jains as a minority under the Act, it ignored the fundamental rights guaranteed to the Jains under Article 30. This, because the Central Government had refused to notify the Jain community on the ground that it believed that it lacked the power to notify. It had not come to any considered conclusion that Jains were not a minority community.

Attributing the best of intentions to the Supreme Court, it is submitted that the deprivation of Fundamental Rights of citizens was certainly not the intention of the Hon'ble Supreme Court.

It therefore appears that the Supreme Court has expressed contradictory views on whether or not Article 30 and section 2(c) of the Act are inextricably linked. The need for an unambiguous opinion of the Apex Court on this issue cannot be stressed enough. If the Central Government and other administrative bodies remain under the misconception that they no longer enjoy the power to notify minorities under the Act, and, at the same time, a notification under the Act is deemed to be necessary for exercising the rights under Article 30, then a grossly inequitable situation arises. Religious and linguistic minorities alike will be deprived of their rights under Article 30 and will be left without the remedy of enforcing them. Until a decisive opinion of the Apex Court is obtained, the rights and benefits guaranteed to religious and linguistic minorities under Article 30 will remain mired in confusion and doubt.

III. WHAT DOES THE WORD 'MINORITY' MEAN?

A. *The General Concept of Minority – The Global Position*

'What is a minority?' This question and the possible responses thereto have formed the subject matter of a number of studies by experts and lengthy debates in many a forum at which minority protection has been addressed. No definite answers have been found and no satisfactory universal definition of the term 'minority' has proved acceptable.¹⁰ According to the office of the UN High Commissioner for Human Rights, the difficulty in arriving at an acceptable definition lies in the variety of situations in which minorities exist.

Before attempting a definition, it may be advisable to examine and probe the history of minority protection a little. Post World War 1, the international community, under the auspices of the League of Nations, through a series of bilateral agreements concluded after the major peace treaties, which contained specific measures to protect minority communities aimed at preventing international conflict. The League was a spectacular let down, and another global armed conflict followed.

The world, having seen its second world war, seemed more cautious with the concept of minority protection, or at the very least, in using the terminology in providing protection to minorities. The European Bank for Reconstruction and Development, in its paper entitled Political aspects of the mandate of the European Bank in relation to ethnic minorities,¹¹ gives three reasons for this. Firstly, minority protection had been used as Germany's pretext for territorial expansion in the period between the two World Wars. Second, the concept that protection of the rights of all individuals was preferable to the protection of rights of minorities was

¹⁰ See, Fact Sheet No.18 (Rev.1), Minority Rights, available at <http://www.ohchr.org/english/about/publications/docs/fs18.htm> (last visited 7 March 2006). The human rights Fact Sheet Series is published by the Office of the United Nations High Commissioner for Human Rights (OHCHR) in Geneva.

¹¹ European Bank for Reconstruction and Development, 'Political aspects of the mandate of the European Bank in relation to ethnic minorities' (1993), available at www.ebrd.com/pubs/insti/5108.pdf (last visited 20 June, 2006).

starting to gain ground. Thirdly, the grant of special rights to ethnic minorities often led to a demand for secession or independence of those communities.

It is argued that it is for these reasons, that the UN and other international bodies have concentrated on defining and reinforcing the natural and civil rights of individuals and have not ever defined the term 'minority'. The United Nations' limited forays into the field have proved to be superficial and ineffectual. The United Nations Declaration on the Rights of Persons Belonging to National or Ethnic, Religious and Linguistic Minorities¹² does not even attempt a definition and the degree of protection offered did not go further than the existing standards set by the Conference on Security and Cooperation in Europe.¹³

The most effective definition put forth by the United Nations was provided by the UN Special Rapporteur Francesco Capotorti. It reads,

'A group, numerically inferior to the rest of the population of a State, in a non-dominant position, whose members – being nationals of the State – possess ethnic, religious or linguistic characteristics differing from those of the rest of the population and show, if only implicitly, a sense of solidarity directed towards preserving their culture, traditions religion or language.'¹⁴

A similar definition has been given by Jules Deschênes in the Proposal Concerning a Definition of the Term 'Minority'.¹⁵

Arriving at a generally acceptable definition has proved to be a mammoth mission simply because of the differing circumstances in which 'minorities' exist. The international community has satisfied itself by adopting the working model of determining minorities in relation to the group that

¹² Adopted by General Assembly resolution 47/135 on 18 December 1992, *available at* <http://www.ohchr.org/english/law/minorities.htm> (last visited 7 March 2006).

¹³ European Bank for Reconstruction and Development *supra* n.12.

¹⁴ Study on the Rights of Persons belonging to Ethnic, Religious and Linguistic Minorities. UN Document E/CN.4/Sub.2/384/Add.1-7 (1977).

¹⁵ Proposal Concerning a Definition of the Term 'Minority' – UN Document E/CN.4/Sub.2/1985/31 (1985).

calls the shots in a community. In most cases a 'numerical inferiority' criterion is the best basis for determining minorities. However, in some cases a numerical minority wields power as it was in colonial India or South Africa under the apartheid regime. Here the numerical majority might still be a 'minority' if the test of non-dominance is applied. This test of non-dominance presents a world of possibilities, and groups like women, tribal people and migrant workers could be brought under the umbrella of minority protection through its application.

Fact Sheet 18 perhaps sums up the position best when it states, 'The most commonly used description of a minority in a given State can be summed up as a non-dominant group of individuals who share certain national, ethnic, religious or linguistic characteristics which are different from those of the majority population.'¹⁶

B. The Indian Perspective

In the Constitutional context, the concept of minority in India is quite different from the prevailing international notion. Neither the Constitution of India nor any other constitutional document defines the word 'minority'. The Constitution only refers to Minorities and speaks of those 'based on religion or language'. The only available definition of the term in India is to be found in section 2(c) of the *National Commission for Minorities Act, 1992*. As stated earlier, this definition is not a definition at all; rather it is an enabling provision, which entrusts the determination of minorities to the Central Government. An advantage of this is that it allows for a great deal of flexibility in determination of minorities. Nonetheless it is in the nature of an unguided power given to an administrative authority (the Central Government). In the circumstances, the Supreme Court, through its numerous decisions on the subject, has had to, and has clarified and interpreted the concept of the term minority in the Constitutional context.

An analysis of the various judgments of the Apex Court reveals two principal guidelines for the determination of minorities for the purposes of Article 30 of the Constitution. The first guideline, enunciated in the

¹⁶ *Supra* n. 11.

TMA Pai Case, is that religious and linguistic minorities must be identified by taking the 'State' as the geographical unit. The second guideline laid down by the Apex Court¹⁷ in determining religious and linguistic minorities is that the only factor to be considered in determining whether or not a community is a minority is the numerical strength of the community in relation to the total population. These two guidelines laid down by the Supreme Court place the discretion offered to the Central Government within tight boundaries and serve to provide a descriptive definition of the term 'minority' as used in Article 30 of the Constitution.

1. The Two Guidelines: Their Clarity And Fallouts

Recent developments have served to jeopardise the efficacious working of both the above guidelines. The two guidelines and their fallouts are considered in some detail below.

a. *The 'State' As The Geographical Unit For Determining Minorities*

The principle laid down in this rule is simple and clear and the opinion of the Supreme Court on this issue has remained consistent in its numerous judgments on the issue. The reasons for this rule being laid down have been dealt with earlier in this article. Briefly stated, after the reorganisation of Indian States on a linguistic pattern, the only logical unit for determining a linguistic minority is the State. Since the Constitution places both religious and linguistic minorities on the same footing, the geographical unit for determining both would have to be the same. Thus the State is the geographical unit on which determination of religious and linguistic minorities will be carried out.

The principle presents no conceptual difficulty. The problem that has arisen, however, has been in its application. As previously stated, whether or not a notification under the Act is essential for the purposes of Article 30 is still not clear. If, as the recent legislation on the issue suggests,¹⁸ indeed a notification is considered to be necessary for a community to

¹⁷ *TMA Pai Foundation and Ors. v. State of Karnataka and Ors.* AIR 2003 SC 355, para 157 and 184.

¹⁸ *National Commission for Minority Educational Institutions Act, 2004.*

be eligible for the rights under Article 30, then it is vital that the Central Government have and retain the power to so notify minority communities. Here the stand taken by the Central Government in the *Bal Patil Case* assumes great importance. In the *Bal Patil Case*, the Central Government, both in their pleadings and through the arguments of their Counsel, stated that since the *TMA Pai Case* laid down that the 'State' would be the unit, the Central Government would thereafter 'have no role to play'.¹⁹ The contention was that the power to notify communities as minorities would now be with 'State authorities'. However, this argument puts forth many difficulties. Firstly, would it be the State Government or the State Minority Commission that would exercise the power? Secondly, a number of States in India do not have a Minority Commission. Lastly neither the State Government nor the State Commissions have been conferred the power to notify by an act of legislature. The judiciary cannot confer such a power; that falls squarely within the precinct of the legislature.

Despite these compelling reasons against the above contention, the Supreme Court has not in terms rejected the contention of the Central Government. It has, however, categorically stated that the Central Government continues to have the power to notify under the Act and only the manner in which this power is to be exercised is regulated by the principle laid down in the *TMA Pai Case*. The position would have been clear had it not been for the decision of the Supreme Court to refrain from issuing a writ of *mandamus* to the Central Government, despite holding that it had the power to notify. As will be shown later, if the conclusion is that the Central Government had the power to notify, it ought to have been compelled to choose to either notify or not notify the Jains as a minority. As it stands, the Central government has not notified the Jains as a minority because it contends that it does not have the power and not because it thinks that the Jains are not a minority. By not directing the Central Government to arrive at a decision on notifying the Jains after due consideration, the Supreme Court has, possibly inadvertently, seconded the Central Government's contention in the *Bal Patil Case*.

¹⁹ *Bal Patil and Anr. v. Union of India and Ors* (2005) 6 SCC 690, para 7 and 10.

Thus, as previously stated, there remains an element of confusion on whether a Central authority or a State authority is to have the power to decide upon the minority status of a community. The more reasonable view seems to be that the Central Government retains the power to notify. Nonetheless, two views are possible, and the need for an unambiguous opinion of the Supreme Court on the point remains the need of the hour.

b. *Numerical Minority: The Sole Criterion?*

That groups must be identified as minorities taking the 'State' to be the basis for determination, has been established. However, whether the sole criterion for establishing minority status is numerical strength or whether other factors such as affluence, social status, deprivation, etc need to be considered as well is a question that is still being answered inconsistently by the Supreme Court in its various decisions.

In its decision in the *Bal Patil Case*, the Supreme Court has held that numerical minority is not the sole criterion in determining minority status under Article 30. It has been held in paragraph 17,

'The power of Central Government has to be exercised not merely on the advice and recommendation of the Commission but on consideration of the social, cultural and religious conditions of the Jain community in each state. Statistical data produced to show that a community is numerically a minority cannot be the sole criterion. If it is found that a majority of the members of the community belong to the affluent class of industrialists, businessmen, professionals and propertied class, it may not be necessary to notify them under the Act as such and extend any special treatment or protection to them as minority. The provisions contained in the group of Articles 25 to 30 are a protective umbrella against the possible deprivations of fundamental right of religious freedoms of religious and linguistic minorities.'

However, the majority opinion in the *TMA Pai Case*, in paragraph 157 of the Judgment expresses a view contrary to the one in *Bal Patil's Case*,

'Article 30 is a special right conferred on the religious and linguistic minorities because of their *numerical handicap* and to instil in

them a sense of security and confidence, even though the minorities cannot be per se regarded as weaker sections or underprivileged segments of the society.' (emphasis supplied)

This view is endorsed and laid down more explicitly by VN Khare, J. (concurring) in the same case in paragraph 184,

'The person or persons establishing an educational institution who belong to either religious or linguistic group who are *less than fifty per cent* of total population of the state in which educational institution is established would be linguistic or religious minorities.' (emphasis supplied)

In view of the doctrine of *stare decisis*, the view of the majority of the Judges in the *TMA Pai Case* prevails over the view expressed by the three Judges of the Supreme Court in the *Bal Patil Case*. Nonetheless, these observations of the Supreme Court in the *Bal Patil Case* seem to be integral to the reasons for not granting relief to the Appellant Jain community. In the circumstances, to prevent a miscarriage of justice and to bring the administration of justice in accordance with the law of the land, a review of the Judgment in the *Bal Patil Case* appears to be imperative.

Further, as long as the judgment in the *Bal Patil Case* stands with these observations in it, this relatively simple proposition of law (in spite of being made explicit by an eleven judge bench of the Apex Court) will remain susceptible to misinterpretation and consequent misuse.

2. Changing The Concept Of Minority In India: An Academic Discussion

The Apex Court in the *Bal Patil Case* has devoted a number of paragraphs to *obiter* observations regarding the historical backdrop of independence and the inclusion of the protection accorded to minorities in the Constitution. The Hon'ble Judges in the *Bal Patil Case* were of the view that divisive and anti-national forces were largely responsible for demands of separate electorates which eventually led to partition of the Country and a necessary and inevitable fallout of the Partition was that certain

religious communities 'were required to be given full assurance of protection of their religious and cultural rights'.²⁰ They state that the historical background of the partition shows that the provisions contained in Articles 25 to 30 were to give a guarantee to only 'identified minorities and thus to preserve the integrity of the country. It was not in the contemplation of the framers of the Constitution to add to the list of religious minorities'.²¹ The Judges were of the opinion that the ideal that must be sought to be achieved is a situation where each citizen has the complete right to freedom of religion, language and education and there need be no reason to protect the rights of the minority communities. The utopian situation would be when each citizen would be more concerned about protecting the rights of others than enforcing his own. In their opinion, across the board, indiscriminate minority protection was divisive and would lead to conflict rather than preserving the integrity of the nation. It is against this backdrop, and with these views, that the Judges have held that numerical minority must not be the sole criterion and that other factors such as social standing and affluence must also be brought to bear on the decision to notify a particular community as a minority. Instead of adding to the list of minorities, what must be done is to improve the standards of the minorities so as to bring them on par with the majority. Once this was done, the protection of Articles 25 to 30, which is really only protection against 'possible deprivations of religious rights of religious and linguistic minorities'²² could be done away with.

However, in most other decisions on the subject, many Judges of the Apex Court have expressed very different views on the intention, nature and effect of Article 30. As already stated above, it was the unanimous view of all eleven judges in the *TMA Pai Case* that numerical minority was to be the only criterion in deciding minority status. The majority also expressed its view that Article 30 was indeed not divisive in paragraph 161 of the judgment,

'161. The essence of secularism in India is the recognition and preservation of the different types of people, with diverse languages

²⁰ *Bal Patil and Anr. v. Union of India and Ors* (2005) 6 SCC 690, para 33.

²¹ *Bal Patil and Anr. v. Union of India and Ors* (2005) 6 SCC 690, para 33.

²² *Bal Patil and Anr. v. Union of India and Ors* (2005) 6 SCC 690, para 17.

and different beliefs, and placing them together so as to form a whole and united India. Articles 29 and 30 do not more than seek to preserve the differences that exist, and at the same time, unite the people to form one strong nation.²³

In paragraph 308, the Supreme Court (per SSM Quadri, J) continues thus: –

‘308. We find no substance in the contention that granting aid to minority educational institutions under article 30, which cater to the needs of the minorities, will infringe the principle of secularism.’²⁴

Further, 7 Judges of the Supreme Court in the case of *PA Inamdar and Ors. v. State of Maharashtra and Ors.*,²⁵ (PA Inamdar Case) have attempted to clarify the nature of the provisions of the Constitution regarding minorities. They have held thus,

‘103. Much of controversy can be avoided if only the nature of the right conferred by Articles 29 and 30 is clearly understood. The nature and content of these articles stands more than clarified and reconciled inter se as also with other articles if only we understand that these two articles are intended to confer protection on minorities rather than a right as such.’

Paragraph 94 of the Judgment in the *PA Inamdar Case* is extremely instructive and provides an insight into the reasons for the inclusion of Article 30 in the Constitution. The relevant passage is reproduced below,

‘The reasons are too obvious to require elaboration. Article 30(1) is intended to instil confidence in minorities against any executive or legislative encroachment on their right to establish and administer educational institution of their choice. Article 30(1) though styled as a right, is more in the nature of protection for minorities. But for Article 30, an educational institution, even though based on religion or language, could have been controlled

²³ *TMA Pai Foundation and Ors. v. State of Karnataka and Ors* AIR 2003 SC 355, para 16.

²⁴ *TMA Pai Foundation and Ors. v. State of Karnataka and Ors* AIR 2003 SC 355, para 308.

²⁵ AIR 2005 SC 3226, para 103.

or regulated by law enacted under Clause (6) of Article 19, and so, Article 30 was enacted as a guarantee to the minorities that so far as the religious or linguistic minorities are concerned, educational institutions of their choice will enjoy protection from such legislation.'

Thus two issues have been clarified by larger benches of the Apex Court. One, that Article 30 is far from divisive and secondly that it is a protective measure and not a remedial measure which confers privileges in order to right wrongs perpetrated on minorities or to emancipate downtrodden minorities. In this context, it is worthwhile to consider the observations by the Judges in the *Bal Patil Case*. Whereas, their interpretation is that Article 30 is in the form of rights granted to oppressed or weaker communities only, a more enlightened view seems to emerge from other cases where minority protection is considered to be a permanent protective shield for numerically inferior groups to educate their members and be protected from the *possible* misuse of power by the Executive or the Legislature controlled by the majority. For this reason, far from being divisive, it instils a sense of security in numerically smaller groups in a democratic polity run by the majority.

The observations in the *Bal Patil Case*, which state that the Constitution framers had specific identified minorities in consideration while framing Article 30 and did not envisage more minorities being added to the list, seem to be slightly misplaced. Firstly, they appear to run contrary to the Article itself, which clearly talks of *all* religious and linguistic minorities and not of any pre-identified ones. Secondly, even if the Constituent Assembly debates reflect a position similar to this, it is noteworthy that the debates have been rejected as a means to interpret the Constitution. The position is elucidated by Quadri, J. in paragraph 298 of the Judgment in the *TMA Pai Case* where a number of Indian²⁶ and English²⁷ authorities

²⁶ See, *A.K. Gopalan v. State of Madras* AIR 1950 SC 27; *State of Trav-Cochin v. Bombay Company Lt* AIR 1952 SC 366. See also *His Holiness Kesavananda Bharati Sripadagalavaru v. State of Kerala* (1973) 4 SCC 225; *R.S. Nayak v. A.R. Antulay* AIR 1984 SC 684; *Indra Sawhney and Ors. v. Union of India and Ors.* AIR 1993 SC 477; *P.V. Narasimha Rao v. State* AIR 1998 SC 2120.

²⁷ See, *Black-Clawson v. Papierwerke AG* [1975 AC 591] and *Administrator-General of Bengal v. Prem Nath Mullick* [1895 (22) I.A. 107].

are relied upon in support of the proposition that debates in the Constituent Assembly or in Parliament ought not to be relied upon to interpret a Constitutional provision although they may be relevant for other purposes.²⁸

Finally, it is submitted that Article 30 differs fundamentally from minority protection as it is understood in the international sense. Under Article 30, minorities are provided a degree of protection to allow them to educate members of their own community as fully as possible so that they may be well-equipped to face the challenges of being in the numerical minority. It is a guarantee to minorities that they will always be permitted *to help themselves*, through what the Constituent Assembly considered to be the best means – education. Internationally, as can be seen from the definitions quoted earlier, the main protection offered to minorities is the right to conserve their language, culture, religion or other traditions. At the very least ‘a sense of solidarity, directed towards preserving their culture, traditions religion or language’²⁹ is necessary to qualify as a minority. Article 30 proceeds on a completely different basis. The Constitution, like other instruments after the Second World War, has given the right to preserve religion, culture, customs and traditions to all individuals, and in the process ensuring that members of the minority communities have these ‘rights’.

In conclusion, it may be stated that for the purpose of interpreting Article 30, the approach leaning towards extending protection to religious and linguistic minorities on the basis of their numerical handicap might be more egalitarian an approach to adopt, rather than to deny purported ‘rights’ to the minorities on the basis of their present socio-economic condition. In the final analysis though, it is for Parliament to make law and it is the role of the judiciary to enforce the law as it is written and not attempt, by judicial fiction under the guise of interpretation, to rewrite it as they would.

²⁸ *TMA Pai Foundation and Ors. v. State of Karnataka and Ors* AIR 2003 SC 355, para 298.

²⁹ *European Bank for Reconstruction and Development supra* n. 12.

IV. THE BAL PATIL CASE: A NEED FOR REVIEW

In the *Bal Patil Case*, the Supreme Court has all but put an end to the claims of the Jain community to minority status. The Supreme Court has not only refused to issue a writ of *mandamus* to the Central Government directing it to exercise its power under section 2(c) of the Act, but has also held Jainism not to be a distinct religion, and has held that it forms a part of the larger Hindu religion. Moreover, the correctness of the decision of the Supreme Court in refusing to issue a writ of *mandamus*, particularly when the writ was required to protect the enjoyment of fundamental rights, is questionable. Further, an issue that necessarily arose for the consideration of the Supreme Court in the *Bal Patil Case* was whether or not a notification was necessary for Article 30. This issue has not been effectively determined by the Supreme Court in the *Bal Patil Case*. For these reasons, a review of the judgment in the *Bal Patil Case* appears to be the need of the hour.

A. *Jains Are Hindus: Factual Inaccuracies In The Bal Patil Judgment*

In the *Bal Patil Case*, the Supreme Court has in unambiguous terms, held Jainism not to be a distinct religion from Hinduism, and has held that it forms a part of the larger Hindu religion. Paragraphs 27 to 31 of the Judgment deal with the issue of Jainism as a religion, and the Supreme Court makes some startling observations therein.

Paragraph 27 opens thus,

‘The so-called minority communities like Sikhs and Jains were not treated as national minorities at the time of framing the Constitution. Sikhs and Jains, in fact have throughout been treated as part of the wider Hindu community which has different sects, sub-sects, faiths, modes of worship and religious philosophies.’

The Supreme Court goes on to examine various aspects of the Hindu and Jain religions and states that there are various similarities in their theory, and that the influence of the Hindu Vedic religion is quite apparent in *inter alia*, ‘the belief and faith of Jains.’³⁰ It is also stated that Jainism is merely a reformist movement amongst Hindus like the Bhramosamajis,

³⁰ *Bal Patil and Anr. v. Union of India and Ors* (2005) 6 SCC 690, para 29.

Aryasamajis and Lingayats. The Supreme Court concludes by saying, 'Thus, 'Hinduism' can be called a general religion and common faith of India whereas 'Jainism' is a special religion formed on the basis of quintessence of Hindu religion.'³¹

The above observations, apart from being *obiter dicta*, directly contradict past observations by the Supreme Court on the same issue. It has been held through a plethora of judgments of the Supreme Court that Jainism and Hinduism are two distinct religions. In *Samatha v. State of A.P. and Ors.*,³² the Hon'ble Supreme Court has listed Jainism as a separate religion along with Islam, Christianity and Hinduism. In *A.S. Narayana Deekshitulu v. State of Andhra Pradesh and Ors.*,³³ the Hon'ble Supreme Court has, in paragraph 88, while discussing religion as it is used in Articles 25 and 26 of the Constitution, held thus,

'Religion is not necessarily theistic and in fact there are well-known religions in India itself like Buddhism and Jainism, which do not believe in the existence of God.'

This, in fact, is one of the chief issues on which there is a divergence of belief between Hinduism and Jainism. While Hinduism talks of thousands of Gods and Goddesses, Jainism debunks the theory of a Creator or indeed, of any intelligent first cause. The Apex Court has also taken cognisance of this facet of Jainism on more than one occasion.³⁴

The observations of the Apex Court in the Babri Masjid Case are interesting to note in this regard,

'Hinduism is a tolerant faith. It is that tolerance that has enabled Islam, Christianity, Zoroastrianism, Judaism, Buddhism, Jainism and Sikhism to find shelter and support upon this land.'³⁵

³¹ *Ibid*, para 31.

³² AIR 1997 SC 3297 : (1997) 8 SCC 191.

³³ AIR 1996 SC 1765.

³⁴ *Commr. HRE v. Sri Lakshmindra Thirtha Swamiar of Sri Shirur Mutt.* [AIR 1954 SC 282 at 290 (1954) SCR 1005]; See also, *State of Rajasthan and Others v. Tilkayat Shri Govindlalji Maharaj* [AIR 196 SC 1638 : [1964] 1 SCR 561] and *State of Rajasthan v. Sajjanlal Panjawat* [AIR 1975 SC 706 : (1974) 1 SCC 500 : [1974] 2 SCR 741].

³⁵ *M. Ismail Faruqui (Dr) and Others v. Union of India and others* (1994) 6 SCC 360, para 158.

Jainism, as a religion, does not believe in the supremacy or the authority of the Vedas and in fact denies the very existence of God which forms the basis of the Hindu religion. It can hence never be equated with the Hindu religion.³⁶ Tilak's working formula of Hinduism has been quoted with approval by the Supreme Court in the case of *Sastri Yagnapurushadji and Ors. v. Muldas Bhudardas Vaishya and Another*.³⁷

'Acceptance of the Vedas with reverence; recognition of the fact that the means or ways to salvation are diverse and realisation of the truth that the number of gods to be worshipped is large, that indeed is the distinguishing feature of Hindu religion.'

Thus, it is clear that by renouncing the Vedas and denying the existence of God, Jainism clearly distances itself from the most basic definition of Hinduism. Since its inception Jainism has always been believed to be distinct and separate from Hindu religion. In fact the learned historian, Heinrich Zimmer states, 'Jainism denies the authority of the Vedas and the orthodox traditions of Hinduism. Therefore, it is reckoned as a heterodox Indian religion'.³⁸ JN Farguhar and Prof Hermann Jacobi, the eminent German Ideologist, both hold that the Jainism is an original and distinct religion and has, in fact, been a rival of Hinduism since its birth.³⁹

Article 25 of the Constitution is a prime example to show that Jains have never been considered to be Hindus, legally or for the purposes of the Constitution. The Explanation to Article 25 of the Constitution lists Sikhism, Buddhism and Jainism as religions distinct from Hinduism, but which are to be considered together with Hinduism for the purposes of Article 25(2)(b). This dichotomy contained in the Constitution,⁴⁰ was also maintained by Parliament in the enactment of the four statutes,⁴¹ of Hindu

³⁶ *Commissioner of Wealth Tax, W. Bengal v. Champa Kumari Singh* AIR 1968 Cal 74.

³⁷ [1966] 3 SCR 242, para 41.

³⁸ Heinrich Zimmer, *Philosophies of India* (1st edn., Princeton University Press, Princeton, New Jersey, USA 1989).

³⁹ JN Farguhar, *Modern Religious Movements in India*, (1st edn., Norwood Press, Norwood, Mass. USA First published 1915, Reprint 1924) 324.

⁴⁰ Article 25 of the Constitution of India.

⁴¹ *The Hindu Marriage Act, 1955; The Hindu Succession Act, 1956; The Hindu Minority and Guardianship Act, 1956 and The Hindu Adoptions and the Maintenance Act, 1956.*

personal law, which also consider Jains along with Hindus for the purposes of those statutes. Other acts like The *Indian Succession Act, 1925*,⁴² and the *Special Marriage Act, 1954* have also recognised Jainism as a separate religion. Moreover, the Indian National Census has, since the first census conducted in British India in 1873, recognised and treated Jainism as a distinct religion.

It is apparent that the observations of the Supreme Court in the *Bal Patil Case* are dubious at best. Moreover, these observations seem to have been made as *obiter dicta*⁴³ and could have been avoided. Many High Courts, including the Bombay High Court, and certainly the lower judiciary and administrative bodies are accustomed to abiding even by observations of the Supreme Court, made *obiter*. These observations, being not founded in unshakable authorities, will therefore close the door on any chances the Jain Community has to get itself notified by the Central Government. These observations will also cause to be scrutinised notifications already issued by some State Minority Commissions giving Jains minority status.

Moreover, the observations deal not only with the Jain religion but also with the Sikh religion. The Sikh community has already been notified as a minority under the *National Commission for Minorities Act, 1992*.⁴⁴ These observations may well lead to a repeal of the notification to the extent which it deals with Sikhs, despite the fact that there was no necessity for the observations and that they are *obiter dicta*. On the other hand, if the notification relating to Sikhs is not taken back, it will lead to an inequitable situation where one community alone will suffer the brunt of the above observations.

⁴² *Indian Succession Act, 1925*, section 29(2)(b).

⁴³ *Bal Patil and Anr. v. Union of India and Ors* (2005) 6 SCC 690, para 20.

⁴⁴ See Notification dated 23rd October, 1993, issued by the erstwhile Ministry of Welfare, now the Ministry of Social Justice & Empowerment.

B. A Writ Of Mandamus – Was It Necessary?

The dismissal of the appeal in the *Bal Patil Case* also seems to be without adequate reasons. As stated above, the Central Government's principal stand in the *Bal Patil Case* was that a writ of *mandamus* ought not to be granted since the Central Government did not have the power to notify. The Supreme Court, in paragraph 17 has clearly held that the Central Government continues to possess the power to notify and in fact states that before the Central Government henceforth considers the claims of Jains as a minority under section 2(c), the identification must be done on a statewise basis. Despite this, the Supreme Court refrains from directing the Central Government to take a decision on the claims of members of the Jain community pending before it. This being a statutory duty imposed on the Central Government by the *National Commission for Minorities Act, 1992*, such a writ of *mandamus* should, in due course, have been issued by the Hon'ble Supreme Court.

The judgment in the *Bal Patil Case*, by dismissing the appeal, has allowed the Central Government to 'shirk its statutory responsibility'.⁴⁵ The Supreme Court has decided that the Central Government does indeed retain the power. It should therefore logically follow that the Central Government must not be allowed to abdicate a power specifically conferred on it.

It is trite law,⁴⁶ that when an administrative authority (in this case the Central Government) is given a discretionary power to be exercised when certain circumstances prevail, that power is coupled with a *duty* to exercise that power reasonably when the conditions envisaged prevail.⁴⁷ In the instant case, according to the 2001 Census,⁴⁸ the Jain community is in a numerical minority in every State in India. Therefore, the instant case is certainly a fit case for the Central government to declare Jains as a religious

⁴⁵ *Bal Patil and Anr. v. Union of India and Ors* (2005)6 SCC 690, para 8.

⁴⁶ *Ratlam Municipality v. Vardhichand* AIR 1980 SC 1622 : (1980) 4 SCC 162. PROVIDE
Per Krishna Iyer, J. See also Hriday Narain v. ITO AIR 1971 SC 33 : (1970) 2 SCC 335. *Per Shah, J.*

⁴⁷ *Julius v. Lord Bishop of Oxford* (1880) 5 AC 214 : 49 LJQB 577. *Per Earl Cairns, LC* at page 225 (AC).

⁴⁸ Census of India 2001(Data On Religion).

minority taking *every* State as a unit. Consequently, the Jains will be afforded the status of a National Minority as is afforded to Muslims, Christians, Sikhs, Buddhists and Zoroastrians.⁴⁹

In the aforesaid circumstances, certainly the conditions existed for the power of the Central Government under section 2(c) of the Act to be exercised, and therefore the Central Government was imposed with the duty to exercise its power in a reasonable manner. The Central Government simply refused to exercise its power and the Supreme Court refrained from enforcing the duty of the Central Government.

This refusal serves only to confuse the situation further. The Central Government, in this situation, will not be certain whether or not it has the power to notify any other community as a minority, be it religious or linguistic. The ramifications of the Judgment in the *Bal Patil Case* are thus far-reaching and are likely to cause unnecessary misapprehensions in the minds of the lower judiciary, administrative authorities and the public at large.

In the circumstances, a review of the Judgment of the Supreme Court in the *Bal Patil Case* may allow for the correction of certain errors which appear to have inadvertently crept into the judgment and may prevent a manifest injustice from being caused to the Jain Community at large. The grounds for a review, both legal and factual, are, it is submitted, sufficient.

V. CONCLUSION

A significant area of the law relating to minorities and the protection granted to them under the Constitution is still in disarray. The Supreme Court has, through an Eleven Judge Bench, in the *TMA Pai Case* clarified some of the issues relating to Article 30. However, some issues, most notably the relationship between a notification under the *National Commission for Minorities Act, 1992* and Article 30 of the Constitution, remain unaddressed, or at least, unclear. An affirmative answer to the

⁴⁹ See Notification dated 23rd October, 1993, issued by the erstwhile Ministry of Welfare, now the Ministry of Social Justice & Empowerment. See also *Bal Patil and Anr. v. Union of India and Ors* (2005) 6 SCC 690, para 9.

question of the necessity of a notification for the purposes of Article 30 will lead to another, more fascinating question – whether or not the right to be notified should be read into Article 30 as a fundamental right of all members of a minority community. If, on the other hand, a notification is deemed not to be a *sine qua non* for enjoying the protection of Article 30, then it follows that like other fundamental rights, this right is vested in a person on his birth in a minority community and continues to so vest in that person until the community to which he belongs ceases to be a minority in the concerned State. This adds a very interesting dimension to the discussion on the issue and stresses the need for a definitive answer.

Moreover, further confusion has been caused by the Supreme Court giving contrary views on what the word ‘minority’ in the context of Article 30 implies. Whereas the majority view in the *TMA Pai Case* is that minority is solely numerical, and does not necessarily refer to underprivileged sections of society, the view expressed in the *Bal Patil Case* is that affluence and social standing must be taken into account while determining minority status. Clarity and uniformity in the views expressed by the Supreme Court on this aspect are also urgently required.

It is submitted that the divergence of judicial opinion on the issue of whether Article 30 confers protection or rights, and therefore what the criteria for determining minorities should be, is caused due to the different nomenclature under which rights normally associated as minority rights have been provided under the Constitution. These rights have been granted to all individuals. Article 30 is unique in its nature, and ought not to be associated with ‘minority rights’ as they are usually contemplated.

Various inconsistencies, both factual and legal in the Judgment in the *Bal Patil Case* merit reconsideration in review. The ramifications and complications created by the views expressed and the order made in the *Bal Patil Case* are grave, and will affect the rights of all minority communities, whether religious or linguistic and whether already notified or not.

An amendment to the *National Commission for Minorities Act 1992* and the *National Commission for Minority Educational Institutions Act, 2004* clarifying: firstly whether one notification is sufficient for both acts; and

secondly the nature and extent of the relationship between such a notification and Article 30 would go a long way in clarifying the matter.

However, a review alone will allow the Apex Court to consider all the issues raised and give a final and conclusive ruling thereon. Whether or not such a review will be preferred and entertained is the subject matter of conjecture, but the need for clarification on the various aspects of the law is as certain as the distinction between Hinduism and Jainism!

CONVERGENCE AND COMPETITION: RECONCILING DIFFERENCES[†]

*Gulnar Mistry**

I. INTRODUCTION

In May 2000, a Japanese author created a website providing content for mobile phones. A simple promotional campaign of handing out leaflets outside Tokyo's Shibuya Station was unexpectedly followed by the serialisation of his novel over SMS, leaving both traditional publishing houses and mobile content providers stunned.¹ This, the mobile novel, is but one of the manifestations of technological convergence. Accessing the Internet over cable systems is another, and carrying on conversations or broadcasting videos across cyberspace is yet another. All these point distinctly to a space where seemingly independent technologies are beginning to merge.

Rigid classifications of voice in radio, text in newspapers, data in microchips and images in video no longer exist. With the emergence of new technologies, such classifications are mere relics, rapidly giving way to digital highways where media and technologies congregate.

However, convergence comes not only in the form of melding of technologies but also the meeting of businesses. Where, two different providers using different technologies operate within the same sector, the merger of these two providers would result in the more profitable manipulation of an existing market. It is with reference to such business convergence that the important element of competition surfaces within the framework of convergence. With companies awakening to the prospect of becoming larger and stronger by simply putting their heads together,

[†] This article reflects the position of law as on 30 June 2006.

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¹ Richard Taylor, 'Japanese Comics Go Mobile' (2006) *BBC News*, at http://news.bbc.co.uk/2/hi/programmes/click_online/4840436.stm (last visited 18 June 2006).

the impetus to converge may eventually result in a set-back to fair trade where a bulk of the market is controlled by a handful of players and a slew of small-scale companies become the prey of an oligopoly. In India, with the increasing convergence of broadcasting and telecommunications, the creation and maintenance of a competitive and monopoly-free market remains a priority.

The International Telecommunication Union (ITU)² explains convergence as a technological, market or legal/regulatory capability to integrate across previously separated technologies, markets or politically defined industry structures.³ It is recognised by legislators that the continuous development of new technologies will result in an inability to predict how convergence will evolve, in the coming years. This particular unpredictability results in the need for flexible and accommodative regulation that provides for contingencies that may occur in the not-so-distant future.

This article proposes to examine the factors of convergence and competition, with an emphasis on the reciprocity of these factors, within the Indian framework. Part II provides a brief background of the telecom sector in India leading up to present-day developments and changing policies. Part III of this article analyses new legislation in the field of convergence, the resultant effect on competition and the interface between the two. Part IV deals with the fatality of differences in entry and access within a converged environment and the remedial measures that may be taken to ensure fairness and equality in the markets. Part V analyses the current powers of regulatory bodies and emphasises the need for clarity in the law as regards the differing jurisdiction of authorities. Part VI puts forth the possibility of successful reconciliation between the seemingly divergent ends of convergence and competition.

² The ITU was founded under the first International Telegraph Convention signed in Paris on 17 May 1865. It was established to standardise and regulate international radio and telecommunications and is one of the specialised agencies of the United Nations.

³ 'Regulatory Implications of Telecommunications Convergence - Chairman's Report of the Sixth Regulatory Colloquium' (11-13 December, 1996) ITU, at http://www.itu.int/itudoc/osg/colloq/chai_rep/sixthcol/37003.htm (last visited 12 August 2006).

II. TELECOMMUNICATIONS IN INDIA: A PARADIGM SHIFT

Traditionally, the telecom sector in India was a playground of state monopoly. TH Chowdhury points out that the Industrial Policy Resolution of the Government determined, as early as 1948, that both telecommunications and broadcasting should be under the monopoly, operation and ownership of the State.⁴ Two key elements were instrumental in the transition of the telecommunications sector from a government monopoly to a competitive structure—the restructuring of the government operator and the entry of private operators.⁵ Pushed into a veritable corner, the government liberalised television and radio broadcasting. Today foreign companies may hold up to 49% equity in internet service provider companies, FM radio stations have been relicensed, and private broadcasters can beam television programmes from across the globe.

The National Telecom Policy⁶ announced in 1994 specified the objectives of the reform in the telecommunication sector in India, being primarily the provision of quick and affordable access to basic telecom services to all. Although the 1994 policy was instrumental in accelerating private participation in the telecommunication sector, the poor design of auctions and conditions for licensing resulted in delays.⁷ In 1999 came the successor of the National Telecom Policy, aptly named the New Telecom Policy,⁸ that recognised that ‘provision of world class telecommunications infrastructure and information is the key to rapid economic and social development of the country.’

⁴ TH Chowdhury, ‘Revolutionary Changes and Conflicting Priorities in India’ in Mark Hukill *et al* (eds), *Electronic Communication Convergence-Policy Challenges in Asia* (1st edn Sage Publications India Pvt Ltd, New Delhi, 2000) 177.

⁵ Sidharth Sinha, ‘Competition Policy in Telecommunications: The Case of India’ ITU (November 2002), *available at* <http://www.itu.int/osg/spu/ni/competition/casestudies/india/India%20case%20study%202.pdf> (last visited 18 January 2006).

⁶ Department of Telecommunication, Government of India, *available at* http://www.trai.gov.in/TelecomPolicy_ntp94.asp (last visited 18 January, 2006).

⁷ TH Arun and FI Nixson, ‘The Transition of a Public Sector Monopoly: India’s Experience’ *Journal of International Development*, 10, 387-95 as cited in Thankom G Arun, ‘Regulation and Competition: Emerging Issues in an Indian Perspective’ (October 2003, Centre on Regulation and Competition, Institute for Development Policy and Management, University of Manchester), *available at* http://www.competition-regulation.org.uk/publications/working_papers/wp39.pdf (last visited 18 January 2006).

⁸ Department of Telecommunication, Government of India, *available at* http://www.trai.gov.in/TelecomPolicy_ntp99.asp (last visited 18 January 2006).

The New Telecom Policy was the first document to recognise the importance of convergence for the development of the Indian telecom sector, stating:

‘Convergence of both markets and technologies is a reality that is forcing realignment of the industry. At one level, telephone and broadcasting industries are entering each other’s markets, while at another level, technology is blurring the difference between different conduit systems such as wireline and wireless. As in the case of most countries, separate licences have been issued in our country for basic, cellular, ISP, satellite and cable TV operators each with separate industry structure, terms of entry and varying requirement to create infrastructure. However, this convergence now allows operators to use their facilities to deliver some services reserved for other operators, necessitating a relook into the existing policy framework.’⁹

The EU Green Paper on Convergence¹⁰ distinguishes the three different levels of convergence—technology convergence, industry convergence, and services and markets convergence. Where cable operators provide you with television in one room and Internet access in the other, it is based on the common application of digital technologies to systems and networks associated with the delivery of services and is an example of technological convergence. Industry convergence may be illustrated by alliances that build on the technical and commercial know-how of the partners in order to exploit new and existing markets such as the AOL-Time Warner mega-merger. Services and markets convergence results from cross-sectoral activity and technological innovation within given sectors; MTNL providing e-mail access through cell-phones is an illustration of services convergence.

⁹ *Ibid*, para 1.3.

¹⁰ European Commission, ‘Green Paper on the Telecommunications, Media and Information Technology Sectors, and the Implications for Regulation: Towards an Information Society Approach’ (1997), 8-10, available at <http://europa.eu/bulletin/en/9712/p102159.htm> (last visited 12 January 2006).

One of the many objectives of the New Telecom Policy is the creation of a modern and efficient telecommunications infrastructure taking into account the convergence of IT, media, telecom and consumer electronics. However, critics state that the recognition accorded to the convergence phenomenon has not been translated into policy formulation and the policy of 1999 despite being 'new' continues to 'look at the sector through a "non-convergent" lens.'¹¹ The current policy and regulatory framework is guided by the New Telecommunications Policy and the *Telecom Regulatory Authority of India Act, 1997*. Fulfilling the prediction of the Fali Nariman Committee that 'the impact of convergence upon regulation may be greater than the impact of regulation upon convergence',¹² the Communication Convergence Bill, 2001 (the Bill) was tabled in Parliament to accommodate the changing needs of the Indian environment.

III. COMPETITION IN THE TIME OF CONVERGENCE:

A BRIEF CONSIDERATION

A. Convergence Legislation

Convergence is coming about largely as a technological, social and economic phenomenon; be that as it may, it is not without legal and regulatory implications. The Bill was tabled in the Lower House of Parliament on 31 August 2001, evidencing recognition by Indian legislators of the fact that with technology converging there is in fact no option but for regulation to converge.¹³ It proposes, *inter alia*, 'to promote, facilitate and develop in an orderly manner the carriage and content of communications (including broadcasting, telecommunications and multimedia)'.¹⁴

¹¹ Sinha, *Supra* n. 5.

¹² See 'Report of the Sub-Group on Convergence' (2000) part IV, para 1.

¹³ 'Consultation Paper on Issues relating to Convergence and Competition in Broadcasting and Telecommunications', Telecom Regulatory Authority of India (02 January 2006), para 4.1.6, available at <http://www.trai.gov.in/trai/upload/ConsultationPapers/4/cpaper2jan06.pdf> (last visited 18 January 2006).

¹⁴ Communication Convergence Bill, 2001 (Long Title).

Intended to be a broad legislation, the Bill proposes to replace the *Indian Telegraph Act, 1885*, the *Indian Wireless Telegraphy Act, 1933*, the *Telegraph Wires (Unlawful Possession) Act, 1950*, the *Cable Television Networks (Regulation) Act, 1995* and the *Telecom Regulatory Authority of India Act, 1997*.¹⁵ The Bill also intends the establishment of a Communications Commission of India (Communications Commission). With effect from the date of such establishment, the Telecom Regulatory Authority of India (TRAI)¹⁶ and the Telecom Disputes Settlement and Appellate Tribunal (TDSAT)¹⁷ shall stand dissolved.

The provision of a choice of services to the people with a view to promoting plurality of news, views and information and the establishment of a regulatory framework for carriage and content of communications in the scenario of convergence of telecommunications, broadcasting, data-communication, multimedia and other related technologies and services is stated to be the focal point of the Bill.¹⁸ The objectives governing administration under the legislation emphasise the need for the communication sector to be developed in a competitive environment with necessary significance given to consumer interest, increasing access to information for greater empowerment of citizens and economic development.¹⁹ The Bill provides for a new licensing regime where the Communications Commission may grant a license to a person to provide a network of infrastructure facilities, networking services, network application services, content application services and value added network application services such as internet services and unified messaging services.²⁰

¹⁵ Communication Convergence Bill, 2001, clause 93(1).

¹⁶ The Telecom Regulatory Authority of India is the broadcast regulatory body established under section 3(1) of the *Telecom Regulatory Authority of India Act, 1997*.

¹⁷ The Telecom Disputes Settlement and Appellate Tribunal is the adjudicatory body established under section 14 of the *Telecom Regulatory Authority of India Act, 1997* to settle disputes relating to technical compatibility and interconnections, revenue sharing arrangements and quality of telecommunication services and interest of consumers.

¹⁸ *Supra* n. 15, Statement of Objects and Reasons.

¹⁹ *Supra* n. 15, clause 17.

²⁰ *Supra* n. 15, clause 26(4)(a) to clause 26(4)(e).

The possibility of the creation of monster corporations and the final demise of small providers is what makes convergence the proverbial double-edged sword. It is this possibility that requires competition authorities to step up regulation to promote fair play and harness the benefits of converged technologies to meet social needs.

B. Competition: The Other Side Of The Coin

The beginning of competition law in India came with the enactment of the *Monopolies and Restrictive Trade Practices Act, 1969* (MRTP Act). In the light of the changing environment in international trade and development in global markets, the MRTP Act was seen to have become, in a sense, obsolete. The 'natural corollary' of the opening up of the economy and the removing of controls was that the Indian market should be geared to face competition from not only within the country, but also outside it—the focus of competition law and policy therefore shifted from curbing monopolies to promoting fair competition.²¹

Published in the Official Gazette of India on 13 January 2001, only some sections of the *Competition Act, 2002* (the Act) are currently in force.²² The Act has been legislated, keeping in view the economic development of the country, to prevent practices having an adverse effect on competition and to promote and sustain competition in markets and ensure freedom of trade.²³

A report of the Organisation for Economic Co-operation and Development (OECD) suggests that in virtually all OECD countries (and it may be noted that this would be the case in India if both the statutes are simultaneously in force), both the national regulatory agency and the competition authority have some responsibility for controlling anti-

²¹ Report of High Level Committee on Competition Policy and Law (2000) para 1.2-2, available at <http://www.dca.nic.in/comp/contents.htm> (last visited 12 January 2006).

²² Sections 7-17, section 22, section 23, section 36, sections 49-65 are currently in force. While the MRTP Act continues to be on the statute books, it will be repealed and the MRTP Commission dissolved, upon the *Competition Act, 2002* coming into force completely.

²³ *Competition Act, 2002* (Long Title).

competitive behaviour in the telecommunications industry.²⁴ Competition authorities have also addressed a large number of concentrations in the telecommunications sector as newly liberalised companies seek to restructure and expand into the related markets of Internet service provision, cable television provision and other services such as Internet or multi-media content.²⁵

Within the extant regulatory framework, different services have different licenses and are governed by different agencies. With the adoption of the Bill may come an impetus to aggressive predation by companies which may, to cite a recognisable example, take the form of bundling masquerading as convergence. The potential for bundling to be anti-competitive was adequately evidenced in the case of *United States v. Microsoft Corp.*,²⁶ where Microsoft's technical and contractual bundling of the Internet Explorer browser with the Windows operating system was found to be anti-competitive and illegal. The self-explanatory term refers to the offering of two or more products together with a view to make them a more attractive buy than they would be individually. There are no provisions under the Bill that pre-empt bundling and the legality of its usage as a sales approach may be cause for concern.

While markets are there to be exploited, the right to so exploit ought to be available to all providers, large and small. An implicit recognition of the fact that converging technologies require adequately converged regulation would go a long way in providing appropriate safeguards for a changing situation.

C. *Convergence And Competition: The Blurring Of Boundaries*

In 1998, Herbert Ungerer of the European Commission Competition Directorate expressed his views (and concerns) on the effects of convergence on competition:

²⁴ 'Competition and Regulation Issues in Telecommunications', Organisation for Economic Co-operation and Development, Directorate for Financial, Fiscal and Enterprise Affairs Competition Committee, (February 2002), 8, available at <http://www.oecd.org/dataoecd/48/39/1834399.pdf> (last visited 18 January 2006).

²⁵ *Ibid.*, 11.

²⁶ 87 F Supp 2d 30 (DDC 2000).

‘Convergence is driving infrastructure provision but it is also defining the future bottlenecks... . We have liberalised to allow innovation. Convergence can now not mean the creation of new super-monopolies - and this danger is very real. It is the immediate question underlying most current competition cases in the area... . The innovation capacity of the sector - and its attractiveness for investment - will therefore depend on our ability to maintain competitive conditions into the new world of convergence and the Internet. Convergence of markets must mean more actors and investors - and not less.’²⁷

The language of the Bill emphasises the importance of a competitive environment and fair, equitable and non-discriminatory access. However, this ideal is set off against the fact that under the Bill, as it stands, the Communications Commission may grant a license to any person for a gamut of services. In light of this, it is imminently possible that there comes a single largest provider of all services. Now: this mega-provider can, at least theoretically, provide you with a phone line at home, a cell phone when you are outdoors, television programs when you are idle, radio when you are driving and the Internet when you are curious. While it is far from mandatory for a single consumer to subscribe to all services from the same provider, it may be more convenient to do so. One could get a phone line from Mumbai Telephone Nigam Limited (MTNL), a cell phone connection from Hutch, a broadband connection from Hathway, and so on, but as for the question of how a monopoly could easily be created, the answer lies in the burgeoning phenomenon of ‘buy one, get one free’. If one were offered three or even all five services by the same service provider in a brilliant package deal, any concerns regarding the eventual creation of a monopolistic market would most likely dissipate in the fact of added convenience and savings.

²⁷ Herbert Ungerer, ‘Beating the Band-Width Bottleneck’ (14 May 1998, Paris), *available at* http://europa.eu.int/comm/competition/speeches/text/sp1998_017_en.html (last visited 18 January 2006).

Henry Jenkins rightly points out the ‘conflicting goals’²⁸ of consumers (you and I), producers (service providers, telephone companies) and gatekeepers (bodies like the Communications Commission that are required to fulfil their statutory mandate). While consumers seek the best services at the lowest prices and producers seek (among other things) the betterment of market position and sales, regulatory bodies must strike a balance between consumer interest and public policy.

Within the framework of the law, the implications of a converged system of communication and broadcasting on competition and free market are being seen to be increasingly complicated. Indeed, the ability of a single company to provide several services under the statute raises important issues for the development of competition more generally. As stated by Katz and Woroch, at the most fundamental level, convergence raises the issue of whether competition will develop and what form it will take. It is to be considered as to whether convergence will drive competition, or promote industry consolidation and create the need for additional regulation.²⁹

IV. A LEVEL PLAYING FIELD: REQUIRED PRE-CONVERGENCE CHANGES

Concerns regarding competitiveness in a post-convergence Indian market remain, but they do not take away the need to establish a common framework prior to such convergence. One of the necessities of facilitating competition in a converged environment is to provide a universal starting point, one which does not result in some sectors being immediately placed on the back foot and others being given an unfair advantage. The Consultation Paper released by TRAI rightfully pays due attention to the problems of imperfect competition, stating that regulatory issues should not be a hurdle in technological developments; at the same time, a provider of a given technology should not be allowed to take advantages of regulatory loopholes such that it affects the level playing field.³⁰ Different

²⁸ Henry Jenkins, ‘Convergence? I Diverge.’ (June 2001), *Technology Review* (Massachusetts Institute of Technology) 93.

²⁹ Michael A Katz and Glenn A Woroch, ‘Convergence, Competition and Regulation’ (1998) *University of California, Berkeley* (1998) available at <http://groups.haas.berkeley.edu/imio/crtp/publications/workingpapers/wp46.PDF> (last visited 18 January 2006).

³⁰ *Supra* n. 13, para 4.

regulation for different sectors may lead to imperfect competition—a regulatory regime that discriminates on account of technology used or services offered will result in bottlenecks in the growth of industry.

In a particular field there may be different technologies which, though providing the same service, are treated differently within the regulatory framework. For instance, voice communication via the mobile phone could employ several alternate technologies such as the analog Advanced Mobile Phone System (AMPS), the digital Global System for Mobile Communications (GSM) or the Wireless Local Loop (WLL). In India, the WLL technology is operational within small areas (each known as a short distance charging area or SDCA) providing users with limited mobility only within the SDCA. GSM technology, on the other hand, is functional across large territories and provides international connectivity.

While the Department of Telecommunications considered allowing full mobility to basic service operators (BSOs), it was seen that with such a move there would be no differentiation in mobile services offered by BSOs and those offered by cellular mobile telephone service operators (CMTSOs) in a circle where both were in business. The financial terms and conditions of licensing of BSOs and CMTSOs being radically different as regards revenue sharing, entry fees, interconnection/access charges, spectrum charges and tariff, the discrepancies were seen to open up a number of issues relating to competition as well as policy concerns relating to convergence.³¹ It can, therefore, be seen how the convergence of diverse technologies could allow providers who pay lower license fees to operate in the same field as others who are required to make higher payments resulting in iniquitous discrepancies.

The discrepancy between the two technologies is not, therefore, technological; it is merely a regulatory restriction imposed to allow fair competition. For instance, several WLL operators have been carrying on

³¹ *Telecom regulatory authority of India* 'Consultation Paper on Policy Issues Relating To Limited Mobility By Use Of Wireless In Local Loop Techniques In The Access Network By Basic Service Providers' part IV (2000) 13, available at <http://www.trai.gov.in/trai/upload/consultationpapers/si/recom1liv.pdf> (last visited 22 September 2006)

their businesses in blatant violation of license conditions. Reliance Communications, for instance, claims to provide roaming services across 673 cities across India—while it is impressive advertising, such an operation is clearly in violation of the license for WLL service which mandates that mobility is to be limited to a SDCA alone.³²

Different limits for foreign direct investment (FDI) in different industries also grants an unfair advantage to certain technologies and service providers over others, even though the end service being provided to the consumer is the same and therefore, such differing limits are fundamentally inconsistent with any move towards convergence. The FDI limits differ greatly across sectors, applications and technologies resulting in unfair, albeit unintended, distortions.

The Consultation Paper puts forth clear examples where it can be seen that when a single enterprise can offer different services with different technologies (either through the use of the same infrastructure or through a combination of business models), a divergent regulatory framework will throw up opportunities for exploiting these differences or, alternatively, will thwart the introduction of new technologies and services.³³ For example, delivery of television signals through satellite based technology has a FDI limit of 20%, while the same product when delivered through cables attracts an FDI cap of 49%. FDI of up to 100% is permitted in the case of Internet Service Providers (ISP) and 74% is permitted in the case of telecommunications.³⁴

Stating that despite the fact that the cable industry and telecom industry are vastly different in terms of their size, entry fees and technology, where they perform similar services, both ought to be treated identically, TRAI recommended that changes in customs duties should be made to promote effective competition among telecom and cable operators.³⁵ Rationalisation

³² Nanda Kasabe, 'BSNL and Reliance on the warpath' (2003) *CIOL IT Limited*, at <http://www.ciol.com/content/news/2003/103073105.asp> (last visited 30 June 2006).

³³ *Supra* n. 13, para 4.1.7.

³⁴ 'Recommendations on Issues Relating to Convergence and Competition in Broadcasting and Telecommunications', Telecom Regulatory Authority of India (20 March 2006), 61.

³⁵ *Ibid*, 33.

of customs duty will also be required in order to ensure a common starting point for all sectors and technologies. There are currently in force different customs regimes in telecom and cable TV network providing broadband services. Despite performing similar functions, the equipment used for providing broadband over cable attracts much higher custom duty than equipment used in telecom networks such as DSL, fibre or Ethernet. Consequently, due to the differential rates of duty, internet services providers offering broadband over cable TV networks are at a disadvantage in comparison to their counterparts who are using different infrastructure.³⁶ TRAI has recommended that items should accordingly be reclassified and duty structures made identical.³⁷

A recent development foretelling a further growth of telecom services is Reliance Communications approaching the government seeking a license to start provision of GSM services in addition to its CDMA presence. If the application is considered favourably, the company will get 5 mhz of spectrum in 1800 mhz and have the option to operate in both technologies simultaneously, a move that could hurt many other aspirants of additional frequency.³⁸

Integration across key technologies raises the potential for anti-competitive behaviour as exponentially as it does growth. A level playing field may be achieved by correcting anti-competitive denial of access and by providing equal opportunities once access is granted.

V. MERGING OF REGULATORY MECHANISMS

A. Role Of The Regulators

While the merging of industries and technologies gains momentum, the necessity of different regulatory mechanisms immediately comes into question. For example as in the case of, FDI caps, different limits pose a problem as to how far the environment for setting up industries is truly

³⁶ *Supra* n. 13, para 4.1.

³⁷ *Supra* n. 13, para 5.1.

³⁸ 'Reliance Communications to start GSM services' *Economic Times*, (New Delhi India 11 June 2006), available at <http://www1.economictimes.indiatimes.com/articleshowicicinri/1637244.cms> (last visited 30 June 2006).

competitive. Similarly, the existence of different regulators for different spheres raises issues as to overlapping jurisdiction and duplicative regimes. The Bill contemplates a single regulatory body that would cover all aspects of telecommunication and broadcasting, including spectrum management and licensing (functions that are hitherto being executed by the Government). As the Bill has not yet been passed by Parliament, and considering the absence of a statutory framework, TRAI recommended the introduction of a Unified Licensing Regime. Currently, TRAI is the regulator for carriage of telecom and broadcasting services. In the event that the Bill is passed, the regulatory mechanism could be seen to be divided between two institutional regulatory bodies—Communications Commission and the Competition Commission of India.

The Communications Commission proposed to be established under the Bill shall be required, in the exercise of its functions, to observe certain objectives and guiding principles, including the development of the communication sector in a competitive environment, in consumer interest and for the promotion of equitable, non-discriminatory interconnection across various networks.³⁹ The duties of the Communications Commission include ensuring that the grant of license or registration does not result in the elimination of competition or the dominance of one or more service providers to the detriment of other providers or consumers, and promoting competition and efficiency in the operation of communication services and network infrastructure facilities.⁴⁰ The Competition Commission of India (the Competition Commission)⁴¹ established under the Act has for its duties the elimination of practices having an adverse effect on competition, the promotion and sustenance of competition, and the protection of interests of consumers and freedom of trade carried on by participants in markets in India.⁴²

On a cursory examination of the legislation, it would appear that the Competition Commission and the Communications Commission would

³⁹ *Supra*, n. 15, clause 17(i) and clause 17(viii).

⁴⁰ *Supra*, n. 15, clause 18(2)(iv) and clause 18(2)(v).

⁴¹ *Competition Act, 2002*, section 7.

⁴² *Ibid*, section 18.

both have jurisdiction with regard to the promotion and maintenance of competition in the sphere of convergence of communication industries.

Under section 14 of the *Telecom Regulatory Authority of India Act, 1997* (still in force), the TDSAT has the power to adjudicate a dispute between a licensor and a licensee, or two or more service providers, or between a service provider and a group of consumers, subject to the proviso that such power shall not extend to matters relating to monopolistic trade practice, restrictive trade practice or unfair trade practice which matters remain within the jurisdiction of the MRTP Commission. The Bill does not contain a similar provision and in its current form provides no reference to the Competition Commission or any deference to its jurisdiction insofar as issues pertaining to competition law emerge within the framework of its own jurisdiction.

In the event of a merger of two telecommunication or broadcasting companies, either body could have jurisdiction in determining the possible anti-competitive consequences of such a merger. While this consideration remains hypothetical, it is so only for the time being. Observing that the benefits of consolidation are manifold, businesses operating in the field of telecom may collaborate successfully in a post-convergence environment; in such a case, the ambit of the two regulators would clearly over-lap. Such an eventuality would result in a significant sub-set of competition and convergence cases. In the absence of exclusive jurisdiction being conferred on one of the two bodies, suits could be filed by opposing parties in both fora. To take the hypothesis a step further, there is a possibility of there being two concurrent judgments by different bodies on the same facts; to take it further still, the judgments in question may be contradictory. In such an event one can presume that the result would be protracting litigation further into the appeal stage where the jurisdiction of both specialised regulators would give way to the usual channels of state judiciary and finally, the Supreme Court.

Given the patent futility of such a situation, it is essential that the same be taken into consideration, and the fallacy of twin jurisdictions resolved, prior to the passing of the Bill by the Legislature.

B. *The Legislative Interface: International Responses To Convergence And Competition*

Boies writes in his *Public Control of Business*⁴³ that the interface between anti-trust and regulation is a veritable no-man's land. Direct economic regulation, entrusted to agencies rather than courts, may supplant anti-trust laws and specific industries for carefully carved-out purposes; but at the edges, these purposes thin out and the anti-trust laws inevitably reappear in the background. At this point, says Boies, it is no small matter to blend the policies of the two conflicting regimes into an overall regulatory purpose that preserves the values of both. International responses to the challenges brought on by technological transformations are worth considering.

The US model may be viewed as a diametrical opposite of India in the inception and growth of competition in its telecommunications sector. To begin with, the telecom industry in the United States was never nationalised. The American Telephone and Telegraph Co. (AT&T) was the single largest provider of telecommunications services, its dominance aided by regulatory policies that pointed to a 'natural monopoly' as the most cost-effective structure for network-based utilities.⁴⁴ The creation of the Federal Communications Commission (FCC) by the *Communications Act, 1934* preserved the 'regulated monopoly' paradigm.⁴⁵ Compounding the problem of a monopoly was the question of legislating for fifty states from Alabama to Wyoming; a question which pointed to the most obvious solution: a national legislation for all the states, the *Telecommunications*

⁴³ David Boies, *Public Control Of Business* (Little Brown Boston 1977) as cited in Tom Sharpe, 'Concurrency or Convergence? Competition and Regulation under the Competition Act, 1998', in Colin Robinson (eds) *Utility Regulation and Competition* (2006) Institute of Economic Affairs, 164, available at <http://www.iea.org.uk/record.jsp?ID=19&type=article> (last visited 30 September 2006).

⁴⁴ Martin I Hamburg and Stuart N Brotman, *Communications Law and Practice* (New York Law Journal Seminars Press 1995), 1.24.

⁴⁵ John Alden, 'Competition Policy in Telecommunications: The Case of The United States of America' ITU (November 2002), available at [http://www.itu.int/osg/spu/ni/competition/casestudies/us/us_case_study.pdf#search=Competition Policy in Telecommunications3ATheCase of The United States of AmericaE280992C2022](http://www.itu.int/osg/spu/ni/competition/casestudies/us/us_case_study.pdf#search=Competition%20Policy%20in%20Telecommunications3ATheCase%20of%20The%20United%20States%20of%20AmericaE280992C2022) (last visited 30 September 2006).

Act of 1996⁴⁶ which replaced the *Communications Act* of 1934⁴⁷. In retrospect, it may appear that the *Telecommunications Act* itself laid the foundations of convergence by allowing companies in distinct industries to compete with one another. Telephone companies were given four alternatives for providing competition to cable service within their franchised areas; conversely, cable operators were allowed to offer telephone service in their franchise areas. Long-distance carriers and others were permitted to enter the local telephone market, and large electric utilities were freed to enter the telephony business.⁴⁸ However, the *Telecommunications Act* has been faced with critics who contend that the statute does not adequately address the current convergence and technological changes.⁴⁹ The United States Congress enacted the statute to address two structural issues of 'technological convergence and legal balkanization', assuming that technological innovation is better fostered in the environment of converging media than through to isolated innovation within particular media.⁵⁰ While bearing in mind the two-sides-of-one-coin situation of competition and convergence, the *Telecommunications Act* brought in its wake a wave of unparalleled consolidation. Ironically, says Mouritsen, Congressional intent to encourage new technological development has in many cases led to this atmosphere of unparalleled mergers; in lieu of developing new technology, many organizations have gained a market share by merging with or acquiring companies which have expertise in areas they need, such as the merger of US West and Continental Cable, while others have simply merged to outdistance competitors by size advantage, as in the case of Bell Atlantic merging with Nynex.⁵¹

⁴⁶ Pub. L. No. 104-104, 110 Stat. 56.

⁴⁷ 48 Stat. 1064.

⁴⁸ Richard E Wiley and Jeffrey S Linder, 'Assessing the 1996 Act: Trends and Tribulations in Telecom' (1999) *CCH Power and Telecom Law*, available at http://www.wrf.com/publication.cfm?publication_id=11586 (last visited 30 September 2006).

⁴⁹ Angele A Gilroy, 'Communications Act Revisions: Selected Issues for Consideration' (January 2006) Congressional Research Service, The Library of Congress, available at [http://fpc.state.gov/documents/organization/60576.pdf#search=22Communications Act Revisions3A Selected Issues for Consideration](http://fpc.state.gov/documents/organization/60576.pdf#search=22Communications%20Act%20Revisions3A%20Selected%20Issues%20for%20Consideration) (last visited 30 September 2006).

⁵⁰ Russel H Mouritsen, 'Telecommunications Act of 1996: Relations to Functional Theory' (2002) *Electronic Journal of the American Association of Behavioural and Social Sciences*, at <http://aabss.org/journal2002/Mouritsen.htm> (last visited 30 September 2006).

⁵¹ *Ibid.*

As is clear from the international experience, competition policy frameworks overlap significantly. Sector-specific legislation and general antitrust law ought to operate in tandem. The Seventh Circuit Court of Appeals stated in the case of *Richard Goldwasser, et al v. Ameritech Corp*, a class action lawsuit where it was argued that Ameritech, a Bell company, had violated both the *Telecommunications Act* and the *Sherman Act*,⁵² that ‘the question that confronts us here is how and where these two competition-friendly regimes intersect.’⁵³ In *Goldwasser*, 17 out of 20 specific allegations cited specific provisions of the *Telecommunications Act*. Affirming the judgment of the lower court, the Court of Appeals held that the plaintiffs had failed to allege any antitrust claim independent of violations under the *Telecommunications Act* and that the ‘more specific legislation must take precedence over the general antitrust laws, where the two are covering precisely the same field’.⁵⁴ This appeared to give the sector-specific *Telecommunications Act* precedence where it overlapped with claims under the more general antitrust laws. However, in subsequent cases, such as *Law Offices of Curtis V Trinko, LLP v. Bell Atlantic Corp* the courts stated that unless there was a ‘plain repugnancy... we will not assume that a regulatory statute implicitly repeals the antitrust laws.’⁵⁵ The position of law elucidated in *Goldwasser* – that the *Telecommunications Act* precluded the making of separate antitrust claims covering the same violations – was therefore modified.⁵⁶

In the United Kingdom, regulation in the age of convergence followed an evolutionary pattern where the ‘false choice’ between breaking down or maintaining the existing regulatory structures was reconciled to gradually encompass the changes taking place. The Green Paper of the Department of Trade and Industry discussed the emerging challenges to

⁵² 26 Stat. 209 (1890).

⁵³ 222 F.3d 390 (7th Cir. 2000) at 391.

⁵⁴ 222 F.3d 390 (7th Cir. 2000) at 401.

⁵⁵ 294 F.3d 307 (2002).

⁵⁶ Alden, *Supra* n. 45.

regulation and set out the UK government's approach to the regulatory issues arising from convergence and states:

'We will work with the regulators to ensure that they co-operate to manage overlaps and anomalies. Where those problems cannot be solved by regulators operating within the current legislative framework, we will, if necessary, amend the legislation on a case-by case basis in advance of possible wider change. The first requirement is to provide greater coherence in economic regulation across all digital delivery media and all parts of the converging value chain... . The regulators and competition authorities (OFTEL, ITC, OFT and DTI) are committed to working together closely on matters affecting the converging sectors, and have announced the establishment of a co-ordinating group... . Secondly, it is essential to reassess the present regulatory distinctions based solely on the method of delivery to the consumer, and to take steps to provide greater consistency in the regulation of similar material delivered via different mechanisms.'⁵⁷

In the overlapping areas of convergence and competition, legislation in the UK provides for greater pro-competition authority across the economy, and converging sectors have been paralleled by a converged principle regulator, the Office of Communications (Ofcom), that currently implements both regulatory policy as contained in the *Communications Act, 2003* and competition law enshrined in the provisions of the *Competition Act, 1998* and the *Enterprise Act, 2003*.

The European Union's response to the changes attending convergence came in the form of an EC Framework Directive, recommending a common regulatory regime for electronic communications networks and services.⁵⁸ The Framework Directive is one of a five-part legislative

⁵⁷ Department of Trade and Industry and Department for Culture Media and Sport, United Kingdom, 'Regulating Communications: Approaching Convergence in the Information Age – A Green Paper' November 1998, available at [http://www.culture.gov.uk/NR/rdonlyres/2DE796D3-CDA5-4B2B-B779-5C06883697EE/0/Regulating communications convergence.pdf](http://www.culture.gov.uk/NR/rdonlyres/2DE796D3-CDA5-4B2B-B779-5C06883697EE/0/Regulating%20communications%20convergence.pdf) (last visited 30 September 2006).

⁵⁸ Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive).

package⁵⁹ aiming to make the electronic communications sector more competitive, while also providing an adequate response to the convergence of technologies and the need for horizontal regulation of all infrastructure thereby making it the best example of the convergence of competition law and regulation.

C. *Regulatory Bodies: A Comparative Analysis*

Legislation in India in the field of both competition and convergence is in its nascent stages and in consideration of the Bill not having been passed and Communications Commission not having been established yet, the attendant difficulties of jurisdiction remain in the realm of hypothesis. However, a reference may be made to countries where such regulatory bodies have already been set up and are functioning side by side.

In most countries, the distinction lies between the application of industry-specific regulation versus application of generic competition law. Cowie and Marsden⁶⁰ in their analysis of different institutional approaches of developed countries have examined the degree of flexibility, efficiency in enforcement and transparency in specific and generic approaches. Australia, where the Australian Competition and Consumer Commission (ACCC) has responsibility for the application of general competition law to ensure that there is no undue restriction of competition in the communications industries, lies at the forefront of de-regulatory policy in

⁵⁹ In addition to the Framework Directive, the current regulatory framework in the European Union includes the following: (i) Directive 2002/20/EC of the European Parliament and of the Council of 7 March 2002 on the authorisation of electronic communications networks and services (Authorisation Directive); (ii) Directive 2002/19/EC of the European Parliament and of the Council of 7 March 2002 on access to, and interconnection of, electronic communications networks and associated facilities (Access Directive); (iii) Directive 2002/22/EC of the European Parliament and of the Council of 7 March 2002 on universal service and users' rights relating to electronic communications networks and services (Universal Service Directive); and (iv) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications).

⁶⁰ Campbell Cowie and Christopher T Marsden, 'Convergence Competition and Regulation' *International Journal of Communications Law* (6-1-1998).

the communications sector. In the United States, the FCC is a unified regulatory body responsible for regulating interstate and international communications by television, telecommunications and radio. In the United Kingdom, the Independent Television Commission (ITC) regulated commercial television (except the British Broadcasting Corporation) and the Office of the Telecommunications Regulator (Oftel) regulated telecommunications services, while competition policy was addressed by the Office of Fair Trading (OFT) and the Monopolies and Mergers Commission (now the Competition Commission). Currently, the UK has united five existing regulatory bodies dealing with communications into one regulator, Ofcom.⁶¹ Regulation of telecommunications could also take the form of multi-sector regulation, where telecom is joined together with other infrastructural utilities such as energy, water and transport.

In India, the Competition Commission has the power to enquire into anti-competitive agreements, abuse of dominant position and regulation of combinations, having regard to factors such as relevant market and turnover.⁶² Section 5 of the Act defines a combination as the acquisition of one or more enterprises by one or more persons, or a merger or amalgamation of enterprises if such a combination leads to a resulting enterprise or group holding assets or turnover greater than the stipulated threshold limits.⁶³ Section 6 of the Act prescribes that a combination which causes or is likely to cause an appreciable adverse effect on

⁶¹ The Ofcom is the super-regulator for media and communications in the United Kingdom and has replaced five existing industry regulators - the Radiocommunications Agency, the Broadcasting Standards Commission, the Independent Television Commission, the Radio Authority and OfTel.

⁶² Competition Act, 2002, chapter II.

⁶³ Section 5 classifies combinations as anti-competitive on the basis of acquisition of control, shares, voting rights or assets. For instance, a merger or amalgamation where the resultant enterprise has either, in India, assets of a value of more than rupees one thousand crores or turnover more than rupees three thousand crores or, in India or outside India, in the aggregate, the assets of a value of more than five hundred million US dollars or a turnover of more than fifteen hundred million US dollars will be considered a 'combination'. Further, if such a combination is found to have an adverse effect on competition in India, it will be declared void.

combination within the relevant market in India shall be void. In India, under the provisions regulating combinations, any person or enterprise that proposes to enter into a combination may give notice of the same to the Competition Commission disclosing the details of the proposed combination within seven days of approval of the proposal relating to the merger or amalgamation or the execution of any agreement or other document for acquisition.⁶⁴ It may be noted that these provisions do not apply to share subscription or financing facility or any acquisition by financial institutions pursuant to any covenant of a loan agreement or investment agreement.⁶⁵ Originally, the Report of the High Level Committee recommended that pre-merger notifications be made mandatory under the Act; provisions of the proposed legislation were, however, considerably diluted in the face of industry opposition. The Indian legislation is, here, in sharp contrast with both US and EU laws that require pre-merger scrutiny.

Competition law in India is not limited to transactions that occur within Indian territory as the Competition Commission has the right to enquire into acts taking place outside India but having an appreciable adverse effect on competition in the relevant market in India.⁶⁶ Stringent penalties are imposed for contravention of the orders of the Competition Commission.⁶⁷ On the other hand, the Convergence Bill provides for penalties pertaining only to offences relating to, *inter alia*, abuse of infrastructure facilities and communication services, and possession of wireless equipment.⁶⁸ While providing effective deterrence against unlicensed use of infrastructure facilities and communication services, the Bill remains silent on the question of jurisdiction over issues relating to competition. Penalties as regards anti-competitive practices within the ambit of a converged industry lie far beyond the scope of the Communications Commission.

⁶⁴ *Supra*, n. 41, section 6(2).

⁶⁵ *Supra*, n. 41, section 6(4).

⁶⁶ *Supra*, n. 41, section 32.

⁶⁷ *Supra*, n. 41, chapter VI.

⁶⁸ *Supra*, n. 15, chapter XVI.

Therefore, two possible regulatory alternatives may emerge in India. On the one hand, considering the scope of the Competition Commission, it may be ideal to allow convergence legislation to withdraw in favour of competition law ie allow the Competition Commission sole jurisdiction to deal with anti-competitive matters. Therefore, license conditions under convergence law may be applied where there is a positive need to promote competition while competition law may be applied to police anti-competitive behaviour. Alternatively, the existing regulators could be converged into a single super-regulator along the lines of the UK's Ofcom.

D. Extent Of Government Intervention

Under the Bill, powers of appointment and removal of members of the Communications Commission rest with the Central Government; in addition, clause 22 of the Bill requires that the Communications Commission follow such policy directives as may be communicated to it by the Central Government, which may include the procedure and mode in which services are to be licensed or registered by way of auction or in any other form. The decision of the Central Government as to whether a question is one of policy or not shall be final.

The regulator is itself subject to the supervision of a higher authority, which could potentially result in the dilution of its powers and the sidelining of its authority. Whether there exists more than a single regulatory body to govern businesses or not, it is essential that such regulatory body (or bodies) be allowed sufficient autonomy in the exercise of its powers and functions. The question of the independence of the regulator, therefore, still remains.

VI. THE MARRIAGE OF CONVERGENCE AND COMPETITION: RECONCILABLE DIFFERENCES

While it may appear that competition and convergence are diametrical opposites, that need not necessarily be the case. The apparent mutual exclusivity of conjoined businesses on the one hand and sustained competition on the other can give way to a balance that can be brought about successfully through the medium of law. The goal of legislation at

the meeting point of convergence and competition ought to be the creation of an equilibrium where the scales do not tilt radically to either side.

Hirsch and Peterson assert that while competition rules emphasise public interest in discouraging unfair distortions, uneven development and unacceptable domination by a few players, liberalisation and globalisation favour the replacement of public service monopolies with private monopolies.⁶⁹ In the final analysis, monopoly may not be a very distant circumstance of convergence of different sectors. The attendant consequences are significant, both for the maintenance of a level playing field as well as public interest and policy.

A. Consequences For Competition

Convergence is resulting in an interactive gestalt where forces combine and synergise to create a resultant effect that is greater than their individual capacities. In her *No Logo* (a book referred to as the bible of anti-corporate militancy), Naomi Klein poses an incisive question: '[W]hat else is a monopoly, after all, but synergy taken to the extreme?'⁷⁰ Large corporations with dominant positions are more than capable of driving out smaller players; while competition law in India provides for safeguards against abuse of dominant position, one cannot help but wonder if the provisions of the Bill leave the door open for such an undesirable contingency.

Clause 16 of the Bill provides that the Communications Commission may, for the purpose of ensuring competition and prevention of monopoly, by regulations specify, *inter alia*, restrictions on ownership and control of the media⁷¹ and restrictions on the number of licenses or extent of accumulation of interest in such licenses by a person.⁷² The powers granted under this clause ought to be exercised without reserve and without regard

⁶⁹ Mario Hirsch and Vibeke G Petersen, 'European Policy Initiatives' in Denis McQuail and Karen Siune (eds) *Media Policy: Convergence, Concentration & Commerce* (Sage Publications Ltd London 1998) 207.

⁷⁰ Naomi Klein, *No Logo* (Flamingo Great Britain 2000) 161.

⁷¹ *Supra*, n. 15, clause 26(1)(ii).

⁷² *Supra*, n. 15, clause 26(1)(iii).

⁷³ 'Consultation Paper on Mobile Number Portability' *Telecom Regulatory Authority of India* (22 July 2006), available at <http://www.trai.gov.in/trai/upload/ConsultationPapers/7/conpaper22jul05.pdf> (last visited 18 January 2006).

to lobbies. In its Consultation Paper on Mobile Number Portability,⁷³ TRAI recommended, as a measure to facilitate competition and promote efficiency, that subscribers be enabled to retain their original telephone number while switching between services, locations or operators and without compromising on quality, reliability, and operational convenience; the move has been strongly contested by service providers. Measures to control concentration of ownership and promote competition must be enforced strictly and the same ought not to be stalled due to commercial considerations.

Trappel and Meier⁷⁴ state that different countries exhibit different models of media ownership restriction:

1. Restrictions On Individual Ownership

Limits may be set as to the capital controlled by one person or enterprise. In certain countries, the maximum financial participation of a single shareholder in a company is clearly stipulated under law. For instance, in France, any legal person cannot own (directly or indirectly) more than 49% of the capital or voting rights of a company holding a national television service.

2. Restrictions On Individuals/Groups

Specific restrictions may be imposed on individuals or companies. For instance, in Denmark, companies from outside the media sector, with the exception of publishers may not exert 'dominant influence' on local radio and television stations.

3. Restrictions On Foreign Capital

In order not to lose control of their own media systems, some countries restrict investment by foreign capital. Such is the case in the United Kingdom, where any applicants for broadcasting licenses have to be resident nationals or a European Economic Area member state.

⁷⁴ Josef Trappel and Werner A Meier, 'Media Concentration: Options for Policy' in Denis McQuail and Karen Siune (eds) *Media Policy: Convergence, Concentration & Commerce* (Sage Publications Ltd London 1998) 191.

If we are to guard against unfair practices, it is essential that dominant players not be allowed to thwart competition from the very outset. Adequate provisions are required to be made to protect against the dangers of over-concentration.

B. *Plurality And Synergy: One Or The Other?*

Linked closely to the considerations of convergence and competition is the question of control, of markets and of minds. Klein observes, 'When any space is bought, even if only temporarily, it changes to fit its sponsors. And the more previously public spaces are sold ... the more we as citizens are forced to play by corporate rules to access our own culture.'⁷⁵ The phenomenon of media convergence while creating economies of scope and scale also begs the question not only of the future of competition, but that of diversity (and, indeed, divergence) of opinion.

Valcke states that the market alone never guarantees diversity and further, that allowing market forces free rein seemingly leads to vertical integration and concentration of media ownership, demonstrated by the radical reduction in the number of daily newspapers in the period following World War II and commercialisation of the audio-visual sector by the end of the 1980s leading to the appearance of 'media tycoons'.⁷⁶ A third wave of alliances is now caused by the increasing convergence between the telecommunications, media and information technology sectors, making carriers and content providers realise that in order to be successful they must pursue alliances, mergers and joint ventures with their former competitors.⁷⁷

In the case of *Secretary, Ministry of Information and Broadcasting, Government of India and Others v. Cricket Association of Bengal and Others*, the Supreme Court made the following salutary observations:

'The right of free speech and expression includes the right to receive and impart information. For ensuring the free speech right

⁷⁵ Klein *supra* n. 70.

⁷⁶ P Valcke, 'Liberalisation and Convergence in the Information Market: The Consequences for Competition Law' (1999,'icri' available at <http://www.law.kuleuven.ac.be/icri/projects.php?projectid=41&where=cl> (last visited 18 January 2006).

⁷⁷ *Ibid.*

of the citizens of this country, it is necessary that the citizens have the benefit of plurality of views and a range of opinions on all public issues. ... Diversity of opinions, views, ideas and ideologies is essential to enable the citizens to arrive at informed judgment on all issues touching them. This cannot be provided by a medium controlled by a monopoly – whether the monopoly is of the State or any other individual, group or organisation.⁷⁸

Convergence of different fora could lead to the homogenisation of content and cross-media monopolies. Easy dismissal of concerns relating to dissemination of information and media control cannot be tolerated. The importance of plurality and diversity of views is aptly recognised by legislators in the drafting of the Bill and by the judiciary in previous judgments. In the event that the Bill finds its way as law, the importance of this principle ought not to be surpassed.

VII. CONCLUSION

By expressing concern about the future of free competition, markets, producers and consumers in the age of convergence, is one no more than a fist-biter? By predicting the creation of monster corporations and the side-lining of others, is one just a failed prophet of doom, or worse, merely reactionary? Suitable mechanisms are required to protect against excessive consolidation and the tyranny of sheer size. The need for flexibility and fairness in regulation remains important in our times, for regulation by old laws of new possibilities would result in an undesirable lacuna.

Legal and regulatory challenges in the era of convergence exist. These challenges are to be met and, if met satisfactorily, the benefits of reconciliation are manifold. As stated, quite emphatically, by Jenkins, 'We need to find ways to negotiate the changes taking place. No one force can set the terms. No one group can control access and participation.'⁷⁹

⁷⁸ AIR 1995 SC 1236.

⁷⁹ Henry Jenkins, 'Welcome to Convergence Culture' *Receiver Magazine*, Issue 13 (Vodafone Group, 2005).

CORPORATE-UNIVERSITY TIE-UPS—SHOULD INDIA GO THE BAYH-DOLE WAY?†

*Nadia Gracias**

‘It is a great mistake to think that the bare scientific idea is the required invention, so that it has only to be picked up and used. An intense period of imaginative design lies in between. One element ... is ... the discovery of how to set about bridging the gap between the scientific ideas and the ultimate product.’

Alfred North Whitehead¹

I. INTRODUCTION

The Bayh-Dole Act,² placed American universities in the eye of a biotechnology storm that spawned a multi-billion dollar industry and set the stage for the conception of ideas and inventions in fields hitherto unheard of. India finally met its international patent obligations in 2006 and is at the threshold of the transnational intellectual property arena. Legal developments in this field will chart the course that India takes, and with business and trade at an all time high (in India), it would not be hyperbolic to expect an intellectual property explosion over the next decade.

The Government and the business community have been quick to realise that in order to nurture the long term growth of this nascent field, the spirit of research will have to be fostered within higher educational institutions and tapped into. Although corporate-university tie-ups currently

† This article reflects the position of law as on 10 October 2006.

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¹ *‘Science and the Modern World’*, p. 98 cited at Mowery & Rosenberg, ‘Paths of Innovation’ Cambridge University Press (1998) p.1.

² This Act conferred patent rights upon universities over inventions that had been developed with federal funds, which in turn presented these institutions with a veritable cocktail of options to access private funding without relinquishing their autonomy.

exist, these arrangements are the result of cautious and inexperienced initiatives of individual universities, each evolving their own policies and formulating their own methodology. Consequently, the Indian Government is considering enacting an adaptation of the US Bayh-Dole Act, 1980 (the Act) in order to formally regulate relations between Indian Universities (and other institutes of Higher Education) owning patent rights over inventions developed with state funds and businessmen.³ Such an enactment will promote and regulate the commercialisation of research activity centred around universities and other autonomous bodies (such as the Indian Institutes of Technology also known as the 'IITs'),⁴ thereby according legal uniformity to business–university tie-ups and paving the way for many more in the future. The objective would be to encourage researchers to assign or licence (on a sole, exclusive or non-exclusive basis) the patent to business enterprises for commercial exploitation, thereby converting the invention into a saleable product which is freely available in the market. This simple proposition presents interested players with the opportunity to strike far more complex and detailed bargains with research centres through corporate investment in exchange for first use rights.

As thrilling as this may appear to be, given that in the US itself the Act had several detractors, is the government being a little hasty in quietly trying to push through what is essentially an American regulatory system? The Act would, undoubtedly, be appropriately modified to suit Indian needs, however, considering that our higher education system was established by the British and modelled on *their* system, what impact would such a modified Act have on our administratively sheltered universities? Is there a way by which the full potential of a corporate–university marriage can be exploited without sacrificing the core values

³ Bureau Report, 'India plans legislation on intellectual property to scientists' (10 September 2006), at <http://www.zeenews.com/articles.asp?rep=2&aid=3521533&sid=N> (last visited 10 October 2006). Mr. Kapil Sibal, Union Minister for Science and Technology stated that he intended to introduce a Bill in the Winter Session of Parliament which has been drafted along the lines of the US Bayh-Dole Act.

⁴ Apart from the IITs, Tata Institute of Fundamental Research (TIFR), Birla Institute of Technology (BITS), Indian Institute of Sciences (IISc), and All India Institute of Medical Sciences (AIIMS) are some of the other autonomous institutes to name a few.

that any educational institution should be guided by? Admittedly, some institutions already own patents and at their own initiative license them out. But this is being done on a completely ad hoc basis and its current rudimentary form certainly requires the stable and well-defined framework of an enactment. What are the legislative safeguards that could be inserted to ensure that such tie-ups are not exploitative of naive and vulnerable science departments and that the greatest beneficiary is the public?

The author endeavours to address these and other crucial questions that ideally should have been publicly debated even before the drafting of a Bill. The article is broadly divided into two parts, the first of which presents an overview of the Bayh-Dole Act and its supporting legislations followed by an evaluation of its impact on innovation in the US. The second begins with an appraisal of the Indian higher education system in comparison with its US counterpart, and concludes with an assessment of the possible effects of the Act on the existing system along with suggested modifications.

II. THE US BAYH-DOLE ACT 1980

An evaluation of the Act, its origins, its implementation and impact on the university education system in the United States of America is central to any analysis of the same in the Indian context.

Commonly referred to as the Bayh-Dole Act after its two main proponents in the Senate, the Honourable Birch Bayh and the Honourable Bob Dole, the *Patents and Trademark Amendment Act, 1980* was passed with the aim of encouraging the commercial exploitation of inventions developed with federal research grants (either partially or completely). This was done by allowing inventors (or their employers) to retain the patent on their inventions, thereby 'facilitating the transfer of technology from the laboratory bench to the market place'.⁵ In order to better understand the context in which the Act was passed it is important to delve a little into the historical background of corporate-university relations in the United States of America.

⁵ 109th Congress 1st Session H.CON.RES. 319, 16 December 2005, p. 3.

A. *Position Prior To Enactment*

In as early as the 1920s, some universities had already begun moving technology from the 'bench to the marketplace'. However, the origins of technology transfer can be found in the decision of the Federal Government to depend on university laboratories for its research rather than on independent research institutes.⁶ During and after the Second World War, the success of the Manhattan Project demonstrated the importance of university research to National Defence, but it was the 1945 Vannevar Bush report that recognised and cemented the significance of this interdependence.⁷ However, the lack of a nation-wide policy governing the ownership of inventions developed with federal funds lead to inconsistencies among various funding agencies.⁸ Consequently, less than five percent of the patents owned by the Federal Government had been exploited commercially. In October 1963 President Kennedy issued a policy statement on the commercialisation of federally supported inventions. As a result of this, the 1960s and 1970s were a period of passionate debate on the future of federal patent policies, which included the principles upon which the Act is based.⁹ This process was critical in strengthening the Act which passed the tests of many drafts before enactment. Until the Act finally came into force on 1 July 1981, the federal

⁶ Henry Steck, *Corporatization of the University: Seeking Conceptual Clarity*, published in 'The Annals of the American Academy of Political and Social Science' vol. 585 (January 2003) p. 66.

⁷ Council on Governmental Relations (COGR), *The Bayh-Dole Act - A Guide to the Law and Implementing Regulations*, September 1999, available at <http://www.cogr.edu/#cogr>. 'Science - The Endless Frontier': This report (the Vannevar Bush Report) not only 'recognised the value of university research as a vehicle for enhancing the economy by increasing the flow of knowledge to industry through support of basic science', but 'became instrumental in providing a substantial and continuing increase in funding of research by the federal government';

⁸ COGR *supra* n.7. It was very rare for the federal government to surrender its ownership to universities. The 26 different Federal agency policies were in existence apart from the fact that the procedure involved was lengthy and arduous. The government was more inclined towards retaining title and entering into non-exclusive licence agreements which had few takers.

⁹ COGR *supra* n.7. 'The debate included such issues as whether exclusive licences would lead to monopolies and higher prices; whether taxpayers would get their fair share; whether foreign industry would benefit unduly; whether ownership of inventions by a contractor is anti-competitive.' See *infra* n.14, 'contractor'.

agencies maintained a vice like grip over their patents. Furthermore the implementation of the Act was tedious and it was not till its benefits became apparent that many of the (perhaps well founded) fears were dispelled.

It can thus be conclusively stated that American universities have a long history of being utilitarian in nature and of servicing societal needs albeit in the absence of a regulatory framework.¹⁰ Yet it is noteworthy that it took the Bayh-Dole Act to accelerate the growth of university-industry relations to the breathless pace it has acquired today.

B. An Overview Of The Objectives And Certain Important Provisions

The objectives of the 'Act' can be briefly summarised as follows:¹¹

- To promote the commercialisation and public availability of federally supported patents;
- To ensure the involvement of small business firms in federal research;
- To promote commercial collaboration with universities and Non Profit Organisations (NPOs);
- To ensure that adequate rights are retained by the government to meet its needs and further to protect the public against non-use or excessive use;
- To ensure that the use of the inventions of NPOs and small business enterprises promote free competition and enterprise and do not hinder future discovery;
- To minimise policy costs in this field.

In order to understand how the abovementioned objectives have been given effect to, an assessment of the principal provisions of the Act is essential.

¹⁰ H. Steck, *supra* n.6, 73.

¹¹ 35 U.S.C. section 200 Policy and Objective.

Some of the key provisions of the Act include 'march-in rights'¹², revenue sharing with the inventor with the remainder to be used for education and research and a preference for small businesses.¹³

Once the research is complete, the contractor¹⁴ has, within two years of disclosing any invention to the federal agency, the right to 'elect' his retention of title to the invention. However, under US patent law this period is reduced to one year upon sale, publication or public use of the patent. He may also within such time file similar applications in other countries where he wishes to retain title. Failure to do so results in the title shifting back to the federal agency, whereupon the inventor is offered the option of retaining title. Further, the agency can claim title in all other nations where title has not been claimed by the contractor.¹⁵

This provision guarantees speedy movement of the invention from the laboratory to the market place which is one of the key objectives of the Act. The right of the Agency to require periodic reports on the commercialisation of the invention by the contractor protects against non-use or excessive use. Notably, the surrender of title is not in totality and the federal agency does retain residuary rights over the invention after the contractor exercises his option.

C. Supporting Legislations

Vital to the success of the idea underlying the Act were the supporting legislations that were enacted during the three decades that followed. The Stevenson-Wydler Act of 1980, the Economic Recovery Act of 1981 and most recently the Cooperative Research and Technology Enhancement (CREATE) Act of 2004 bolstered the working of the Act, providing the collateral legal support necessary for successful corporate-

¹² *Infra* 'Compulsory licences vis-à-vis March-in Rights'.

¹³ 35 U.S.C. section 201 et seq.

¹⁴ 35 U.S.C. section 201c. 'Contractor' is the general term used to refer to any person, nonprofit organization or small business firm that is party to a funding agreement. Section 201(i) defines 'nonprofit organization' to include universities and other institutions of higher education.

¹⁵ 35 U.S.C. section 202c.

university tie-ups. An appraisal of the contribution of the key provisions of these enactments follows:

1. The Stevenson-Wydler Act, 1980 (the SWA)

Enacted right before the Bayh-Dole Act, the SWA laid the essential groundwork for the transfer of technology between universities and the industry and its later amendments continued to promote increased cooperation and interaction between the two. Although the SWA's thrust was much broader, including within its scope government research institutes, the continuous monitoring provided the industry with a distinct edge over other competing markets overseas.

2. The Cooperative Research and Technology Enhancement Act, 2004 (the CREATE Act)

The CREATE Act was enacted to negate the verdict of the Federal Circuit Court of Appeals in the case of *Oddzon Products, Inc v. Just Toys, Inc., et al*¹⁶ with respect to the 'prior art' status of the subject matter. The court had held that any disclosure made, including private confidential communication, between two individuals not part of the same organisation would constitute 'prior art'. This meant that the invention of the recipient of this critical information would be unpatentable. This decision hit at the foundation of the Bayh-Dole Act which encourages synergistic work between universities and the industry by rendering obsolete any joint research project between the scientists of separate entities. Hypothetically, any information passed on by a university researcher (R) to a scientist (S) in a pharmaceutical laboratory under a joint research agreement would be useless to the latter S as the information divulged by R would constitute 'prior art' and any invention developed subsequently by S based on such information would not be patentable.

Expressing its inability to interpret the statute in any other manner except as was intended by Congress, the court invited the lawmakers to modify the language of the law to conform it to the true intent of the Bayh-Dole Act. It was in this context that the CREATE Act was passed in order to provide a 'safe harbour' to university researchers affiliated with single or

¹⁶ 43 USPQ2d 1641 Fed. Cir 1997.

multiple organisations conducting collaborative research programs. Earlier a similar 'safe harbour' was available to researchers working as a team within the same organisation. The concept of the team has been carried forward by the CREATE Act to include the possibility of team members from different organisations working together under a 'Joint Research Agreement'¹⁷.

D. Bayh-Dole: A Success Story

One indisputable economic success story of Bayh-Dole has been the unprecedented growth of the biotechnology and life sciences industry. In its nascence in 1980, the Act helped spawn over 2200 new companies.¹⁸ Although federal funds have flowed into as many as nine¹⁹ different disciplines over the past twenty-eight years within the field of science and engineering, by 1998 almost fifty percent of the patents filed were pharmaceutical patents. This figure does not even include the non-drug life science technologies such as medical devices and research tools.²⁰ Innumerable inventions have been made available to patients, doctors and hospitals across the US not to mention infinite advancements in fields as diverse as nanotechnology, energy, environmental protection and information technologies. 'On the face of it Bayh-Dole makes sense. ... [It] helped create the \$43-billion-a-year biotech industry and has brought valuable drugs to market that otherwise would never have seen the light of day.'²¹

¹⁷ The CREATE Act, section 2 defines the term 'Joint Research Agreement' as 'a written contract grant or cooperative agreement.' It may be pertinent to note that this definition does not restrict itself to any form or even number of agreement(s), nor can it be said to exclusively apply to joint research agreements under the Bayh-Dole Act. The term is defined broadly enough to include governmental or even private sector cooperative research, development or other transaction agreements.

¹⁸ COGR *supra* n.7.

¹⁹ Roger Benjamin, 'The Environment of American Higher Education: A Constellation of Changes', (Jan. 2003) vol. 585 p. 8. 'The Annals of the American Academy of Political and Social Science' The nine disciplines are engineering, geological sciences, interdisciplinary and other sciences, life sciences, mathematics and computer sciences, medical science, physical science, psychology, social sciences; at p. 29.

²⁰ Walter Powell & Jason Owen-Smith, 'The New World of Knowledge Production in the Life Sciences', published in *The Future of City Intellect - The Changing American University*, (2002) Stanford University Press, 107 at p.120 & 126.

²¹ Clifton Leaf, The Law of Unintended Consequences, 19 September 2005, Fortune Magazine.

There is however, a darker side to all of this as the statistics are extremely deceptive. Nearly seventy-five percent of the licensing revenue in 1998 went to the top twenty research universities, with a meagre twenty-five percent to the rest. These were universities that were already in collaboration with the industry long before the passage of the Act which merely untangled the knotty red tape for them—universities which today have left the rest far behind, manoeuvring themselves comfortably into dominant positions from where they enter into agreements on their own terms.²² The rest pounce on the leftovers often resorting to questionable methods and compromising on principles of scientific inquiry in order to bag lucrative deals.²³ In fact when research institutes have to carry out clinical trials on drugs they develop as part of their contractual agreement, the possibility of abuse arising from financial and ethical conflicts of interest is very real.²⁴ University administrations lobby hard for funding in commercially prized fields, allowing equally important but commercially unviable subfields such as ecology and evolutionary biology to take a back seat. Even Columbia University, the single most successful revenue earner in 1998, spent over \$260 million on their research departments while earning only \$73 million that year from licensing revenues!²⁵

University patent litigation has perhaps the grimmest tale to tell. The lawsuits that have been filed since the passage of the Act in the life sciences exceed the lawsuits for all other fields combined.²⁶

²² Powell & Owen-Smith *supra* n.20, 123. '[U]niversities, such as MIT [Massachusetts Institute of Technology] and Stanford, ... began patenting and licensing activities well in advance of the Bayh-Dole act.'; "Stanford can afford to take moral stances." The ability to draw the line at some types of commercial involvement, then, may be a privilege available only to the successful.'

²³ *Supra* n.20, 124.

²⁴ See Robert Kelch MD, 'Maintaining the Public Trust in Clinical Research' Vol. 346:285-287 (24 January 2002) No. 4, The New England Journal of Medicine.

²⁵ Powell & Owen-Smith *supra* n.20, 127. See also COGR *Supra* n.7. 'Although the proportion of academic R&D expenditures supplied by industry has been rising fairly steadily, it still only represents a fraction (7%) of total academic R&D support.'

²⁶ Leaf, *supra* n.21. Between 1992 and 2003, pharmaceutical companies were embroiled in over 494 patent disputes.

III. INDIA

As has already been observed, right from the early 1900s, American universities have been centres of research. During the Second World War and even during the post-war scenario they made massive contributions to the bolstering of National Defence. The passage of the Act in 1980 merely cemented the legal position of the universities, thereby strengthening their bargaining power in their commercial dealings. On the contrary, the position in India is completely different. Apart from the IITs, which were established with the primary objective of growing into future research centres,²⁷ most universities are relics of a bygone colonial era teetering on the verge of collapse. They are plagued by myriad problems not the least of which is insufficiency of funds. These educational institutions undeniably need the financial impetus for a research and development overhaul, but in order to equip them to astutely and beneficially leverage their patents and avoid becoming easy prey for seasoned businessmen, they need the cloak of protection afforded by a legislated regulatory framework as is being envisaged by the government.

A. *Commercialisation Of Education In India?—The Need For An Enactment*

Perhaps the most interesting, yet little known fact about the Bayh-Dole Act is that universities were included belatedly in the Bill more as an afterthought, long after the decade of fiery debate had blown over.²⁸ American universities had been in any case accepting, even relying on, corporate and alumni funding right since the turn of the century. Yet, it was only during the early 1980s as Federal funding declined considerably, that universities began proactively exploring alternative funding avenues and tapping into corporate resources.

The Indian educational system on the other hand has had a far more varied history. The earliest universities were established by the British chiefly to reduce labour costs by employing Indians in the lower

²⁷ See <http://www.iitb.ac.in> (last visited 12 October 2006).

²⁸ Eisenberg (1996) cited at Powell & Owen-Smith *supra* n.20, 116.

bureaucratic strata. In order to ensure complete control, they were to be governed and administered by the colonial rulers rather than by academics. Even worse, they were merely affiliating bodies conducting exams with much of the teaching imparted at the affiliated colleges. The professoriate was appropriated by college lecturers resulting in college and university positions being occupied by teachers rather than prestigious scholars.²⁹

Regrettably, very little has changed even today. The rulers have changed hands but universities are still controlled by governments as are appointments. Consequently, these are teaching and not research based institutions. Thus the people pulling the purse strings of funding agencies are closely linked to, if not the same as, the authorities having administrative control over government run institutions. Far worse to conceive is the effect of the probability of this controlling administrative rot seeping down into the patent cells of institutions. A case in point is the Intellectual Property Policy of the University of Pune which confers wide sweeping discretionary powers upon the Management Council, which, acting on the advice of the university patent committee, decides the final fate of the patent. The principal researcher retains no right to demand commercialisation of the patent.³⁰ This hard reality makes emulating the US model almost a lost cause, as the thrust of moving the patent into the market expeditiously then takes a backseat with petty bureaucracy taking precedence. Thus, this group is the most vulnerable to being torn apart betwixt the government and the industry and is most in need of the consistency and stability afforded by a uniform regulatory system. Since they have little or no autonomy and scant resources, they are in no position to hold fort and need the most protection.

²⁹ Tariq Rahman, 'Pakistani Universities: Past, Present, and Future', 125, 1st edn (2000) (Bergin & Garvey, Connecticut USA) 'The University in Transformation – Global Perspectives on the Futures of the University'.

³⁰ Intellectual Property Policy, University of Pune, July 2004, at <http://www.unipune.ernet.in/chairs/iprchair/> (last visited 12 October 2006). 'Clause 7: Commercialisation: 7.2 The IPC may determine whether the University has a legal interest in the commercialization of the property. However, *the University is not legally bound to commercialization of each property and the originator may not claim such right*. It shall be in the *sole discretion of the Management Council* on advice from the IPC to determine commercialization of the property.' (emphasis supplied).

The 'autonomous institutes' such as the IITs, which were established by an Act of Parliament, are in a different league altogether. One of their main objectives is research, due to which they have already been filing patents annually³¹ and are understandably itching to get their hands on a piece of the corporate pie. Inspired by the success of their US counterparts, some IITs have already created on-campus incubation cells so as to encourage and promote the fledgling companies of their professors and alumni.³² Already world-class institutions, their scientists (and students) will, in the fecund ground laid by the new policy change, very likely conceive a new era of technology, creating jobs, springing small businesses, infusing new strength into the economy and, of course, making the new breed of research professors very rich.

The last and emergent category is that of the new age bourgeoisie 'deemed universities' that are being established nationwide. These would also be very keen on entering into lucrative deals with the industry but would need the most monitoring. Owing to administrative independence, such institutions would very likely possess the strongest negotiating position vis-à-vis the government as well as corporate investors. Interestingly, a growing trend has been observed of research institutions and laboratories acquiring deemed university status possibly in order to have an in house bred student pool to groom into researchers.³³

1. A Fair Balance Of Forces

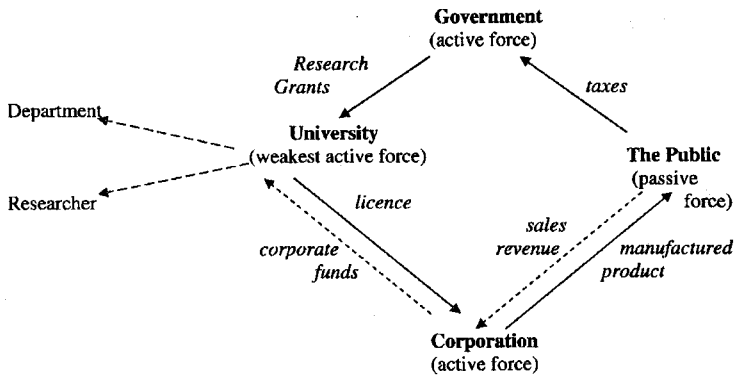
A successful working of the principles embodied in the Act, is premised on the presumption of the pre-existence of three strong, independent

³¹ 43rd Convocation of IIT Bombay, Report of the Director of the Institute, Prof. Ashok Misra, available at <http://www.alumni.iitb.ac.in/news/Convocation2005.htm>. 'Activities related to Intellectual Property Rights saw a significant rise, with 22 applications filed, an increase of 40%. Technology transfers to the industry has grown too, ...'. (last visited 12 October 2006).

³² CV Ramakrishnan, 'Growing Industrial R&D in India' *Economic Times* (Mumbai, India) 21 October 2005 Guest Column. 'These companies are envisioned to be high-technology entrepreneurship ventures. A lot of startups have come up through this route and have already generated good amount of wealth.'

³³ Bhupati Chakrabarti, 'Research and Teaching or Research versus Teaching?' (25 September 2006) vol. 91 No. 6 *Current Science* 735.

and well defined forces, *viz.* the government, the university and the corporate entity. Since these are the only three forces exercising a direct influence over the entire process beginning with the research grant and ending with the issuance of a licence, ideally, it is only when all three are on an equal footing that the maximum benefit is derivable for the community as a whole. In India, the blurring lines between university administrators and the government will prove to be a serious handicap and it is doubtful whether science departments can be said to possess even the minimum threshold of bargaining power indispensable to maintaining even a semblance of equality and fair balance of forces.



The Cycle Of Direct Benefit

Traditionally, the industry and the university in India have always remained aloof from each other, with the former engaging in applied sciences research and the latter restricting itself to research in the pure sciences. However the nation's economic upswing has increasingly narrowed this distance.³⁴ Grants are awarded to university research projects by the government from tax payers' money. One of the primary objectives of the Act cites making inventions freely available to the public through the licensing of patent rights by the university to the industry. The most potent concern is that the exclusive licence would lead to a monopoly and drive up the prices making the product unaffordable to most. The most powerful balance to the corporation as demonstrated in the Cycle of Direct Benefit (above) would have to be the Central government. However, considering the economic benefits expected to flow from such

³⁴ Ramakrishnan *supra* n. 30 .

arrangements, it is also the least likely to create any barriers. Citizens are passive recipients of any benefits and public opinion is practically non-existent on the subject. Therefore concrete legislative provisions are essential. This has been discussed in greater detail under the section titled 'Regulatory Framework'.

2. The Current Scenario And Looking Forward

Currently, although institutions (as discussed earlier) are already filing patents, the commercialisation process remains unregulated. Admittedly, the Indian position certainly differs from that in the US in respect of the fact that prevalent patent laws already allow researchers (and through 'assignment' universities and other institutions) to own patents. However, ownership of the patent by the institution is only the first baby step in the arduous techno-legal process of converting the patent into a product. The chain of events that follows the grant of the patent requires regulation and supervision along with supporting machinery. All of which can be successfully mandated only through an enactment. Bodies such as TIFAC³⁵ must be empowered to provide a wider range of support services comparable to those provided by NIH³⁶ and AUTM³⁷ in the US. Mere financial support to universities and entrepreneurs is insufficient to place them on an equal footing with the industry. Legal support, business and ancillary support and other services would be vital to foster closer and successful university-business collaborations.

³⁵ Technology Information Forecasting and Assessment Council (TIFAC) is an autonomous organisation under the Department of Science and Technology. It has launched a 'Home grown Technology' programme under which 'financial support is extended to R&D Institutes & Academia and also to ... Start up companies for supporting highly innovative technologies, which carry high risk, are at a pre commercial stage and have significant market potential. The support would be towards up scaling to prove and demonstrate their viability at a larger scale so as to generate Industry confidence.' At <http://www.tifac.org.in/> (last visited 25 October 2006).

³⁶ The National Institute of Health was established by the US Government as a primary funding agency. At <http://www.nih.gov.in/> (last visited 25 October 2006).

³⁷ The mission of the Association of the University Technology Managers (AUTM) is 'To promote, support and improve academic technology transfer worldwide and demonstrate its benefits globally through education, advocacy, networking and communication.' At <http://www.autm.net/> (last visited 25 October 2006).

In a press conference, the Minister for Science and Technology, Mr. Kapil Sibal announced that a draft Bill, along the lines of the Bayh-Dole Act, will soon be circulated to the Cabinet and tabled in the Winter session of Parliament. The indicated objective is to (a) introduce flexibility in the Indian university system; (b) make research incentive based; and (c) introduce a model based on the US system by which researchers in university laboratories receive ownership to the intellectual property they create. The flexibility proposed to be introduced in the system will allow professors the opportunity to work more closely *in* the industry for up to three years without losing their lien or seniority in the university. But most importantly the intention is to create a specific mandate so as to stimulate a manifold increase in innovation.³⁸ Given that internationally, not even ten per cent of all patents are commercialised and that nearly fifty per cent of all granted patents do not live out their term,³⁹ such a mandate then takes on tremendous importance in ensuring that the registered patents are licensed out by the institutions.

Furthermore, the new Act will blanket the system with the necessary uniformity that is sorely lacking presently. While some institutions choose to allow the scientists themselves to own the patent only to subsequently have it assigned back to the university, others claim sole ownership rights. While many have drafted institutional 'policies' and constituted governing committees to oversee the grant of their patents, inconsistencies abound.

B. Some Additional Concerns

1. Practical Limitations On The Dynamics Of Technology Transfer

“Technology transfer” is the process of getting an invention that has been demonstrated successfully in the laboratory into the marketplace.⁴⁰ From a researcher's perspective it comprises the

³⁸ Anil K. Joseph, 'India Plans Legislation on Intellectual Property to Scientists', (10 September 2006) at http://www.outlookindia.com/pti_news.asp?id=413590

³⁹ Prabuddha Ganguly, 'Adventure with knowledge ... stepping ahead with Intellectual Property Rights' at http://www.ircc.iitb.ac.in/IPCourse04/UGCLecture_pg.doc. (last visited on 11 October 2006).

⁴⁰ Timothy Lee Wherry, *Patent Searching for Librarians and Inventors* (1995) American Library Association (Chicago, USA) p.70.

transformation of the invention into a saleable product. To a businessman or investor on the other hand, tech-transfer involves the targeting of promising inventions to develop or stocks to invest in respectively. The licensing agreement bridges these divergent objectives and effects the seamless transition from an invention to a product useful for mass (or even limited) consumption. Obviously, in order to clinch lucrative licensing deals, a talent for sharp negotiation and proficiency in strategic marketing are indispensable skills-neither of which researchers and scientists can be reasonably expected to hone! Yet it is the academics sitting in university patent offices who are the primary negotiators of most licensing agreements. Even in Indian (both private and government run) research institutes the situation in the past decade has been no different.⁴¹

This is where Columbia University set itself apart by recognising this vital inadequacy and establishing the Columbia Innovation Enterprise (CIE) unit in 1983 to manage the University's patent portfolio and formulate its licensing strategy. CIE provides corporations with a one window access to all faculties of the university whether it is to licence patents or for research projects, but far more importantly relieves academics of an uneasy burden (as negotiators) by retaining them only in an advisory capacity. This approach worked marvellously for Columbia as is evidenced by its emergence as a patent royalty leader in the US.⁴²

Instead of thrusting the role of a negotiator upon a reluctant researcher, the Indian Act could require universities to appoint business professionals alongside the researchers in patent cells to manage their patents.

2. Revenue Sharing Policy

Since the Act itself contains no specific provision for the sharing of the licence revenue, most institutions evolve individual revenue sharing

⁴¹ Reshma Patil, 'Global agents, Indian ideas', *Hindustan Times* (Mumbai India 12 August 2006) p.1. '[S]cientists confess they lacked negotiating skills in the 22 US patents they licensed since 1995. ... "The next step is ... improved negotiating skills."'

⁴² Bruce Berman, '*From Ideas to Assets: Investing Wisely in Intellectual Property*', (2002) John Wiley & Sons, Inc. (USA) p.179 to 189.

policies which could be variable across faculties. Columbia University has adopted a standard policy for revenue distribution. Forty per cent is given to the individual researcher and twenty per cent to his laboratory if the revenue received is up to \$100,000, and for amounts exceeding \$100,000, twenty per cent to the researcher and twenty per cent to his laboratory. In case Columbia accepts equity in a start-up company, part of it is also distributed to the inventor. This break up is considered by many to be unduly generous to the scientists and even harmful to the neutrality of scientific inquiry by making research in profitable fields incentive based.⁴³ However, since it is the same argument that is oft used to criticise the Act itself, the only pertinent issue that survives is whether revenue distribution percentages in India should be regulated by law.

In the author's view the law could stipulate a minimum threshold percentage that should be given to the researcher but it certainly must specify the minimum percentage that should be channelled back (a) into the same or second line research in the subject-matter of the patent; and (b) for infrastructure for the scientist's laboratory or department. In the United Kingdom (as well as in Europe generally) universities have been censured by the industry for the disproportionate percentage of revenue income they misguidedly spend on administrative infrastructure rather than on effecting technology transfer.⁴⁴ A lack of regulations has allowed the universities this latitude, resulting in many wrongly prioritising the setting up of bureaucratic machinery over actual research. Restricting the scope of administrative discretion in revenue distribution in India, by the insertion of specific directions in the law is bound to guarantee, if only to a limited extent, the fulfilment of one of the principle objectives of the enactment.

⁴³ *Ibid.* pp. 184 & 185.

⁴⁴ Dr. DJ Naylor, 'Lambert Review of Business-University Collaborations', available at <http://www.lambertreview.org.uk/pdf/files/busin/bcorusdrdjnaylor.pdf>. p.7.

3. Technology Donation

The concept of donating orphan patents⁴⁵ by companies to universities and non-profit research institutes in return for tax credits was introduced in the US by the Internal Revenue Service (the IRS) in 1958. However, it was only in the 1990s that corporations began donating technologies to universities and claiming millions in tax deductions. While the practical implementation of the concept in its current form may be flawed and therefore easily abused, the underlying idea certainly deserves preservation. There is growing resentment against the fact that tax-payers should pay the industry to donate overvalued patents of doubtful utility. Consequently, instead of the prevalent method of patent valuation, a moderate tax benefit could be allowed accompanied by tax bonuses in proportionate increments in exchange for grants made along with the donation. Further, allowing the industry to participate in the profits by receiving royalties will encourage the donation of patents that are useful to the community.⁴⁶

This proposed change which is currently under consideration in the US, would help foster closer university-industry ties and bring out many a valuable patent from cold storage apart from considerably reducing public expenditure. While the Indian Act should facilitate such a backward transfer of technology, in the author's opinion, the basic tax benefit should be modest with larger benefits reserved as bonuses for grants and any other follow up support. Furthermore, the company should be required to effect a know-how transfer to the university (which would include revealing related patent ownership and documentation in addition to disclosure of scientific information) in order to update the university scientists on all research performed on the patent until the transfer.

⁴⁵ Ron Layton & Peter Bloch, '*Please Donate Patents on the Shelf; Tax benefits can be Focused for Greater Good*', 15 March 2004, Legal Times Magazine, p. 30 available at http://www.iipi.org/articles/IP_Donations.pdf 'Orphan Patents' are those that 'were not consistent with a company's core technologies or mission; were not appropriate for licensing to third parties; and had no value for defensive purposes in competitive markets.' (last visited 20 June 2006).

⁴⁶ *Ibid.*

C. Regulatory Framework

The regulations framed under the Bayh-Dole Act impose detailed reporting obligations, periodical audits and full responsibility upon any institute electing to retain a patent.⁴⁷ Above the federal agency is the General Accounting Office which in turn oversees the agencies. Furthermore, the Comptroller General is required to periodically review the efficacy of the legislation and regulations outlined there under and present his findings to the Judiciary Committee of the House of Senate.⁴⁸ The Indian Parliament will have to establish a separate autonomous body to oversee university-corporate patent licensing agreements apart from the Controller under the Patents Act. To prevent governmental interference such a body should ideally have to present its annual report in Parliament.

1. Monopoly

In the US this was countered by the insertion of section 211 thereby attracting all US Antitrust laws to Bayh-Dole transactions.⁴⁹ In India on the other hand the safety net of a compulsory licensing system needs to be fastened securely to restrict cases of patent abuse.

2. Compulsory Licences vis-à-vis March-in Rights

Section 203 of Title 35 of the United States Code provides for 'March-in' rights. This entitles the federal agency funding the research to 'march-in' and require a licensee (or assignee or contractor as the case may be) to issue further licenses on reasonable terms, and in case the licensee does not comply then to issue such licenses of its own accord. Interference in the enjoyment of the licence through 'march-in' rights is justified in cases of not 'working' the patent, public health or safety emergencies, insufficient 'public use' and where the product is sold but not manufactured within the country.

⁴⁷ 37 CFR Part 401.

⁴⁸ 35 USC section 202(b)(3).

⁴⁹ 35 U.S.C. section 211 'Relationship to antitrust laws: Nothing in this chapter shall be deemed to convey to any person immunity from or civil or criminal liability, or to create any defences to actions, under any antitrust law.'

Section 85 to section 92 of the Indian Patent law,⁵⁰ lay down extensive and detailed provisions empowering the Controller⁵¹ to issue compulsory licenses in specific cases. Perhaps the key difference between these and the march-in rights is that in the latter the discretion to 'march-in' is left to the federal agency concerned, whereas in the former 'any person interested' can petition the Controller upon expiration of three years from the date of the patent grant. More importantly, non-affordability is one of the grounds for making such an application.⁵²

The necessity of applying compulsory licensing provisions and *not* march-in rights to any Bayh-Dole adaptation in India cannot be over emphasised. The fact that in twenty-five years this provision has not been invoked even once by the National Institute of Health is worrisome.⁵³ Add to it the statistic that more than eight thousand academic patents were granted between 1993 and 1997 alone and it is plain that the march-in provision is dead letter.⁵⁴ Allowing a government funding body alone compulsory licence application rights would be in contravention of the basic principles of patent law in India and in any case to the detriment of public interest. It is after all the taxpayers' money that is channelled to research institutes. Applying the compulsory licensing provisions *in toto* will ensure that the patent is made available at prices as low as commercial viability permits.

3. Confidentiality

Acknowledging the importance of confidentiality, the Act authorizes federal agencies to protect, from disclosure to the public, patent information that it may possess or have access to until the patent application is filed.⁵⁵ Federal scholarships and grants for educational purposes are specifically included within the purview of the Act to ensure that the recipient retains patent ownership rights over his invention.⁵⁶ This provision prevents the differentiation of educational scholarships from research

⁵⁰ *The Patents Act, 1970.*

⁵¹ *Ibid.* Section 2(1)(b) "Controller" means the Controller General of Patents, Designs and Trademarks referred to in section 73.'

⁵² *Supra* n 17. See Section 84 'Compulsory Licences'.

⁵³ C Leaf *supra* n.21.

⁵⁴ COGR *supra* n.7.

⁵⁵ 35 U.S.C. section 205. 'Confidentiality'.

⁵⁶ *Ibid.* section 212. 'Disposition Of Rights In Educational Awards'.

grants, but more importantly bars any federal agency from claiming patent ownership rights over the recipient's invention even by agreement.

IV. CONCLUSION

'Universities are one of the central pillars of civil society. The core values and mission of the university must be sustained if the university is to fulfil its traditional role of learning, scholarship, and service.'⁵⁷

The reality is that when such an Act is finally passed, the policy change will have to be driven by economic concerns and not by academic ones. It would therefore be a grave fallacy to regard the enactment of legislation similar to the 'Act' as a magic remedy for all the ills that plague business-university relations in general and our educational system in particular. Great ideas have to be transformed into locally adapted laws, moulded to suit Indian needs. Modelling our regulatory framework along the lines of its US counterpart is only one facet of any attempt at replicating the success of the US in this area. The law must mandate the setting up of requisite machinery to support the sustained long term growth of technology transfer from universities to the marketplace. This is what will decide the difference between an Indian repeat of the unprecedented growth in the US or the dismal failure of Europe. For this, healthy debate is essential to ensure that all perspectives are taken into consideration including that of the universities—a passive but indispensable player. Even in the US, it took almost fifteen to twenty years of debate to reach a consensus in Congress,⁵⁸ and several amendments to refine the law.

If our educational institutions are to weather these tumultuous times and still emerge strong, then the most vulnerable link in the cycle of benefit needs the most protection. It is insufficient to merely draw lessons from the pitfalls of the Bayh-Dole Act without perceiving the dissimilarities in the Indian and US educational systems as well as the disparity in their historical origins and evolution. But it is far more crucial to avoid the mistakes of the European experience, especially while reiterating the fact that our educational system was established by the British. Institutions of

⁵⁷ H. Steck *supra* n. 6.

⁵⁸ *Supra* n.5.

higher learning can be said to have one purpose alone—scholarship. An integral part of this is academic excellence and research in the pursuit of knowledge that is freely available to all. This must never be forgotten. Universities have replaced the solitary researcher and are today the budding ground of ideas and inventions. It is therefore imperative that the foundations of (seemingly) lofty ideals that these institutions are built upon, are safeguarded adequately through express legislative provisions and sufficient judicial safeguards.

CLINICAL TRIALS IN INDIA[†]

*Neha Shah**

I. INTRODUCTION

The past few years have witnessed an incredible rise in outsourcing of clinical trials¹ from the developed countries to the developing countries by multinational pharmaceutical companies.² There are a variety of reasons for such augmentation, ranging from low costs to a genetically diverse human volunteer base in a country like India.³ Another conspicuous reason is the laxity of the Government in laying down stringent norms for regulating and conducting clinical trials; though there are a number of guidelines, these are merely policies which cannot be strictly enforced by the Government. The only legislation presently governing clinical trials in India is the *Drugs and Cosmetics Rules, 1945*, framed under the *Drugs and Cosmetics Act, 1940*. News reports indicate that the Biomedical Research Human Subjects Promotion and Regulation Bill is awaiting approval of the Union Cabinet and is expected to be introduced shortly

[†] This article reflects the position of law as on 20 June 2006.

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¹ Clinical trials refer to the study conducted on human subjects, by pharmaceutical companies, to determine the safety and efficacy of the drug. The drug regulatory authority stipulates that such trials be conducted before the drug is marketed. For a statutory definition, see *infra* n. 19.

² According to the recent McKinsey report, the clinical trial market in India is expected to touch Rs. 50 billion by 2010 and will employ 50,000 people in the next five years. 'It is a prediction of the Government of India that it will be more than Rs. 10,000 crores business in coming five years.' Dr Chirag Shah, 'Clinical Research in India: An Introduction', available at <http://bioinformatics-india.com/new/?q=node/18&PHPSESSID=f7927f52715afd70de6a0ec370ca89d5> (last visited 15 January 2006).

³ The other reasons include the fine balance between a large number of hospitals, qualified doctors and widespread illiteracy, leading to a lack of awareness. Thus, finding enough participants for the trials is one of the most cumbersome exercises in developed countries. India is preferred over China, another leading destination for research and development, because of its regulatory framework, as well as fluency in speaking and understanding the English language.

in Parliament.⁴ Recent reports of clinical trials being conducted without following proper procedure have further raised concerns over Indians being used as 'guinea pigs'.⁵ Amendments to the *Patent Act, 1970* to strengthen patent protection⁶ as well the Schedule Y to *Drugs and Cosmetics Rules, 1945* have encouraged outsourcing of clinical trials to India. The phenomenon of outsourcing clinical trials to India has also been termed as a new form of imperialism.⁷

In Part II of this article, the author will provide an overview of the present laws and ethical principles governing clinical trials⁸ internationally and more specifically, in India, Part III reviews the Biomedical Research Human Subjects (Promotion and Regulation) Bill and the need for more

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- ⁴ YV Phani Raj, 'Biomedical Research Human Subjects Promotion Bill awaits Cabinet nod', *Chronicle Pharmabiz* (Mumbai India 5 January 2006) vol 6 [3], 1, available at <http://www.pharmabiz.com/article/detnews.asp?articleid=31198> (last visited on 14 January 2006).
- ⁵ See generally, 'Fast growing business: Unethical clinical trials in India', *Alliance for Human Research Protection* (2004) at <http://www.ahrp.org/infomail/04/07/27.php> (last visited 14 January 2006). See also GS Mudur, 'Patients turn guinea pigs minus cover', *The Telegraph* (Calcutta India 24 October 2005) available at http://www.telegraphindia.com/1051024/asp/nation/story_5391745.asp (last visited 15 January 2006).
- ⁶ Increased patent protection has led to an increase in comfort levels for multinational pharmaceutical companies and a corresponding rise in the number of clinical trials being conducted in India. The new product patent regime has also led Indian pharmaceutical companies to invest in research and development.
- ⁷ Anjana Ahuja, 'Poor, sick, desperate. What more could Big Pharma ask in Indian drug trials?', *Timesonline* (8 May 2006) available at <http://www.timesonline.co.uk/article/0,,20909-2170155,00.html> (last visited 11 June 2006) quoting Glenn McGee, 'Salt in the Wound : Will India rise up against the oppression of foreign clinical trials?' vol 20 [4] *The Scientist* 26. Contra 'India, Drug Trials, and So-Called Imperialism', available at <http://www.businessethics.ca/blog/2006/04/india-drug-trials-and-so-called.html> (last visited 11 June 2006).
- ⁸ There are a variety of other trials which are conducted for determining the effect of vaccines, clinical trials with surgical procedures, treatment trials to name a few. Vaccine Trials focus on effectiveness in prevention of the disease (Prevention Trials are similar to but more expansive than Vaccine Trials); Clinical Trials with surgical procedure / medicine devices assist in improving the overall health care services provided to the patient; Diagnostic Trials are conducted to determine better methods for diagnosing a particular disease; Treatment Trials are conducted to test experimental treatments such as a new combination of drugs; Screening Trials help in detecting certain health conditions; and Quality of Life Trials explore means to improve the comfort and quality of life of people suffering from chronic illness. Some of these trials have been recognised by the ICMR Guidelines.

stringent legislation and Part IV analyses the effect of the new legislation on the economy while protecting the human volunteer's interest and rights.

II. OVERVIEW

The Hippocratic Oath has been amongst the oldest ethical guidelines in the field of medicine; however it was only in the 20th century that clinical trials have received long overdue attention. The Nuremberg Code was the first international document to lay down ten tenets for the protection of human volunteers.⁹ It was adopted after World War II as a result of the barbaric atrocities inflicted by medical practitioners on the inmates of the Nazi concentration camps without their consent. The Nuremberg Code was followed by a number of guidelines, codes and regulations to ensure the protection of the human volunteers participating in clinical trials; among these the most important documents are the Declaration of Helsinki, 1964,¹⁰ Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979 (the Belmont Report)¹¹ and

⁹ *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law* (Washington, DC: US Government Printing Office, 1949) vol 2 [10], 181–182. The full text of the Nuremberg Code is available at <http://ohsr.od.nih.gov/guidelines/nuremberg.html> (last visited 21 June 2005).

¹⁰ The Ethical Principles for Medical Research Involving Human Subjects (known as the Declaration of Helsinki) acts as a 'statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects'. Its basic purpose is to acknowledge the priority of the patient's health over the physician's interest in science and society. World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects was adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, available at <http://www.wma.net/e/policy/b3.htm> (last visited 2 July 2006). Though this principle may appear obsolete taking into regard the technological advancement in the last few decades but they still followed and acknowledged by all the countries as well as by international bodies/organisations.

¹¹ The United States Congress passed the *National Research Act, 1974* in response to unethical trials conducted in Tuskegee, Alabama; which lead to the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The main purpose of setting up the National Commission was to identify and summarise the basic principles governing conduct of research on human subjects. The object of the Belmont Report is 'to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects'. The Belmont Report Ethical Principles And Guidelines for the Protection of Human Subjects of Research; The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 18 April 1979, available at <http://ohsr.od.nih.gov/guidelines/belmont.html> (last visited 26 June 2006).

International Ethical Guidelines for Biomedical Research Involving Human Subjects.¹²

A. Laws Governing Clinical Trials In India

The only statutory recognition for the procedure for conducting clinical trials can be found in the *Drugs and Cosmetics Act, 1940* and the *Drugs and Cosmetics Rules, 1945*. The Ethical Guidelines for Biomedical Research on Human Subjects, 2000 (ICMR Guidelines) issued by the Indian Council for Medical Research as well as the Good Clinical Practices (GCP) Guidelines prepared by the Central Drugs Standard Control Organisation (CDSCO) are based on guidelines issued by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO),¹³ the International Conference on Harmonisation (ICH)¹⁴ and the United States Food and Drug Authority.

1. Drugs And Cosmetics Act, 1940

India has become a hub for conducting clinical trials.¹⁵ Under the present regime, in order to import for manufacture or marketing of a new drug for clinical trials, an application is to be made to the Licensing Authority (Drug Controller General of India) along with the necessary data.¹⁶

¹² International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS, 2002. The Council for International Organizations of Medical Sciences (CIOMS) is an international nongovernmental organisation set up with the support of WHO and the United Nations Educational, Scientific and Cultural and Organization in 1949. These guidelines deal with issues governing research in developing countries, available at http://www.cioms.ch/frame_guidelines_nov_2002.htm (last visited 2 July 2006).

¹³ See International Ethical Guidelines for Biomedical Research Involving Human Subjects, available at http://www.cioms.ch/frame_guidelines_nov_2002.htm (last visited 2 July 2006).

¹⁴ See <http://www.ich.org/LOB/media/MEDIA482.pdf> (last visited 9 January 2006).

¹⁵ *Supra* n. 2.

¹⁶ Rule 122-A and Rule 122-B of the *Drugs and Cosmetics Rules, 1945* (DCR) provide for the procedure for application for import of new drugs and approval to manufacture new drugs other than those classified under schedule C and C1 respectively.

Permission, in writing, of the Licensing Authority is mandatory in order to conduct clinical trials for a new drug or investigational new drug.¹⁷ Section 27 of the *Drugs and Cosmetics Act, 1940* (DCA) provides for penalty for manufacture, sale, import and distribution of drugs in contravention of Chapter IV of the DCA. It is worth noting that there is no other legislation in India which provides for any penal provisions vis-à-vis clinical trials.

2. Drugs And Cosmetics Rules, 1945

Schedule Y of *Drugs and Cosmetics Rules, 1945* (DCR) was amended in January 2005 to regulate conduct of clinical trials. Under the DCR,¹⁸ clinical trials¹⁹ are conducted in four phases.²⁰

a. Phase I Trials (*Human / Clinical Pharmacology Trials*)

Phase I Trials are conducted to determine maximum tolerated dosage in humans, pharmacodynamic²¹ effect, adverse reactions²² (if any) and

¹⁷ Rule 122-DA of DCR.

¹⁸ Rule 122-DA of DCR.

¹⁹ Rule 122-DAA of DCR defines clinical trials as 'a systematic study of new drug(s) in human subject(s) to generate data for discovering and / or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effects with the objective of determining safety and / or efficacy of the new drug.'

²⁰ Under the ICMR Guidelines the first three phases of clinical trials require ethical clearance.

²¹ According to Wikipedia, Pharmacodynamics is 'the study of the biochemical and physiological effects of drugs and the mechanisms of drug action and the relationship between drug concentration and effect', available at <http://en.wikipedia.org/wiki/Pharmacodynamics> (last visited 2 July 2006). It is the study of the action or effects of the drugs on the living organism, available at <http://medical-dictionary.thefreedictionary.com/pharmacodynamics> (last visited 2 July 2006).

²² GCP Guidelines define Adverse Event (AE) as 'Any untoward medical occurrence (including a symptom / disease or an abnormal laboratory finding) during treatment with a pharmaceutical product in a patient or a human volunteer that does not necessarily have a relationship with the treatment being given.'

GCP Guidelines define Averse Drug Reaction (ADR) as 'In clinical trials, an untoward medical occurrence seemingly caused by overdosing, abuse / dependence and interactions with other medicinal products is also considered as an ADR.

'Adverse drug reactions are type A (pharmacological) or type B (idiosyncratic). Type A reactions represent an augmentation of the pharmacological actions of a drug. They are dose-dependent and are, therefore, readily reversible on reducing the dose or withdrawing

pharmacokinetic²³ behaviour of the drug. These are generally conducted on at least two human volunteers.

b. *Phase II Trials (Therapeutic Exploratory Trials)*

Phase II Trials are performed on a limited number of human volunteers to determine the therapeutic use, effectiveness of the drug and the short-term side-effects and risks associated with the drug which would assist in determining the dosage for Phase III Trials.²⁴

c. *Phase III Trials (Therapeutic Confirmatory Trials)*

Phase III Trials are conducted in order to confirm the safety and efficacy of the drug. It corroborates the preliminary evidence accumulated in Phase II Trials as regards safety and effectiveness of the drug on the human volunteers and it also assists in procuring market approval for Phase IV Trials.

the drug. In contrast, type B adverse reactions are bizarre and cannot be predicted from the known pharmacology of the drug.'

GCP Guidelines define Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (SADR) as 'An AE or ADR that is associated with death, inpatient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.'

²³ According to Wikipedia, Pharmacokinetics is 'a branch of pharmacology dedicated to the study of the time course of substances and their relationship with an organism or system. In practice, this discipline is applied mainly to drug substances, though in principle it concerns itself with all manner of compounds residing within an organism or system, such as nutrients, metabolites, endogenous hormones, toxins, etc. So, in basic terms, while pharmacodynamics explores what a drug does to the body, pharmacokinetics explores what the body does to the drug'. available at <http://en.wikipedia.org/wiki/Pharmacokinetics> (last visited 2 July 2006). It is the process and study of the process by which a drug is absorbed, distributed, metabolised and eliminated by the body, available at <http://medical-dictionary.thefreedictionary.com/pharmacokinetics> (last visited 2 July 2006).

²⁴ The criteria for selecting subjects at this phase are narrower as compared to the previous phase thus ensuring uniformity. There is also an increase in the number of subjects participating in Phase II Trials as well as the centres at which such trials are conducted. Doses used in Phase II Trials are usually (but not always) less than the highest doses used in Phase I Trials.

d. Phase IV Trials (Post Marketing Trials)

Phase IV Trials are carried out after approval of the new drug.²⁵ Phase IV Trials help in determining and assessing the efficacy and safety of the drug. Although, these trials are discretionary, approval may be required by the DCGI to collect additional information about the drug.

Schedule Y governs issues ranging from grant of permission to conduct clinical trials at every phase to informed consent of human volunteers to the responsibility of Investigators and Ethics Committees.²⁶ In order to conduct clinical trials the investigators need to first obtain permission from DCGI.²⁷ Once permission has been granted by the DCGI and the Ethics Committee, only then can the clinical trial of the new drug be initiated.²⁸

3. Guidelines

Under the GCP Guidelines it is compulsory to reveal all the necessary information to the human volunteer. The ICMR Guidelines as well as the GCP Guidelines together cover issues concerning the human volunteers which are supplementary to the issues dealt with in Schedule Y. While Schedule Y deals with the procedural aspect for conducting clinical trials; the ICMR Guidelines and GCP Guidelines deal with the

²⁵ For further details See Schedule Y, DCR.

²⁶ All proposals on biomedical research involving human subjects have to be cleared by an appropriately constituted Institutional Ethics Committee (IEC), also referred to as Institutional Review Board (IRB) in many countries, to safeguard the welfare and the rights of the participants. 'The basic responsibility of an IEC is to ensure a competent review of all ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity. IECs should provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committees.' The ICMR Guidelines and GCP Guidelines provide for, *inter alia*, basic responsibility, composition and review procedure to be followed by the IEC. Schedule Y lays down restrictions while conducting studies on special population such as geriatric patients and paediatric studies (includes children, pregnant / nursing women); the ICMR Guidelines as well as the GCP Guidelines also provide for guidelines governing selection of special group as research subjects; this, *inter alia*, includes vulnerable groups as well.

²⁷ Para 1(iv)(a)-(b) of Schedule Y, DCR.

²⁸ *Supra* n. 16.

ethical issues. The ICMR Guidelines²⁹ also lay down 12 principles to be followed while conducting clinical trials. The ICMR Guidelines as well as the GCP Guidelines provide for constitution of Ethics Committees, procedure to be followed to obtain informed consent, selection of human volunteers and compensation.³⁰

The European Parliament had passed a Directive³¹ to regulate and administrate the laws in member states relating to implementation of good clinical practices and conduct of clinical trials on human volunteers. The member states of the European Union have enacted legislation in their respective states to implement and conform to this directive. For instance, the *Medicines for Human Use (Clinical Trials) Regulations 2004* (UK Regulations) were passed by the United Kingdom Parliament.³² These regulations provide for compensation to human volunteers and indemnify the investigator against liability. In order to conduct clinical trials in a third country simultaneously (when it is conducted in the United Kingdom) it is necessary to give an undertaking allowing the licensing authority to inspect the premises in the third country to ensure that good clinical practices are adhered to while conducting clinical trials.³³

B. *The Other Side*

The ethical principles for conducting biomedical research on human volunteers have been adopted by the international community; the same have been accepted at the state level as well. The Nuremberg Code recognised the principle of informed consent. The Declaration of Helsinki acts as a handbook for physicians providing, guidance to physicians and persons participating in medical research involving human volunteers,

²⁹ Available at <http://icmr.nic.in/ethical.pdf> (last visited 15 January 2006).

³⁰ The Indian Council of Medical Research has laid down guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research, available at http://icmr.nic.in/ethics_SOP.pdf (last visited 30 June 2006).

³¹ Directive 2001/20/EC of the European Parliament and of the Council, 4 April 2001, Official Journal of the European Communities, available at http://eudract.emea.eu.int/docs/Dir2001-20_en.pdf (last visited 28 May 2006).

³² The *Medicines for Human Use (Clinical Trials) Regulations 2004* came into force on 1 May 2004. Statutory Instrument 2004 No.1031.

³³ Regulation 21 of the *Medicines for Human Use (Clinical Trials) Regulations 2004*.

so as to help safeguard the health of the latter. It ensures that the guidelines set forth in the Declaration are abided by over and above the ethical, legal and regulatory requirements in one's own country. The Belmont Report is also an important document dealing with the basic ethical principles of respect, beneficence and justice.

1. Basic Ethical Principles

a. *Respect For Persons*

The principle of Respect for Persons means that the person / volunteer should be treated as an autonomous agent, capable of taking his own decisions. However it also includes persons incapable of deciding for themselves due to some incapacity.³⁴ The incapacity of a person and his ability to decide may vary over a period of time. This should in no way diminish respect for the person. Neither should a person be coerced into participating in a clinical trial, nor should he be deprived of the opportunity of participating in the trial on account of his status in society or under any law for the time being in force (subject, however to his health).

In India there are no regulations or legislation governing this issue. The principle set out in the ICMR Guidelines and GCP Guidelines provides that 'respect for persons' implies that the person should voluntarily enter such research trials only if he comprehends the (adequate) information provided to him by the investigator.³⁵ Breach of such respect would indicate a denial of the person's freedom to act on his own judgement and would also amount to concealing information. Thus it is obvious that the requirement of 'informed consent' stems from the principle of 'respect'.

b. *Beneficence*

The second principle recognised in the Belmont Report states that the researcher should protect the human volunteer from any harm and further ensure his well being.³⁶ The maxim '*do no harm*' is a fundamental principle of medical ethics. Notwithstanding the benefit to others, this principle

³⁴ Belmont Report, Part B 1.

³⁵ See General Ethical Issues, ICMR Guidelines, 17 and Para 2.4, GCP Guidelines.

³⁶ Belmont Report, Part B 2.

obligates the researcher to protect the patient from any harm, the only exception being when the harm caused to the human volunteer is considered reasonable in proportion to the benefits obtained for society at large.

In India however there have been instances where patients with alternate remedies have been subjected to drug trials. The maxim seems to have been misinterpreted by researchers who often conduct drug trials for their personal benefit, rather than that of society at the cost of ignorant patients. Thus under the guise of *benefit of society* they conduct clinical trials which cause severe adverse reactions on the volunteers.³⁷ This background is the basis of formulation for the principle of non-exploitation which has been discussed later in this Part of the article.

c. *Justice*

The concept of justice refers to equal distribution of benefits and burdens of the research.³⁸ The concept of justice may vary according to the research involving the human volunteer. The Belmont Report states that:

‘[T]he selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.’³⁹

One of the major concerns raised, in India, over clinical trials is that they are generally conducted on ignorant people (mainly due to the lack of understanding and literacy on the part of the patient). Moreover, one of the main reasons for India being called a ‘guinea pig’ is due to the

³⁷ The RCC Trials are an example of how basic ethical principles are flouted in India without much inconvenience to further the personal glory of researchers. See Part III for further details.

³⁸ Belmont Report, Part B 3.

³⁹ *Ibid.*

capitalistic attitude of the multinational pharmaceutical companies. These companies carry out clinical trials on human volunteers in India, but once the drug has been cleared by the competent authorities, it becomes unaffordable for the very same people, and/or even for patients who had participated in the trials.

These are general ethical principles recognised and accepted by states and institutions the world over. In fact the same have been incorporated by states in their regulatory framework governing clinical trials on human volunteers. Thus, the foundation for the ethical issues discussed below are these three basic principles.

2. Informed Consent

The Nuremberg Code laid great emphasis on the aspect of 'informed consent'.⁴⁰ The first principle of the Code provides for voluntary consent. It states that the volunteers should possess sufficient knowledge and be provided with all the necessary information that would help them to make an enlightened decision. Another important principle concerning clinical trials is that the volunteers should be allowed to withdraw at any stage even if it means terminating the trial, if it is not possible for them to continue; further even the scientist (Investigator) can terminate the experiment if it is likely to result in the 'injury, disability, or death'⁴¹ of the *experimental* human volunteer. It is also necessary to consider if there arises a *positive duty* on the Investigator to terminate the experiment in the event of such occurrences.

⁴⁰ The concept of informed consent was introduced in the Nuremberg Code, 1947 and Declaration of Helsinki, 1964, available at <http://www.wma.net/e/policy/pdf/17c.pdf> (last visited 21 June 2005). See also Good Clinical Practices Guidelines (GCP) which defines informed consent as 'voluntary written assent of a subject's willingness to participate in a particular study and in its documentation. The confirmation is sought only after information about the trial including an explanation of its status as research, its objectives, potential benefits, risks and inconveniences, alternative treatment that may be available and of the subject's rights and responsibilities has been provided to the potential subject,' available at <http://unpan1.un.org/intradoc/groups/public/documents/APCITY/UNPAN009867.pdf> (last visited 09 January 2005).

⁴¹ The Nuremberg Code, 1947, *Ibid*.

In India the concept of 'informed consent' was first recognised in the ICMR Guidelines⁴² followed by the GCP Guidelines.⁴³ In 2005, Schedule Y to the DCR was amended to include, *inter alia*, informed consent of volunteers.⁴⁴ It is based on the principle that the proposed volunteer is competent to decide whether he wishes to participate, the only exceptions being when research involves minimal risk or in case of an emergency. In fact there have been a number of instances where the patients have signed consent forms without realising the consequences.⁴⁵ Theoretically the Institutional Review Boards and Ethics Committees are to ensure that trials are conducted after taking into consideration and following guidelines laid down by the various authorities. Practically, this does not happen, as seen in the Regional Cancer Centre controversy, where patients were made to participate in drug trials of a drug which had not been tested properly on animals.⁴⁶ Consent obtained by luring the volunteer with medical benefits or treatment he would otherwise not be able to afford is not 'informed consent' as provided for in the rules and/or guidelines. Such consent is a result of undue influence and coercion. The DCR, ICMR Guidelines as well as the GCP Guidelines provide for the presence of an *impartial witness*⁴⁷ during the informed consent process whose signature is also appended on the consent form to ensure that there was free and voluntary consent. Though these rights are recorded and accepted by the patient on paper, how often is he informed of all the

⁴² General Ethical Issues, ICMR Guidelines.

⁴³ The ICMR Guidelines and GCP Guidelines appear to be overlapping but when read together they seem to be exhaustive. These Guidelines provide for the consent process for special subjects as well.

⁴⁴ See Appendix V (1), Schedule Y, DCR – Checklist for study subject's informed consent. This checklist is almost identical to the provisions of 11 USC § 50.25. However, unlike the US legislation (11 USC §§ 50.23 and 50.24), in India there is no legal provision under which informed consent is exempted either generally or in case of emergency research, although it does exist in the ICMR guidelines. Incorporation of such exceptions should be pro-subject and exhaustive to prevent any misinterpretation.

⁴⁵ See generally, 'Drug trials outsourced to India', BBC NEWS, available at http://news.bbc.co.uk/2/hi/south_asia/4932188.stm (last visited 21 May 2006).

⁴⁶ For further details see Part III of this article.

⁴⁷ An Impartial Witness as defined in the GCP Guidelines means 'An impartial independent witness who will not be influenced in any way by those who are involved in the Clinical Trial, who assists at the informed consent process and documents the freely given oral consent by signing and dating the written confirmation of this consent.'

risks/harm that the researcher may be aware of? However, it is to be noted that there have been instances, though miniscule in number, where patients aware of their rights opt out if they receive no benefit from the trial.⁴⁸ The Ethics Committee should ensure that the informed consent form fulfils all the items stated in the checklist. In case of doubt, the Committee should speak to the patients personally to determine their competence to give consent to participate in the trials as well as to comprehend the effects of such participation at every stage. This will avoid any sort of confusion between the researcher and human volunteer. The Government should enforce strict liability on the sponsors (pharmaceutical companies) to prove that not only had informed consent been taken; but also that the volunteer had understood the risks involved in participating in the clinical trial.

In a recent investigation conducted by the BBC, it was reported that there are a large number of illegal / unethical drug trials being carried out through out the country.⁴⁹ It cited some drug trials wherein the participants were not informed that they were a part of a clinical trial. For instance, in Gujarat a psychiatric patient was given a drug free of cost and was only told that it was an American drug, without being informed that by consuming such drug he had become a subject of the clinical trial conducted by a pharmaceutical company. However, the pharmaceutical company maintains that informed consent was obtained from all the patient participants. This is an instance of how the practical working of the Guidelines is very difficult to monitor, as also the difficulty of pinpointing liability.

3. Remuneration And Compensation

The ICMR Guidelines and GCP Guidelines provide protection to the human volunteers by not only ensuring voluntary and informed consent

⁴⁸ Sandhya Srinivasan, 'Indian Guinea Pigs for Sale: Outsourcing Clinical Trials', India Resource Centre, available at <http://www.indiaresource.org/issues/globalization/2004/indianguineapigs.html> (last visited on 25 November 2005).

⁴⁹ 'Drug trials: The Dark Side', BBC NEWS, available at http://news.bbc.co.uk/2/hi/programmes/this_world/4924012.stm (last visited on 21 May 2006). See also *supra* n. 45.

but also providing compensation. Such compensation is not merely monetary but may be in the form of medical services for injury caused during the period of participation. Compensation, reimbursements or remuneration should not be so large that they would cause undue influence in any manner whatsoever. The sponsor may also state that he shall not be liable for any injury caused after completion of the trial. Where can the volunteer / patient go then?⁵⁰ Is it fair to allow such a disclaimer to absolve the sponsor of liability?

In India, unlike the United States, the patient cannot approach the court unless there is a causal relation between the trial and injury (including death). In the United States, courts grant compensation for any injury (whether related to the trial or not) caused during a trial (research). In India, the patient may at times even hesitate from approaching the court to demand for justice due, the lack of financial resources for a lengthy legal battle being one of the causes. This phenomenon is one of the reasons why multinational pharmaceutical companies are outsourcing trials to India. Even if they have to compensate the volunteer, the amount will not be as great as it would have been in the developed countries. The 2001 European Union Directive⁵¹ provides for compensation in case of injury or death attributable to the clinical trial; in fact the Association of British Health Care Industries has drafted guidelines dealing with basic principles, nature, limitation and assessment of compensation. The volunteer can and is entitled to be compensated for injury or death caused due to participation under the ICMR Guidelines as well as the GCP Guidelines. The Government needs to provide for the procedure as regards the liability of the sponsor and limitation thereof in the absence of a clear contract. Thus, till legislation is in place, the ICMR and the Government could consider adopting similar guidelines for determining remuneration and compensation which the volunteer would be entitled to for participating in a clinical trial as well as the indemnity and liability of the researcher/sponsor while conducting clinical trials in India. Compensation and insurance should be payable for injury caused, whether

⁵⁰ Neither the DCR nor the two Guidelines provide for such a scenario.

⁵¹ *Supra* n. 31.

the injury was foreseeable or not. Such benefits should be available to the volunteer during and after the trial has been completed in respect of any effect that it may have on the volunteer and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary.

Would the sponsors differentiate between a healthy volunteer and a patient? If so, would one be given preference over another, leading to discrimination amongst the volunteers? The pharmaceutical company should in its contract clearly provide for parameters for distinguishing remuneration and compensation payable to a healthy volunteer and a patient. Similar parameters should also be provided for single blind and double blind trials.⁵² The companies should not be allowed to contract out from their duty towards the volunteers, and in this regard, compensation and expenditure related to the trial, payable to the volunteer, for foreseeable and unforeseeable events should be clearly stated before commencement of the trial.

4. Non-Exploitation

The Principle of Non-Exploitation provides that the volunteers should be remunerated for their involvement in the research and should be informed about the developments of the clinical trial without any consideration to their status in society so that they are able to understand the risks as well as moral implications of the research, whether to themselves or others. Volunteers need to be chosen carefully to prevent exploitation of a particular group of persons.

In India, the ICMR Guidelines and GCP Guidelines provide for the principle of non-exploitation. But we first need to define and distinguish between healthy volunteers and patients whose best option (due to ignorance, poverty, etc) would be to participate in these drug trials. Once distinguished, the authorities should lay down the procedure to be followed

⁵² Blinding refers to a method of control experimentation in which either one or both the parties participating in the trial is not informed about the treatment being given. In the case of single blind, the patient is not informed, while in the case of double blind, both the subject and researcher are not informed.

in each case to prevent exploitation under the given circumstances. Thus, for instance, informing a patient (irrespective of the fact whether such person is literate or not) that he is being given an American drug without any further details would amount to exploitation of the volunteer.

5. Confidentiality

The Principles of privacy and confidentiality like other principles have been provided to protect the volunteers. Privacy ensures that personal details regarding the volunteer would not be disclosed to the public at any time during or after the trial. The identity of the volunteer should at no cost be disclosed to the public, to ensure that he does not suffer from any form of hardship. Similarly, confidentiality would refer to non-disclosure of sensitive information to the public. However, this should not prevent the sponsor from disclosing relevant information gathered during the course of the clinical trial- the sponsor, must also comply with the principle of public domain; such disclosure in fact would help the Ethics Committee to determine whether the trial should be terminated or whether any steps need to be taken to prevent any harm to the volunteer. Since very often volunteers participate in the drug trials attracted by the remuneration offered;⁵³ the Government could set-up a data-base of persons participating in clinical trials. A data-base would also help the Government monitor the number of clinical trials a person has participated in within a given period and also prevent participation in such trials from becoming an alternate source of income. The Government had planned to set up a registry to follow up on clinical trials conducted in India; the same could also be used as a data-base for volunteer information. Confidentiality and privacy prevent the sponsor / researcher from disclosing sensitive information to the world at large but it should not be so exaggerated as to impede disclosure to the volunteer himself. All information collected in course of the trials should not be used in any other trial without prior consent of the patient.

⁵³ In such cases the participants cannot be treated as victims of any kind of abuse.

6. Jurisdiction

In 1996,⁵⁴ Pfizer conducted drug trial of an unregistered drug in Nigeria on children suffering from a fatal strain of meningitis, resulting in the death of five children. The Nigerian Government had not authorised Pfizer to conduct these trials. A suit was filed in the New York Federal Court in 2001, but the same was dismissed on grounds of lack of jurisdiction. One of the options considered by the US Senate, to avoid such mishaps in the future, has been to pass a bill to regulate clinical research in developing countries. In India, if a similar incident were to have taken place it would have been very difficult, if not impossible, to nail the culprits since the guidelines laid down are not mandatory. Thus, the pharmaceutical company need not prove its innocence; it can merely take advantage of the loopholes and get away. The issue of jurisdiction would largely determine the liability of the sponsor/investigator; 'informed consent' would predominantly be governed by the law of contract, which varies from country to country. This very lack of uniformity provides an escape route for the sponsors/investigators.

The various guidelines and principles seem to provide for every minute detail from insurance cover to compensation for the human volunteers participating in these trials. However, the question to be answered is whether these 'volunteers' actually receive the protection they rightfully deserve or do the Clinical Research Organisations⁵⁵ (CROs) take an undue advantage of the volunteer's ignorance.⁵⁶ With the sudden boom in clinical

⁵⁴ Joe Stephens, 'Panel Faults Pfizer in '96 Clinical Trial In Nigeria Unapproved Drug Tested on Children', *The Washington Post* (Washington D.C. USA Sunday 7 May 2006), available at http://www.washingtonpost.com/wpdyn/content/article/2006/05/06/AR2006050601338_pf.html (last visited 21 May 2006).

⁵⁵ Clinical Research Organisation also known as Contract Research Organisation are organisations which undertake various task dealing with clinical trials from recruiting subjects to conducting the trials. India has seen a sharp increase in the number of CROs on account of rise in outsourcing of clinical trials. Further a number of these CROs have been set up in collaboration multinational pharmaceutical companies.

⁵⁶ In 2003, a Delhi based Non Governmental Organisation Aadar Destitute and Old People Home filed a petition in the Supreme Court (Writ Petition No 91 of 2004) against the unethical clinical trials conducted by pharmaceutical companies. See generally Scott Carney, 'Testing Drugs on India's Poor' *Wired News*, available at http://wired.com/news/medtech/0,1286,69595,00.html?tw=wn_tophead_1 (last visited on 15 January 2006).

trials, all's not well, and the government needs to ensure that the volunteers, the citizens of this country, are protected and not exploited. In a number of hospitals, drugs are used on patients without their consent or without briefing/cautioning the patient of all the necessary details, under the garb of beneficial treatment. It is unlikely that patients are aware of the difference between treatment and research. This phenomenon is especially common among persons unable to afford expensive treatment. The present legislation does not provide for adequate protection to the volunteers; while the guidelines seem to exist only for cosmetic purposes.⁵⁷ Thus it has become necessary to legislate on certain issues governing clinical trials.

III. THE ROAD AHEAD

The Government has finally realised the necessity and urgency of legislating on biomedical research on human volunteers. The Biomedical Research Human Subjects (Promotion and Regulation) Bill (the Bill) is set to be introduced in Parliament.⁵⁸ News reports state that the Bill covers all aspects of clinical trials and it shall be an umbrella legislation governing procedural and ethical issues. The Bill is broadly based upon the Schedule

⁵⁷ Shantha Biotech and Biocon were said to have conducted Phase III trials of genetically engineered drugs (insulin for diabetes by Biocon and streptokinase for heart attacks by Shantha) without proper approval, from the DCGI and Genetic Engineering Approval Committee (GEAC), leading to the death of eight persons. News reports indicate that the pharmaceutical companies applied for and received DCGI permission but applied to the GEAC only after the trials started. See Sandhya Srinivasan, 'Indian Guinea Pigs for Sale: Outsourcing Clinical Trials' *India Resource Center* (2004) at <http://www.indiaresource.org/issues/globalization/2004/indianguineapigs.html> (last visited 15 January 2006). *Contra* N Suresh 'Shameful Episode' *Biospectrum* (2004) at <http://biospectrumindia.com/content/editorial/10410041.asp> (last visited 15 January 2006). In another case more than 400 women trying to conceive, inadvertently without informed consent enrolled in a clinical trial to verify whether Letrozole (solely for the purpose of treating breast cancer and can not be used for any other purpose) could induce ovulation. The pharmaceutical company conducting this trial bypassed DCGI approval. A petition was also filed against this company by a non governmental organisation, *supra* n. 5 and Srinivasan *supra* n. 48.

⁵⁸ Phani Raj *supra* n. 4. See also Bhuma Shrivastava, 'Bill drawn up to regulate research on humans', (December 2005) *Business Standard*, available at http://www.business-standard.com/common_storypage.php?hpFlag=Y&chklogin=N&autono=208462&leftnm=lmnu2&leftindx=2&lselect=0 (last visited 14 January 2006).

Y to the DCR and the ICMR Guidelines. The Bill shall also provide for constitution of a regulatory authority to govern and supervise conduct of biomedical research; a mechanism to protect the patients as well as the rights and welfare of the volunteers (ie independent review and informed consent). One of the main functions of the authority is to ensure that basic principles of biomedical research are followed,⁵⁹ and also review the ethical guidelines from time to time.⁶⁰ In addition to these safeguards, the author believes that the Bill could provide for the constitution of distinct authorities—one to monitor procedural matters, the second to monitor ethical issues and the third being a supervisory authority. Thus it could provide for a National Ethics Committee to oversee and monitor the local IECs, similar to the mechanism under the UK Regulations.⁶¹ Further, the Bill and the law that shall be promulgated should specifically state whether a person (human volunteer, researcher or sponsor) would be entitled to a right to appeal or a review of the decisions of the Authorities constituted under the law. In order to provide for greater transparency, the composition, jurisdiction and duties (both administrative as well as judicial) of each of the Authorities constituted under the law should be distinctly and clearly stated. This would also reduce the burden on the DCGI, who at present is solely responsible for granting approvals to conduct trials. The Government should also not allow the pharmaceutical companies and CROs to recruit human volunteers till the appropriate approvals have been sanctioned by the competent authorities.

Recently in London, a drug trial of the compound TGN1412 (manufactured by TeGenero and conducted by Paralex at Northwick Park Hospital) caused severe adverse side effects leading to some of the volunteers taking seriously ill, while several others were in a critical

⁵⁹ The four basic principles of biomedical research are: respect for persons, beneficence, non-maleficence and justice.

⁶⁰ The details regarding regulatory authority and its functions are as stated at a presentation of the prior draft ie the Biomedical Research on Human Subjects (Regulation, Control and Safeguards) Bill, 2005.

⁶¹ *The Medicines for Human Use (Clinical Trials) Regulations, 2004* came into force on 1 May 2004. Statutory Instrument 2004 No.1031.

condition.⁶² As a result of the uproar created by these trials, the British Parliament is considering setting up a group of experts to prevent/avoid recurrence of such incidents.

A few years ago, the John Hopkins University conducted cancer drug trials at the Regional Cancer Centre in Thiruvananthapuram. It was for the first time that the drug was being tested on humans (adequate tests on animals were not conducted). Basic but crucial procedural approvals required for conducting clinical trials had been flouted.⁶³ However, the Central and State Governments refused to recognise this brutal truth, and as regards the way in which the clinical trials were conducted, the State Government is recorded to have stated that there were merely *procedural irregularities*. The State Government appointed a one-man commission to inquire into the controversy while the Central Government suspended further trials at the Regional Cancer Centre for a period of six months. Ironically, the investigators who conducted the trial have won an international award for their research conducted at the Regional Cancer Centre.

While the British Parliament has been so efficient in protecting patients and tightening its regulation, the Central Government, in India, has still not taken any concrete action against defaulters either in the RCC or Letrozole trials. The Central Government needs to act fast to avoid any

⁶² The Medical and Health care products Regulatory Agency which permits such drug trials has stated that the adverse reaction was unexpected. This view is also supported by the manufacturer and the company conducting the clinical trial. However other persons were of the opinion that such reaction was predictable. See Pallabh Ghosh 'Doubt cast over drug trial safety', available at <http://news.bbc.co.uk/1/hi/health/4989810.stm> (last visited 21 May 2006). See also, 'Drugs trial rules are tightened', available at <http://newsrss.bbc.co.uk/1/hi/health/4880190.stm> (last visited 21 May 2006). The victims are presently negotiating compensation with Paralex.

⁶³ For instance the scientist had not received approval from the university's Institutional Review Board; further even approval to export the drug to India had not been obtained from the United States federal authorities.

The report of the John Hopkins University states that the drug trials were not conducted properly; they violated not only mandatory procedural requirements but also ethical guidelines. 'Hopkins Scientist Sanctioned over Drug Trial in India', News Release, available at http://www.jhu.edu/news_info/news/home01/nov01/india.html (last visited on 11 June 2006).

further controversies. The Central Government should consider enacting the law at the earliest to avoid further abuse of patients' / volunteers' rights as also to regulate the procedure for conducting clinical trials. Thus the Government, while passing the Bill, should take into consideration and ensure that not only the Guidelines but also other issues such as accountability, jurisdiction⁶⁴ and penal provisions which would act as a deterrent to by-pass any approvals or ethical considerations are incorporated in the legislation.

What are the limits of the patient vis-à-vis his rights, or rather does he enjoy any rights at all? What is 'informed consent'⁶⁵ 'confidentiality' and 'essential information'? How can terms so important be exhaustively defined so as to safeguard the rights of the volunteer and at the same time ensure that there is no escape route for evading accountability and liability on the part of the pharmaceutical companies and researchers?⁶⁶ In India, since most of the patients are considered naïve and unaware of their rights, the first question may be considered a bit far fetched. Nevertheless, safeguards against demands by unscrupulous volunteers are also necessary if India is to sustain the clinical research boom. Under the Nuremberg Code, the patient is at liberty to terminate the experiment, the ICMR Guidelines also allow withdrawal of the volunteer at any stage. But can he hold the sponsor and researcher at ransom and demand for benefits which he is not entitled to? Who shall be liable for any injury caused after completion of trial, where the injury in question does not have a direct nexus with the trials? Which authority can the victim (the

⁶⁴ The extent liability of pharmaceutical companies whose head offices are based in other countries and to what extent will the laws of those countries affect (immunise) the pharmaceutical companies vis-à-vis the clinical trials conducted in India should also be included.

⁶⁵ Article 2 (j) of the EU Directive defines 'informed consent' as 'decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.' The definition provided in the *Medicines for Human Use (Clinical Trials) Regulations 2004* is similar to this definition.

⁶⁶ The terms 'sponsor', 'researchers' and 'subjects' also need to be defined under the Bill.

researcher/sponsor in the former case and the patient in the latter) approach? This leads us to the inevitable question: what are the remedies available in the absence of legislation?

Presently, the ICMR Bill awaits cabinet approval; news reports state that the ICMR Bill is exhaustive—covering procedural as well as substantive issues. But till it finally finds its way and receives the nod, clinical trials will continue to be conducted perhaps unethically. As mentioned earlier, the only penal provision dealing with clinical trials is found in the DCA, which again enforces a fine for non-compliance only with provisions to apply for permission to conduct these trials. However, persons involved in unethical trials go scot-free since no legislation penalises non-compliance of any of the guidelines. Although there is no legislation to deal with the ethics issue, the volunteer can approach the court on grounds that the consent was neither free nor informed as required. All these are pressing issues which need to be dealt with at the earliest. Confidentiality should not be to such an extent that the patient himself is deprived of the information. Breach of such principle should be penalised, since it would also amount to breach of trust of the patient. The Government had planned to set up a regulatory authority to monitor clinical trials, however no such body has been set up so far. The laxity worsens the plight of the naïve volunteers. Laying down a procedure which not only entails the sponsor and researcher to comply with safeguards laid down by the Government but also makes the pharmaceutical company responsible in the country where the main research is conducted would help in raising the standards for conducting clinical trials. The onus of proof should be upon the sponsor / researcher to prove whether procedure has been followed or not and if not why. In order to ensure that there is no bias, the sponsor should be allowed to request a review of the decision taken by the competent authority. Further the Government should also ensure that researchers as well as pharmaceutical companies submit a detailed report (a minimum of two copies of the report should be submitted—one in an electronic medium and the other to be personally delivered to the office of the Competent Authority) of the AEs, ADRs, SAEs and SADR of trial at every stage as well as after the trial has been completed. This post-trial period should not be so short so as to seem that it has been incorporated

for mere cosmetic effect but should also not be so exaggerated that it might have a negative effect on the researcher. The adverse effects should not be restricted to the ones mentioned in the form; in fact the pharmaceutical company should also be held liable for unexpected adverse effects/events.⁶⁷ The Government could appoint persons to follow and monitor the trials closely (similar to an impartial witness) and report to the Competent Authority in case of any flaw, mishap, adverse reaction or severe adverse reaction occurring during the trial. Such monitoring should be continued even after completion of the trial.⁶⁸ However, such monitoring could deter pharmaceutical companies from outsourcing trials to India as it would increase cost of the trials significantly.

IV. CONCLUSION

With an Act in place, we can expect the incidence of unethical trials to reduce. How far will the Act be effective? One of the main reasons for choosing India is the low cost involved in conducting clinical trials. According to the UNCTAD survey India is the third most attractive prospective R&D location.⁶⁹ Some pharmaceutical companies state that this is beneficial to the patients in the long run since it would lower the cost of the drug and make it available in the market at affordable prices. But how often are these *benefits* actually passed on to the volunteers / patients? The UNCTAD World Investment Report, 2005 states that in order to attract greater Foreign Direct Investments (FDIs) governments may offer incentives at the cost of lowering regulatory standards as well as tax revenue. This may also be one of the reasons why there has been

⁶⁷ The term unexpected AE / ADR should not be confused with SAE and SADR. In fact the term unexpected adverse event and unexpected adverse drug reaction should be defined in the Bill.

⁶⁸ Like the EU Directive which provides for pharmacovigilance procedure to monitor adverse effects the Bill could provide for appointment of persons to monitor clinical trials. Such persons should not be associated with the researcher or sponsor but should follow-up on the subject's health and whether the subject is receiving the benefits of the trial (if any).

⁶⁹ Figure IV.11, Chapter IV, R&D by TNCs and Developing Countries, United Nations Conference on Trade and Development (UNCTAD), World Investment Report, 2005, Transnational Corporations and the Internationalization of R&D, 153, available at http://www.unctad.org/en/docs/wir2005ch4_en.pdf (last visited 26 July 2006).

no legislation passed to govern the ever-increasing clinical trials in India.⁷⁰ While promoting clinical research in the country is important for economic reasons, the Government should ensure that drugs for which trials are conducted in India on Indian volunteers are available at a reasonable price in the Indian markets. The Government has to strike a balance between the Preventive Principle which requires submission and approval of application before conducting clinical trials and the Progressive Principle which ensures that India continues to be a major player in the global market while adhering to the international guidelines and principles.⁷¹ Thus by putting the rights, safety and interests of the volunteer before those of society proves that the volunteer's rights are of paramount importance. The Progressive Principle would bind the Government not to enforce any harsh liability on the pharmaceutical companies but the Government cannot sacrifice the interest of its own citizens in the name of development. In fact the Government should restrict the number of trials that a person can participate in simultaneously; this would be beneficial for the volunteer as well as the researcher and pharmaceutical company. However it would lead to an increase in the cost of conducting trials in India due to a reduction in the availability of *guinea pigs*. The road does not end here.

The Government needs to work towards regulating the outcome of the results being made available to the public to ensure that the trials are conducted as per the norms laid down by it.⁷² Confidentiality and privacy of the volunteer should in no way be confused with disclosure of details and result of the trial. In fact, mandatory disclosure of such information to the public would augment the trust of the people and encourage them to participate in these trials. The Government needs not only to codify

⁷⁰ Chapter VI, Development Implications, United Nations Conference on Trade and Development (UNCTAD), World Investment Report, 2005, Transnational Corporations and the Internationalization of R&D, 192–193, available at http://www.unctad.org/en/docs/wir2005ch6_en.pdf (last visited 26 July 2006).

⁷¹ Preventive Principle secures and protects the interest of the subject while through the Progressive Principle the Government promotes the economy of the country.

⁷² Public access to result of the trials does not suggest violation of Principles of Privacy and Confidentiality. The Declaration of Helsinki, 1964 deals with necessity of privacy of human subjects.

ethical issues into a proper legislation but also issues concerning and recognising improvements in the fields of biotechnology and bioequivalence. Similarly research such as non commercial clinical trials not extensively recognised in most countries due to various reasons should also be covered within the ambit of the proposed legislation.⁷³ The Government should not only take into consideration the various legislations governing clinical trials passed by other countries but look at the filling up the loopholes found in those legislations.⁷⁴ These measures should be dealt with simultaneously with the Act.

⁷³ Non-commercial clinical trials refer to trials conducted by researchers without the assistance of pharmaceutical companies. These trials provide great benefits to the patients. This concept has been provided for in the EU Directive 2001, however most member states are still to incorporate the same in their national legislation according to their specific requirements.

⁷⁴ Thus while the British Parliament plans to tighten its regulatory procedures after the TeGenero incident, the Indian Government should learn from these mishaps and prevent occurrence of such accidents in India. Similarly it can also avoid an episode like Kano Trials by incorporating appropriate measures protecting the subjects.

GENDER WARS: AN IDENTITY CRISIS[†]

*Savita Sadananda**

‘Over himself, over his own body and mind,
the individual is sovereign.’

John Stuart Mill¹

I. INTRODUCTION

Alex, a 13 year old girl, an inhabitant of Australia is not just another girl from the neighbourhood. Alex faced a very atypical and uncharacteristic dilemma with regard to her gender identity. She had an overwhelming sense of discomfort with her anatomical sex and had a strong desire to live as a male to add to that had gone to distressing lengths to conceal her female body.² In these gender wars, Alex is not alone.

‘Gender identity is the internalised sense of being male, female or having an ambivalent sexual status, the self awareness of knowing to which sex one belongs.’³

Gender identity is the sense of belonging that one feels for a particular sex not only biologically but also psychologically and socially. Transsexuality therefore can be explained as a variant gender identity in which there is an incongruity between a person’s external genitals and his psychological sense of gender. There is a persistent discomfort with

† This article reflects the position of law as on 23 January 2006.

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¹ John Stuart Mill, ‘*On Liberty and Other Essays*’, (1859) Oxford University Press, 1991 Reprint.

² *Re Alex: Hormonal Treatment For Gender Identity Dysphoria* [2004] FamCA 297, available at <http://www.familycourt.gov.au/presence/resources/file/eb001848a4fb4f4/realex.pdf> (last visited 27 July 2006).

³ *A Descriptive Dictionary and Atlas of Sexology*, Greenwood Press, 1991, 241.

his or her anatomical sex and a sense of inappropriateness in the gender role of that sex.⁴

The object of the article is to highlight the legal hassles faced by transsexuals and the subsequent need for legislations that would safeguard their basic rights. It is imperative that the law recognises the gender assertions they have made through seeking reassignment.⁵ The article will also touch upon the laws adopted by various countries that recognise a transsexual's acquired sex.

II. SEXUAL REASSIGNMENT SURGERY & CONDITIONS

Transsexuals seek their gender assertions through a sexual reassignment surgery. In order to assess whether a patient is in need of the surgery, which is irreversible, doctors in the United States of America apply the criteria as contained in the Diagnostic and Statistical Manual of Mental Disorders. This manual has laid down five criteria that must be met before a diagnosis of a transsexual can be given:

- There must be evidence of strong and persistent cross-gender identification.
- This cross-gender identification must not merely be a desire for any perceived cultural advantages of being the other sex.
- There must also be evidence of persistent discomfort about one's natural sex or a sense of inappropriateness in the gender role of that sex.

⁴ Dr. Russell Reid *et al*, *Transsexualism: The Current Medical View Point* (18 January 1996) 2nd edn, available at <http://www.pfc.org.uk/medical/mediview.htm#sum-legal> (last visited 12 May 2006). This work was produced as part of the work of the UK Parliamentary Forum on Transsexualism chaired by Dr. Lynne Jones MP. The purpose of the document is to provide an overview of current best practice in providing effective health care for persons with the transsexual syndrome. It describes the nature of the syndrome, its diagnosis, treatment and outcomes; recognises its biological aetiology; and makes recommendations for the legal status of people experiencing transsexualism.

⁵ Stephen Whittle, *Legislating for Transsexual Rights: A Prescriptive Form* [17 May 1996] available at <http://www.pfc.org.uk/legal/whittle3.htm> (last visited on 12 May 2006).

- The individual must not have a concurrent physical intersex condition.
- There must be evidence of clinically significant distress or impairment in social, occupational, or other important areas of functioning.⁶

Sexual re-assignment surgery will be undertaken only if each and every one of these conditions is satisfied. The need to apply such standards for surgeries in India is urgent.

III. EFFECTS ON ELEMENTS OF PERSONAL LAWS

A. Matrimonial Laws

Marriages between gender-conflicted and non-gender conflicted fall into two categories:

1. Marriages between a person of one sex and a person of the opposite sex who was formerly of the same sex (post operative marriage).
2. Marriages between two persons of the opposite sex, one of whom subsequently became a member of the same sex.⁷

A cursory glance at the relevant matrimonial laws in India would be essential. Under Section 5 of the *Hindu Marriage Act, 1955* a marriage will be solemnized between any two Hindus, if neither party has a spouse living at the time of the marriage, the bridegroom has completed the age of twenty-one years and the bride is of the age of eighteen years at the

⁶ The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR), published by the American Psychiatric Association, is the handbook used most often in diagnosing mental disorders in the United States, available at <http://www.psych.org/research/dor/dsm/dsmintro81301.cfm> (last visited on 13 May 2006). The criteria that has been categorically stated is available at http://en.wikipedia.org/wiki/Gender_identity_disorder#DSM-IV (last visited on 13 May 2006).

See also <http://www.pfc.org.uk/node/634> (last visited on 13 May 2006).

⁷ See Sr. Mary Elizabeth, *Legal Aspects Of Transsexualism* (J2CP Information Services California 1998), available at http://www.transgendercare.com/guidance/resources/legal_aspects_ts.htm#b6 (last visited 27 July 2006).

time of marriage. *The Parsi Marriage and Divorce Act, 1936*,⁸ and the *Indian Christian Marriage Act, 1872*,⁹ also have analogous provisions. Under Mohammedan law, marriage (nikah) is defined to be a contract performed to acknowledge the legitimacy of procreation.

The 1970 case of *Corbett v. Corbett*,¹⁰ for the first time, questioned the validity of marriage of one April Ashley, a post-operative male-to-female transsexual, registered at birth as a male and raised as one, with Arthur Corbett. Arthur Corbett, prior to marriage, knew the facts of this gender transition. In December 1963 both filed petitions for a declaration that the marriage was null and void. Omrod, J. held that:

‘The question ... becomes what is meant by the word “woman” in the context of a marriage. Only a biological female is “a person who is naturally capable of performing the essential role of a woman in a marriage”....The law should adopt the medical criteria of sex at birth, namely, “the chromosomal, gonadal and genital tests, and if all three are congruent [at birth, as in this case] determine the sex for the purpose of marriage accordingly, and ignore any operative intervention....Marriage is a relationship which depends on sex and not on gender.’¹¹

Omrod, J. thus, declared the marriage void.

However, marriages between a person of one sex and a person of the opposite sex, who was formerly of the same sex, should be allowed because the post-operative transsexual, psychologically as well as socially, is as ordinary as any non-transsexual in his acquired sex. The validity of such a marriage would obviously hinge on factors like fraud and absence of consummation. But if the spouse of such a transsexual is aware of his/her past and entirely understands the fact they will never be able to consummate the marriage and have a child of their own, there is no reason why a transsexual must not be allowed to marry. By not permitting them to marry we are circuitously making them a victim of social stigma.

⁸ *The Parsi Marriage and Divorce Act, 1936*, section 3.

⁹ *The Indian Christian Marriage Act, 1872*, section 60.

¹⁰ [1970] 2 All ER 33.

¹¹ [1970] 2 All ER at 48-49.

Some countries today, recognise gay and lesbian marriages, so why discriminate against the transsexuals by not recognising their marriages.

The same view was recognised in the case of *M. T. v. J. T.*,¹² wherein the New Jersey Appellate Division unanimously declared in 1976 that an individual who changes sex through surgery is entitled to all the legal rights enjoyed by others of the same sex, including marriage. The Court rejected previous decisions in this country and abroad, that held a person's sex was determined solely by his or her chromosomes designated at birth. The Court ruled that '[I]f the anatomical or genital features of a genuine transsexual are made to conform to the person's gender, psyche, or psychological sex, then the identity must be governed by the congruence of these standards.' Therefore, it was held that a marriage between a postoperative individual and a person of the opposite sex is valid as long as the transsexual does not conceal the fact that he is one.

The above view has been re-affirmed in *Re Kevin's Case*,¹³ by Justice Chislom of the Family Court of Australia, who held that a marriage between a post-operative male and a female is valid. The crux of the matter was whether the husband was a man at the date of the marriage. The Commonwealth argued that the meaning of the word 'man' or 'woman' in the *Marriage Act, 1961* (Commonwealth) should be understood in the context in which the words were used at the time the legislation was passed. Granting a declaration that the marriage was valid, it was held that for the purpose of ascertaining the validity of a marriage under Australian law, the question whether a person is a 'man' or a 'woman' is to be determined as of the date of the marriage. Anything to the contrary in *Corbett v. Corbett* does not represent Australian law.

On 11 July 2002, the European Court of Human Rights delivered its judgment in the case of *Goodwin v. The United Kingdom*,¹⁴ and held that

¹² 140 N.J.Super. 77, 355 Atl. 2d 204.

¹³ [2001] FamCA 1074, available at http://www.austlii.edu.au/au/cases/cth/family_ct/2001/1074.html (last visited 14 May 2006).

¹⁴ (2002) 35 EHRR 18.

the United Kingdom had breached the right to private life and the right to marry.¹⁵ In response to this judgment, the Parliament of United Kingdom passed the *Gender Recognition Act, 2004*.

B. Divorce

Another issue to be dealt with is whether a married person undergoing sexual reassignment surgery would be entitled to maintain his/her marital status. Legislation should make provision for upholding of the same to be dependent on the acceptance of the other spouse. However, sexual reassignment surgery should be included as a ground for divorce if the other spouse does not concede to it. If a marriage is solemnised with prior knowledge of the spouse's transsexuality, then the other spouse should not be allowed, at a later date, to use the ground of impotency as a means of nullifying the marriage.¹⁶

The law must ensure that the physicians will not provide hormone therapy and the surgeons will not perform sex reassignment surgery prior to a divorce action being completed and the issues of status of the marriage and children born of the marriage is ascertained.

¹⁵ The applicant, Christine Goodwin, lodged a complaint with the European Commission of Human Rights on 5 June 1995 as regards the lack of legal recognition of her post-operative sex and about the legal status of transsexuals in the United Kingdom. The case was transmitted to the European Court of Human Rights on 1 November 1998. On 11 September 2001 a Chamber of the Court (Third Section) relinquished the case to the Grand Chamber and a hearing was held on 20 March 2002.

¹⁶ It seems to be the policy of the *Hindu Marriage Act, 1955* that it is a matter of individual liberty whether a person feels like marrying an impotent. Section 12 of the *Hindu Marriage Act, 1955* states, 'Any marriage solemnised, whether before or after the commencement of this Act, shall be voidable and may be annulled by a decree of nullity on any of the following grounds, namely, that the marriage has not been consummated owing to the impotence of the respondent. A party is impotent if his or her physical or mental condition makes consummation of marriage a practical impossibility. Impotency means inability to perform sexual act or inability to consummate the marriage. Impotency is either physical or mental. Instances of the former are malformation of, or structural defects in the organ.' 'Impotency' has been further defined in Paras Diwan, *Modern Hindu Law* (13th edn Allahabad Law Agency 2000) p 99.

C. Alimony Laws

The determining factor, in cases for maintenance, is the financial status of the spouse and not the sex of the person.¹⁷ Therefore, a mere change of sex by a woman should not disentitle her of maintenance. Thus, the financial status of both the spouses should be the only determinant. The same principle must be applied to maintenance provided under section 125 of the Criminal Procedure Code, 1973.

This view has also been expressed in a recent decision by the Ohio Court of Appeals. The Court concluded that the mere fact that the supported spouse has undergone a sex-change operation does not alleviate the other spouse's support obligation. In *Moore v Moore*,¹⁸ the marriage was dissolved after 25 years. The husband was ordered to pay spousal support. Eight years later, the husband sought relief from payment of alimony on the basis that the wife had undergone sex reassignment surgery and was now a male. The husband's motion for relief was denied by the trial court, which stated that the husband had failed to establish the existence of any significant change in the former wife's financial circumstances that would warrant any relief. The Ohio Court of Appeals re-affirmed the trial court's decision.

The existing laws in our country are not equipped to deal with such contingencies and should be amended to provide for the same.

D. Child Custody

The welfare of children is of paramount consideration and not the rights of the parents.¹⁹ This principle applies to all cases involving children. A

¹⁷ The criteria for disbursement of alimony has been laid under section 37 of the *Indian Divorce Act, 1869* and section 25 of the *Hindu Marriage Act, 1955* and section 40 of the *Parsi Marriage and Divorce Act, 1936*. The criteria laid down is that the husband shall, to the satisfaction of the Court, secure to the wife such gross sum of money, or such annual sum of money for any term not exceeding her own life, as, having regard to her fortune (if any), to the ability of the husband, and to the conduct of the parties, it thinks reasonable; and for that purpose may cause a proper instrument to be executed by all necessary parties.

¹⁸ 158 Ohio App. 3d 489, 817 N.E.2d 111 (2004).

¹⁹ *Rosy Jacob v. Jacob A Chakramakkal* AIR 1973 SC 2090 and *Nirmala Jain v. State (Delhi)* AIR 1983 Del 120. See also section 13 of *Hindu Minority and Guardianship Act, 1956*.

case involving a gender-conflicted parent presents a unique situation in child custody matters, the contentious question being whether the gender-conflicted are by definition *unfit* parents. A *fit* parent is one who would not only provide for all the necessary needs of the child but also provide the child with love and support for the proper development of the child. A transsexual parent cannot be considered to be an *unfit* parent merely on the ground that he/she has undergone a sex reassignment surgery, since the requirements of a *fit* parent have nothing to do with the sex of the person. In custody disputes, any parent seeking a material change in the terms of the custody agreement has to demonstrate to the court that there has been a material change in the circumstances affecting the child. It is clear that the test for custody and access is always determined keeping the best interests of the child in mind. Therefore, a parent's decision to change his gender *does not constitute a material change* in circumstances to warrant alteration of the child custody arrangement. (emphasis supplied)

The Colorado Appellate Court ordered that the custody must remain with the natural 'mother' (presently a male) in *Christian v. Randall*.²⁰ The court found that 'the record contained no evidence that the environment of the respondent's home in Colorado endangered the children's physical health or impaired their emotional development.'

In 1987, a Minnesota Appellate Court,²¹ reasoning that the best interests of the child would be so served and sustained the grant of sole custody of a daughter to her 'transvestite' father. Pertinent to the decision was the fact that the father did not cross dress at home, would tell his daughter about his cross dressing at an appropriate time with the help of a therapist, and, perhaps critically, that the child had been abused while in the mother's custody.

In *Re Mackenzie*,²² the Arizona Supreme Court upheld the lower courts' decisions and ruled that the defendant's cross-dressing and preoperative

²⁰ 516 P.2d 132 (Co Ct App 1973).

²¹ *In re the Custody of TJ.*, 1988 Minn. App. LEXIS 144 (Minn. App. Feb. 2, 1988) (unpublished decision).

²² *Supra* n. 7.

transsexual lifestyle was not an issue significant enough to cancel either custody or visitation.

Whether the gender-conflicted are *per se* unfit parents is clearly unresolved scientifically and judicially at this time. Preliminary psychiatric data, however, indicates that as parents, the gender-conflicted do not adversely affect their own child's sexual identity.

This view has been further supported by the judgment of *Kantaras v. Kantaras*²³ wherein the petitioner Michael Kantaras, a female-to-male transsexual, had pleaded for dissolution of marriage and child custody rights. In February 2003, Circuit Court Gerard O'Brien, J. issued a groundbreaking decision holding that Michael was legally male, affirming the validity of the marriage, and awarding Michael primary custody of the couple's two children. On appeal, the respondent, Linda Kantaras pleaded that the petitioner must be stripped of all his parental rights merely on the ground that he was a transsexual. The Court of Appeal did not uphold this contention and ruled that transsexualism must not be the ground on which a parent is stripped of his parental rights. However, the Court declared the couple's marriage to be void.

E. Inheritance Laws

The aspect of transsexualism came into the limelight in India due to the high-profile Mafatlal family feud between the youngest son Atulya and his transsexual brother Ajay (who earlier was Aparna). Late Yogendra Mafatlal had during his life-time given control of the Mafatlal companies to Atulya and had also distributed family property among Atulya and his four daughters. Though the question of which sex, male or female, of the transsexual brother would be used to determine inheritance, did not arise in court, there was much media speculation on the issue. The law of inheritance with regard to transsexuals in India is another element of family law that needs examination. A person inherits either by testamentary succession or by intestate succession.

²³ Case No. 2D03-1377, Court of Appeal of Florida, Second District, 884 So. 2d 155. The decision by Fulmer, J. of the Court of Appeal is available at <http://www.transgenderlaw.org/cases/kantarasopinion.pdf> (last visited on 8 January 2006).

Presently Hindus are governed by the *Hindu Succession Act, 1956*, wherein the general rules governing succession to the property of a male Hindu dying intestate and a female Hindu dying intestate differ.²⁴ In case of Mohammedans, the rule is that the son shall take two third share of the property and the daughter shall take only one third share.²⁵ When one reassigns his biological sex to align it with his psychological sex his rights of inheritance are altered. The law needs to ascertain the stand that it would take in a situation where a transsexual dies intestate or the heir is a transsexual, as there may be instances where one may undergo the sex reassignment surgery to just avail of benefits of succession. This is especially important where in an intestate succession, male and female inheritance is unequal.

To illustrate, consider a male to female Hindu transsexual dies intestate, the question that arises in such cases is whether section 8 or section 15 of the *Hindu Succession Act, 1956* would apply with regard to the devolution of property. The stand that should ideally to be taken, by a welfare state, such as India, would be to divide the property in accordance with the sex of the person at the time of his death. The same must be done in the case of Mohammedans, Parsis and Christians. In cases where the heir changes his or her sex, the law must recognise the sex of the person at the time the estate devolves upon him/her. Furthermore, if the transsexual has changed his sex prior to succession he should be recognised by the sex he has acquired but if he has changed his sex after succession he cannot then inherit as per the reassigned sex. The properties of a Hindu woman, also known as stridhan, are significantly affected by sex reassignment surgery. If a male transsexual had acquired stridhan at the time of marriage, such property should remain vested with him. The other problem that would arise is in situations wherein the will is ambiguous as regards the legatee. For example, if a testator bequeaths his property to his son and three daughters and subsequently one of his daughters undergoes a sex reassignment surgery prior to succession and the will does not provide for the same, the judge must apply the 'arm chair rule'

²⁴ *Hindu Succession Act, 1956*, section 8 and section 15.

²⁵ Mulla, *Principles of Mohamedan Law*, 19 Edn 1990, p.254.

in order to ascertain what the testator intended by his will. Thus rules of succession should be amended so as to recognise the rights of a transsexual.

IV. RECORDS & DEMOGRAPHIC BALANCE

The Indian law requires every birth to be registered by the Registrar appointed by the State Government.²⁶ The details to be registered are the names of the child and parents, the child's sex etc. The customary criteria used for determining sex are the biological criteria: chromosomal and genital congruity.²⁷ The law provides for an entry in the birth register to be corrected at any time if it can be shown to the satisfaction of the Registrar, that the entry registered is erroneous.²⁸ This includes the circumstances where the new born was not in fact of the sex recorded in the register.

Since the importance of a birth certificate is evident it is unreasonable to not issue transsexuals with a new birth certificate which would serve as evidence of their acquired sex. It will also lead to an anomaly that a person may be born a man but post operation dies a female or vice versa.

The condition of gender dysphoria is not an error. Although the Indian law does not provide for any change in the register, otherwise than an error, it is submitted that the reassignment operation is by choice and

²⁶ *The Registration of Births and Deaths Act, 1967*, section 7.

²⁷ Working Group, 'Report of the Interdepartmental Working Group on Transsexual People', Home Office, United Kingdom, p.9. The working group was set up by the Home Secretary of the United Kingdom in April 1999 to consider, with particular reference to birth certificates, the need for appropriate legal measure to address the problems experienced by transsexual people, having due regard to scientific and societal developments, and measures undertaken in other countries to deal with them.

²⁸ Section 15 of *The Registration of Births and Deaths Act, 1969* states, 'If it is proved to the satisfaction of the Registrar that any entry of a birth in any register kept by him under this Act is erroneous in form or substance or has been fraudulently or improperly made, he may, subject to the rules as may be made by the State Government with respect of the conditions on which and the circumstances in which such entries may be corrected or cancelled, correct the error or cancel the entry by suitable entry in the margin, without any alteration of the original entry and shall sign the marginal entry and add thereto the date of the correction or cancellation.'

does not indicate an error in recognition of the sex at the time of birth. Therefore, the provision to make changes on the basis of reassignment of sex is absent in the *Registration of Births and Deaths Act, 1969* and needs to be included in order to give transsexuals complete recognition of their newly acquired gender.

V. EFFECT ON EMPLOYMENT & VOCATIONAL TRAINING

There is a crucial need to provide for regulations that prohibit discrimination against in the spheres of employment and vocational training on the basis that a person has undergone, is undergoing or intends to undergo gender reassignment. Article 16 of the Constitution of India (Constitution) protects government employees against discrimination on the grounds of sex. This principle has been incorporated in the policies of most private companies.

There may be exceptional instances where it may not be unlawful to discriminate on grounds of gender reassignment such as:

- When a person's sex is a Genuine Occupational Qualification (GOQ) for that employment; or
- The nature of employees' duty involves the conducting intimate searches pursuant to statutory powers (eg *The Police and Criminal Evidence Act*);
- The duty involves the employee working in a private home and reasonable objection can be shown by the employer because of the intimate contact in those circumstances.

It is submitted that in these limited cases alone, discrimination at employment may be permitted.

A. Vocational Training

Articles 15(4) and 16(4) of the Constitution empower the State to make special provisions for the advancement of any socially and educationally backward classes of citizens or for the Schedule Caste and Schedule

Tribe, in the field of education and public employment. Article 46²⁹ of the Constitution reiterates the commitment of the Government in protecting the interest of the Schedule Casts and Schedule Tribes.

Pursuant to the National Policy on Education, 1986 and the Programme of Action (POA), 1992, a reservation policy was framed in order to give an impetus for the development of the backward classes. This reservation also provides for girls in various educational institutions. The question that we would face is whether a male to female transsexual must be considered to be a female for reservation purpose. The law must recognise them in accordance with their acquired gender and provide them with all the rights as per that gender.

VI. ABUSE OF THE SURGERY

In as much as this surgery is a boon to transsexuals, at the same time this surgery could be chosen for malevolent desires. Female infanticide is one social taboo India has not yet done away with. Unfathomable desires of many parents to have a son could generate situations wherein they are seen seeking this procedure to alter the sex of their girl child. Sexual reassignment surgery conducted without consent, on a child or an adult, would amount to a violation of the individual's right to life guaranteed by Article 21 of the Constitution. It would also attract the provisions of section 320 of the Indian Penal Code that deal with the criminal offence of causing 'grievous hurt'³⁰.

²⁹ Article 46 of the Constitution states, 'The State shall promote, with special care, the education and economic interests of the weaker sections of the people, and, in particular of the Scheduled Castes and Scheduled Tribes, and shall protect them from social injustice and all forms of social exploitation.'

³⁰ The following kinds of hurt only are designated as 'grievous': First-Emasculation, Secondly-Permanent privation of the sight of either eye, Thirdly-Permanent privation of the hearing of either ear, Fourthly-Privation of any member or joint, Fifthly-Destruction or permanent impairing of the powers of any member or joint, Sixthly-Permanent disfiguration of the head or face, Seventhly-Fracture or dislocation of a bone or tooth, Eighthly-Any hurt which endangers life or which causes the sufferer to be during the space of twenty days in severe bodily pain, or unable to follow his ordinary pursuits.

It is, however, submitted that this procedure must be permissible in case of adults, of their own volition as they believe that they are trapped in the wrong body and infants who suffer from *hermaphroditism*, which is a sex disorder wherein infants are born with ambiguous genitalia having both testicular and ovarian tissue or genetic syndromes that confound a simple designation as a male or female, and doctors have to assign a sex to them.

Thus, any kind of a sex-change operation should not be permitted in children as long as gender dysphoria is diagnosed. Such situations could be regulated by laws that make it imperative to acquire permission from a Committee comprising of senior doctors of the district or a certificate regarding the condition of the child be acquired from an independent doctor appointed by the Court.

In India, the prevalent practice followed by ethical doctors is as follows:

- To analyse the patient's psychological condition by three psychiatrists of Medical College standing;
- To certify that the patient is sane;
- That he/she is a transsexual;
- That the operation is going to make the patient happy and that the patient, if not operated upon, would commit suicide.

If only they certify in the affirmative to the above four queries should the patient be considered fit for the surgery. Subsequent to receiving the certificate, the plastic surgeon would ask the patients

- To cross dress for a period of three months in order to get acquainted with life after the surgery;
- If the patient is still prepared to undergo the surgery, he/she is administered hormone therapy for six months;
- It is only after these nine months would the surgery be conducted.

The panel consisting of doctors, psychologists and legal experts if constituted under the regulation would aid in preventing the abuse of surgery. Thus, it is imperative that the above procedure is governed by law.

VII. COMPARISON OF LAWS IN VARIOUS COUNTRIES

Several countries have enacted legislation in order to confer full recognition to transsexuals. A study of the laws in various countries would not only highlight the importance of such legislation but also lay down certain accepted principles.

A. *United Kingdom*

The United Kingdom (UK) has enacted the *Gender Recognition Act, 2004* in order to provide transsexuals with the prospect of achieving legal recognition of their acquired gender. This Act not only enables them to acquire new birth certificates but also entitles them to equal rights and liberties. Only adults (18 years and above) are entitled to a gender recognition certificate provided their conditions are as mandated by section 2 of the said Act.³¹ Two kinds of certificates are granted under the said Act, one to an unmarried applicant, a full gender recognition certificate, and the other to a married applicant who is issued an interim gender recognition certificate.

The Sex Discrimination (Gender Reassignment) Regulations, 1999 of Great Britain lays down measures to prevent discrimination against transsexual people on the grounds of sex, in pay, treatment in employment and vocational training. The effect of the Regulations is to insert into the *Sex Discrimination Act, 1975* a provision which furthers the scope of the said Act, to include prohibition of discrimination on gender reassignment grounds.

³¹ This section requires, *inter alia*, that the applicant has gender dysphoria and has lived in the acquired gender throughout the preceding two years and intends to live in the acquired gender.

B. Germany

Since 1980, Germany has a law that regulates the change of first names and legal gender.³² The *German Transsexuals' Act, 1980* (the TSG Act) provides two options, which may be applied either successively or independently of each other. The first option refers to changing the applicant's first name in accordance with the transsexuals acquired gender.³³ The second option is that after the individual has undergone sex reassignment surgery he may apply for change in gender. For both proceedings, two mutually independent expert opinions are necessary. These expert evaluations have to certify that a diagnostic criterion for transsexualism has been in existence for at least three years, and that the condition is of a permanent nature. The requirement of a minimum age of 25 years, which had been prescribed for both the abovementioned proceedings, was eliminated for the legal status change in 1982.

C. Australia

The first major advances in Australia occurred when two Supreme Court decisions, one in Victoria,³⁴ and the other in New South Wales,³⁵ held that following sex affirmation treatment, a woman who is a transsexual is regarded as a female for the purpose of the Criminal law. On 3 January 2005, a new legislation was introduced by the Brack's Government in Victoria to provide for the correction of the legal record of sex of its citizens who had undergone sex reassignment surgery.³⁶

³² 'Gesetz über die Änderung der Vornamen und die Feststellung der Geschlechtszugehörigkeit in besonderen Fällen (de:Transsexuellengesetz - TSG, 1988)'-'Law About The Change Of First Name And Determination Of Gender Identity In Special Cases (Transsexual Law - TSG)'. Translated version available at <http://translate.google.com/translate?hl=en&sl=de&u=http://www.cgil.it/org.diritti/transsex/legted.html&prev=search%3Fq%3DBeschl%2Bd.%2BBVerfG%2B%26hl%3Den%26lr%3D%26ie%3DUTF-8%26sa%3Dg> (last visited 13 May 2006).

³³ Section 1 of the TSG Act.

³⁴ *R v. Cogley* [1989] VR 799.

³⁵ *R v. Harris and McGuinness* [1988] 17 NSWLR 158.

³⁶ *Births, Deaths and Marriages Registration (Amendment) Act 2004*, Act No. 29/2004.

In the year 2001, Justice Chislow a judge of the Family Court of Australia gave a groundbreaking judgment which held that marriage between a postoperative male transsexual and a woman is valid.³⁷ The Court further ruled that transsexuals, like others with intersex conditions, should be able to choose their sex, affirm it and marry as a member of that sex. This judgment brings Australian law in conformity with a growing tendency internationally to recognise a transsexual's acquired gender.

The South Australian Legislature has passed the *Sexual Reassignment Act, 1988* to provide recognition in their new gender to people who have undergone gender reassignment,³⁸ by issuing a recognition certificate that would identify a person who has undergone a reassignment procedure as being of the sex to which that person has been reassigned.³⁹

D. France

One of the earliest judgments which compelled France to change their laws is the case of *B v. France*⁴⁰. In 1992, a French transsexual, B, took France to the European Commission of Human Rights over the refusal to change the civil record. This Court ruled in favour of the transsexual and forced the French Supreme Court, the Court of Cassation, to overturn its earlier ruling, and in November 1992 the right of transsexuals to change civil status was recognized in France.

E. United States of America

Out of 50 states constituting the United States of America, 48 states have enacted and amended legislative procedures to integrate transsexuals in the civil society. The 2 states that have not made amendments are Tennessee and Ohio. In 1975, the City of Minneapolis became the first governmental entity in the United States to pass trans-inclusive civil rights protection legislation.⁴¹

³⁷ *Re Kevin's Case supra* n. 14.

³⁸ Act No. 49 of 1988. The object of this Act is to allow the reassignment of sexual identity; to regulate the performance of reassignment procedures; and for other purposes.

³⁹ *Sexual Reassignment Act, 1988*, section 4.

⁴⁰ 13343/87 [1992] ECHR 40 (25 March 1992).

⁴¹ See http://en.wikipedia.org/wiki/LGBT_movements_in_the_United_States (last visited 30 August 2006).

The first case that dealt with transsexualism in the US was *Mtr. of Anonymous v. Weiner*,⁴² which involved a petition for a change of sex in a birth certificate from the Bureau of Vital Statistics in the New York City Health Department. The transsexual's application in *Weiner* was denied. The aggrieved applicant filed a suit, but the court ruled that granting of the request was not permitted by the New York City Health Code, which only permitted a change of sex on the birth certificate if an error was made recording it at birth.

In 1968, in the case of *Matter of Anonymous*,⁴³ a similar request was denied. However, a request for change of name was granted. The decision of the court in *Weiner* was again affirmed in *Mtr. of Hartin v. Dir. of Bur. of Recs.*,⁴⁴ and *Anonymous v. Mellon*.⁴⁵

With regards to marriage, the first case in the United States which found that post-operative transsexuals could marry in their post-operative sex was the New Jersey case of *M.T. v. J.T.*⁴⁶ Here the Court expressly considered the English *Corbett v. Corbett* decision, but rejected its reasoning. Thus, from an overview of the situation in the United States of America, it can be inferred that the states have taken steps to assimilate the community of transsexuals in a civil society.

F. Canada

Legislation which affords recognition and protection to transsexuals has been accepted in most of Canada. The procedure for changing of sex in

⁴² 50 Misc. 2d 380, 270 N.Y.S.2d 319 (1966). This judgment has been cited in the case of *in Re Gardiner Estate* 29 Kan. App. 2d 92, 22 P.3d 1086 (2001), where the Supreme Court of the State of Kansas concurred with the decision in *Litleton v. Prange*, 9 SW3d 223 (Tex. Civ. App. (1999)), invalidating the marriage of J'Noel Gardiner, a transsexual woman, and her late husband Marshall. After Marshall's death in 1999, his son Joe challenged the validity of his father's marriage to J'Noel and thus her share of the \$2.5 million estate upon finding out her status as a transsexual woman. In this case, the Court asserted that the legislative intent behind the marriage law which presumed terms 'male' and 'female' in the biological sense; that the legal definition of 'female' did not include transsexual women.

⁴³ 57 Misc. 2d 813, 293 N.Y.S.2d 834 (1968).

⁴⁴ 75 Misc. 2d 229, 232, 347 N.Y.S.2d 515 (1973).

⁴⁵ 91 Misc. 2d 375, 383, 398 N.Y.S.2d 99 (1977).

⁴⁶ *Supra* n. 13.

the birth register in British Columbia is governed by *Revised Statutes British Columbia, 1974*. One of the essential conditions is that the transsexual must be unmarried and has to apply to the Director of Vital Statistics to change the legal sex.⁴⁷ The regulation also provides that the changed birth certificate will reflect only the newly acquired sex ie it shall be issued as if the original registration had been made showing the sex designation as changed under this section.

Thus, as seen above the leading countries of the world are leagues ahead of India, which presently has no legislation on the subject. The total number of cases cannot be a parameter to judge the need for law. Once a need for a law or lacunae in the law is pointed out, the Legislature has to suitably enact a new law and amendments to the existing related laws to provide for the community of transsexuals irrespective of their low population.

VIII. CONCLUSION

In the cases of transsexualism, medical treatment does not bring resurrection from one's ashes; it is not a cure, it is not a completely new start, it is a rehabilitation process. Conditions for successful rehabilitation of the transsexuals must be created. They should no longer be marginalised and be entitled to enjoy full citizenship rights including the right to marriage, right against discrimination etc. Till the law recognises transsexuals in their acquired gender and protects their rights, receiving acceptance from the society would just remain a dream.

To conclude it would be appropriate to cite an observation made by Judge Martens dissenting in *Cossey v. UK*:⁴⁸

'The principle which is basic in human rights and which underlies the various specific rights spelled out in the Convention (European Convention on Human Rights) is respect for human dignity and human freedom. Human dignity and human freedom imply that a man should be free to shape himself and his fate in a way that he deems best fits.'

⁴⁷ Sub-section 1 of section 21, Chapter 66 of *Revised Statutes of British Columbia, 1974*.

⁴⁸ [1990] 13 EHRR 622, pg 648, para 2.7.

LIABILITY FOR COPYRIGHT INFRINGEMENT ON THE INTERNET†

Sumreen Siddiqui and Sonali Mathur***

I. INTRODUCTION

The pervasive intrusion of the internet into our routine lives, easy and free access to copyrighted software, files and music and the evolution of advanced concepts like peer-to-peer file sharing¹ and masked IP addresses, have all contributed in making a mockery out of copyright protection. Owners of copyright across the world are up-in-arms against the easy and anonymous access internet users have to their copyrighted material and the failure, in most cases, to apprehend the actual offenders. Generally, the obvious soft targets that can be held responsible for copyright infringement on the internet are the Intermediaries, particularly the 'Internet Service Providers' (ISP), as it is assumed that the ISPs have the capability to monitor and control the content that is transmitted through their networks.

The authors seek to analyse the position of law as it presently exists in India regarding the liability for the offence of copyright infringement on the internet, with particular emphasis on the role and liability of an ISP. This proposition has to be addressed within the boundaries of traditional Indian copyright law, the *Information Technology Act, 2000* and the *Indian Penal Code, 1860*, since the categories of ISPs have not been defined neither have the rights and obligations of ISPs been enumerated under

† This article reflects the position of law as on 2 October 2006.

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¹ File sharing is the practice of making digital files available for users to download over the Internet. File Sharing using the 'peer-to-peer model (P2P)' means that the files are stored on users' personal computers, eliminating the need for server storage space and enabling faster file downloads.

Indian law.

Under Indian law, in order to constitute the offence of copyright infringement, the element of 'knowledge' of infringement is the *sine qua non*. However, in most cases, to impute knowledge of infringement to an ISP is virtually impossible, because it is impracticable and extremely burdensome for an ISP to screen each and every content posted/uploaded/downloaded on or from the internet. Although there have been no cases wherein the Indian Courts have been posed with a question on the aspect of the liability of an ISP for copyright infringement on the internet, for the sake of guidance it would be important to consider the case law that has arisen in the United States of America on this aspect. Under traditional Indian Copyright law if the ISP is to be held liable for the infringement of copyright merely because of alleged 'knowledge', it would open the floodgates of litigation and the ISPs would be saddled with onerous responsibilities and would hamper the internet from being the world's fastest growing medium.

II. KEY PLAYERS ON THE WORLD WIDE WEB

The Internet has been described as the 'World's Biggest Copy Machine'². While the internet has provided a new medium for various artists, writers, musicians, researchers and other copyright holders to exhibit their work on a global level, on the flipside, it has also opened a pandora's box by making it possible for any user to duplicate information and replicate it as his own, thereby facilitating 'copyright' infringement.

A copyright confers an exclusive right on the owner, for a finite period, to prevent others from exploiting its subject matter - an invention, a design, or a literary or other artistic work.³ Thus, copyright may exist in, *inter alia*, text, images, music and video files that are transmitted via the medium of the internet, which would come within the ambit of the term 'work' for the purposes of copyright protection. One of the most debatable issues

² Lauren Gibbons Paul, 'It's the World's Biggest Copy Machine', PC Week, 27 January 1997, available at <http://www.zdnet.com/pcweek/business/0127/27copy.html> (last visited 5 August 2006).

³ Rodney D Ryder, *Intellectual Property and the Internet* (Lexis Nexis- Butterworths 2002) 64.

associated with the distribution of information on the World Wide Web is the question regarding the liability for the unlawful transmission of information created by third parties, particularly copyrighted music works.

A. Internet Transactions: How do they work?

Every internet transaction requires the participation of multiple parties and intermediaries who play a distinctive role or part in such a transaction. 'Intermediaries' are organisations whose services are used to facilitate a transaction between communicating parties.⁴ For example, an individual, 'A' desires to view a copyrighted article on a web page, which is posted by 'B' without authorisation. 'A' will instruct his software to fetch that page from the host server 'C' on which the webpage is stored, and A's software will send a packet across the network lines to the host server C mentioned in the web page address (URL), requesting for the page. Then, through the network to which A's computer is connected, the host server C shall send the constituting packets of the document to A's computer. This is a simplified example of how the internet proves to be a medium for copyright infringement, which also helps us understand the key players involved in the information transaction, ie the originator (B), the end user (A) and the intermediaries ie host server (C) and the network. However, some cases involve the use of multiple hosts and several other intermediaries. For example, the website may be stored on host C but the downloadable copy might be stored on another host server D, thereby introducing more intermediaries in the internet transaction.

B. Originator

The Originator means a person who sends, generates, stores or transmits any electronic message or causes any electronic message to be sent, generated, stored or transmitted to any other person but does not include an intermediary.⁵

⁴ Chris Reed, *Internet Law* (2nd edn Cambridge United Kingdom 2004) 27.

⁵ The *Information Technology Act, 2000*, section 2(1)(za).

C. *The End User*

End users from any part of the world accessing the internet make use of its communication and information retrieval services, at the click of a mouse button. An end user is referred to as an Addressee, who is a person intended by the originator to receive the electronic record, but does not include any intermediary.⁶

D. *Intermediary*

An 'intermediary' is defined as *any person who on behalf of another person receives, stores or transmits that message or provides any service with respect to that message.* (emphasis supplied)⁷ Intermediaries may be classified in a number of ways depending on their role and functions, such as Payment Intermediaries,⁸ Auction Intermediaries⁹ and Internet Service Providers¹⁰.

An ISP¹¹ is a business or organisation that offers users access to the Internet and related services.¹² Therefore, an ISP is a species of the genus 'intermediary' and its role goes beyond mere internet connectivity. ISPs are capable of performing myriad functions such as e-mail, internet

⁶ *Ibid*, section 2 (1)(b).

⁷ The *Information Technology Act, 2000*, section 2(1)(w).

⁸ Payment intermediaries facilitate the transfer of funds between parties to internet transactions.

For example, when a person uses the internet for online shopping or incurs some expenditure at websites that charge money for the activities conducted on the site, payment intermediaries are involved in the chain of events required for the transaction to be consummated.

⁹ Auction Intermediaries like eBay perform the services on mediating in online auctions facilitating sales between remote parties.

¹⁰ Ronald J. Mann & Seth R. Belzley, 'The Promise of Internet Intermediary Liability', (2005) *The University of Texas School of Law*, available at http://www.utexas.edu/law/academics/centres/clbe/assets/Internet_Intermediary_Liability.pdf (last visited 11 March 2006).

¹¹ Also known as an Internet Access Provider.

¹² Wikipedia definition: Internet Service Providers, available at http://en.wikipedia.org/wiki/Internet_service_provider (last visited 5 August 2006).

hosting,¹³ web hosting,¹⁴ running mailing lists, a transmission medium, as temporary storage of material and as a search engine. Google, Rediff, VSNL, Bulletin Boards etc all fall within the ambit of an ISP.

III. COPYRIGHT VIOLATIONS ON THE INTERNET- WHO IS TO BLAME?

As discussed above, the key players in any internet transaction are the Originator, End User and the Intermediary, which includes an ISP. Before analysing the individual liability that may be foisted upon the above stated key players, it is essential to understand what action constitutes copyright infringement in India. Copyright in a work shall be deemed to be infringed when any person, without a license granted by the owner of the Copyright or the Registrar of Copyrights under the *Indian Copyright Act, 1957* or in contravention of the conditions of a license so granted or of any condition imposed by a competent authority under this Act, does anything, which exclusive right to do is, by this Act, conferred upon the owner of the copyright.¹⁵

Some of the 'exclusive rights' of a copyright owner in the case of a literary, dramatic or musical work, which are affected in an unauthorised internet transaction, are as follows:

- (i) to reproduce the work in any material form including the storing of it in any medium by electronic means;
- (ii) to issue copies of the work to the public,
- (iii) to communicate the work to the public; (emphasis supplied)¹⁶.

¹³ An Internet hosting service is a service that runs Internet servers, allowing organisations and individuals to serve content on the Internet, available at http://en.wikipedia.org/wiki/Internet_hosting_service (last visited 5 August 2006).

¹⁴ A web hosting service is a type of Internet hosting service that provides individuals, organisations and users with online systems for storing information, images, video, or any content accessible via the Web. Web hosts are companies that provide space on a server they own for use by their clients as well as providing Internet connectivity, typically in a data center, available at http://en.wikipedia.org/wiki/Web_hosting_service/ (last visited 5 August 2006).

¹⁵ *Indian Copyright Act, 1957*, section 51(a)(i).

¹⁶ *Ibid*, section 14.

Copyright shall also be deemed to be infringed when any person *distributes* either for the purpose of trade or *to such an extent as to affect prejudicially the owner of the copyright.* (emphasis supplied)¹⁷

The question to be considered is who shoulders the responsibility for copyright infringement? Is it the service provider, the end user or the person who is the source of the infringement or all of the above? A bare reading of the abovementioned provisions demonstrates that when copyrighted content is transferred via the internet, it involves the processes of reproduction, storage, communication and distribution, which are the exclusive rights conferred on the copyright owner. On the basis of the aforesaid processes, the liability of the key players involved in these processes are now analysed in detail.

A. *Liability of the End User*

The liability of the end user depends upon the degree and extent of the unauthorized use, which varies according to circumstances.¹⁸ Suppose an individual downloads music files from the internet to his laptop, the individual infringes copyright due to the acts of 'reproduction' and 'storage', but he may escape liability by using the defence of private use.¹⁹ In *Helliwell v. Piggott-Sims*,²⁰ Whitford J. observed in connection with the private recording of broadcast live music:

I think the tapes that he made to keep in his collection could properly have been said to have been made for his private and domestic use only if he had never done, or had never contemplated doing anything else but enjoy listening to them. ... He could have taken as many records from the live performances, however indirectly as he pleased, *provided that he kept them strictly for his own private domestic use.*' (emphasis supplied)

¹⁷ *Ibid*, section 51 (b) (ii).

¹⁸ *ProSieben Media A.G. v. Carlton U.K Television Ltd* [1999] FSR 610, 619.

¹⁹ *The Indian Copyright Act, 1957*, section 52.

²⁰ [1980] FSR 582.

End Users may also hold the view that the author of a copyrighted work has granted an implied consent for the use of the material by the public, by placing the work in the public domain. However, if an end-user deliberately and with complete knowledge and intention downloads the copyrighted work from the Internet to circulate/distribute or reproduce the same, he/she must be guilty of copyright infringement.

However, given the prodigious increase in the number of Internet users and the developing new technology which allows anonymity and obscurity regarding the identity of the users, it may be a mammoth task to identify the guilty end-users.

B. Liability of the Originator

It is submitted that the Originator or a person who posts the copyrighted work on the internet is the main culprit and must be held liable for copyright infringement as he/she has the requisite knowledge and the intention of committing the copyright infringement. However, the abovementioned practical difficulties in apprehending the blameworthy end users are also faced while foisting liability on the originators.

Thus, if the person posting the work is fully aware that copyright of the work is being violated, then the defence that the violator was ignorant of the existence of any such law or regulation that protects copyright in the works is not tenable.²¹

C. Liability of An Internet Service Provider

The liability of an ISP for copyright infringement shall depend on its role and function in the internet transaction. ISPs are broadly categorised as 'Content Providers'²² and 'Access Providers'²³. Often the content provider's facilities will play a part in the process of reproduction, storage, distribution

²¹ Ryder *supra* n. 3, 320

²² The Originator uploads web pages onto his website which is physically located on the server of the content provider or the hosting service provider, where the data is temporarily reproduced, in whole or in part, during transmission and is repeatedly 'stored and forwarded' to the end users.

²³ The data stored on the host servers becomes instantly available to everyone with an Internet connection, which access is provided by an access provider.

and communication of the copyrighted material. Thus, an ISP, due to the architecture of its system, may appear to commit literal infringement of the distribution, display or performance rights exclusively reserved for the copyright holder.²⁴

An argument that favours access providers is that they perform the role of a 'carrier' such as a telecommunications service provider, and thus cannot be held liable for the content that the users are permitted to access. The logic applied in this case is that 'Hutch' or 'BPL' cannot be held liable for providing mobile connection to people who might use the phones to co-ordinate illegal activities. However, if an ISP such as a bulletin board publishes unauthorised information, it is likely to be held liable for the content published, as it would be expected to monitor and regulate the third party content.

The multifarious roles of an ISP and the different liabilities arising therefrom are explained in the following illustrations:

If the Government Law College (GLC) website (located on Server X) posts an article of a student which is plagiarised from a copyrighted article, the College can be held liable for infringement in the role of an 'Originator'. However, if GLC has its own server with a homepage which provides access to external sources which contain copyrighted information, it will slip into the garb of an ISP and its liability will depend on the kind of ISP and the level of involvement and knowledge of the server in the infringing activities.

Similarly, if 'Manupatra.com' has its own host server and it posts a copyrighted article without authorisation, it shall be liable as Originator and as an ISP. If it merely provides links to articles which are copyrighted, it might not be liable as it will only provide a search engine facility.

²⁴ Ryder *supra* n. 3, 459.

D. *The Digital Millennium Copyright Act, 1998*

The Digital Millennium Copyright Act, 1998 (DMCA) is a pioneer legislation in the United States that addresses the various kinds of Service Providers and their liabilities for copyright infringement according to the role that they play in the internet transactions. Before discussing the Indian law applicable to an ISP, it is imperative to understand the different roles and liabilities of an ISP in light of the DMCA. The DMCA²⁵ provides the following categories of services performed by an ISP:

1. Transitory Communication

Transitory communication means that the service provider merely transmits, routes or provides connections for material coming through a system i.e. the ISP acts as a '*passive conduit*', as it performs these functions *without selection of the material or without modification to the content sent or received*.²⁶ For example MTNL / VSNL/ Satyam Online/ Reliance which merely provide access i.e. actual connection to the Internet to its customers.

2. System Caching

Caching is a process whereby the web browser stores a set of web page images temporarily either on the hard disk of the user or on the server of the ISP so they may be redisplayed quickly when the user returns to them thus, speeding up the time it takes to access information on the internet.²⁷

For example Search Engines such as Google often store cached versions of copyrighted web content in their search databases and index files and reproduce this content to users in their search results. The process of caching may ensnare the ISP within the ambit of Section 14 and 51 of the

²⁵ Title II of DMCA: *Online Copyright Infringement Liability Limitation Act*, 17 U.S.C section 512 Limitations on liability relating to material online.

²⁶ Ivan Hoffman, 'Are you a "Service Provider?"' (2001) available at www.ivanhoffman.com/provider.html (last visited 11 March 2006).

²⁷ Osborne Clark, *A Practical Guide to E-commerce and Internet Law* (ICSA Publishing London 2002) 101.

Indian Copyright Act.²⁸ However, the US Courts in the case of *Religious Technology Centre v. Netcom On-Line Communications Services Inc.*,²⁹ held that an act of volition by the ISP is a pre-requisite for copyright violation. It is submitted that the ISP should not be held liable if a cache is created to improve system performance.³⁰

3. Storage of Materials at the Direction of A User, of Material That Resides on A System or Network Controlled or Operated By or for the Service Provider

In this case, the provider is one who hosts sites or runs mailing lists, news groups, chatting services, bulletin boards etc. and thus may deal with copyrighted works at the direction of third parties. For Example:-

- a. eBay,³¹ an internet auction web service was charged with secondary liability for copyright infringement, for participating in and facilitating the unlawful sale and distribution of pirated copies of 'Manson' DVDs by providing an online forum, tools and services to the third party sellers, however limited or automated in nature.
- b. In the case of *Corbis Corporation v. Amazon.com, Inc.*,³² *et al.*, the Court held that the DMCA immunizes Amazon.com, Inc. (Amazon) from copyright infringement damage claims arising out of the storage and sale by non affiliated vendors on Amazon.com of photographs in which the plaintiff claimed a copyright.

4. Information location tools, meaning that the provider is a search engine facility linking users to an online location containing infringing material or infringing activity, by using information location tools, including a directory, index, reference, pointer, or hypertext link for example: Google, Yahoo, Rediff.

²⁸ *Supra* n.15,16,17.

²⁹ 907 F Supp 1361 (ND Cal, 1995).

³⁰ *Society of Composers, Authors and Music Publishers of Canada (SOCAN) v. Canadian Association of Internet Providers*, 2002 FCA 166.

³¹ *Hendrickson v. Ebay Inc.*, 165 F. Supp. 2d 1082, 60 U.S.P.Q.2d (BNA) 1335 (C.D. Cal. 2001).

³² 17 U.S.C. section 512(c).

To be eligible for protection under the DMCA, an ISP performing this function may escape liability if:

- a. It has neither actual knowledge that its system contains infringing materials nor an awareness of facts or circumstances from which infringement is apparent;
- b. It receives no financial benefit directly attributable to infringing activity; and
- c. It responded expeditiously to remove or disable access to material claimed to be infringing after receiving from the copyright holder a notification conforming with requirements of section 512(c)(3).

The DMCA provides for a detailed 'notice and take-down' procedure and also provides for action against frivolous claims. The DMCA provides a definite standard against which the actions of ISPs may be tested. However, unlike the DMCA, the Indian position on this aspect is still quite ambiguous and obscure.

IV. THE INDIAN LEGISLATION APPLICABLE TO AN ISP

A. *Information Technology Act, 2000*

Although copyright infringement has not been specifically listed as one of the offences under the *Information Technology Act, 2000*, it is provided that if any person *without permission of the owner* or any other person who is in charge of a computer, computer system or computer network, *downloads, copies or extracts any data, computer data base or information* from such computer, computer system or computer network including information or data held or stored in any removable storage medium, he shall be liable to pay damages by way of compensation not exceeding one crore rupees to the person so affected. (emphasis supplied)³³

Further, under the Act, the offence of 'hacking' also brings within its ambit the offence of copyright infringement. It is provided any person

³³ The *Information Technology Act, 2000*, section 43(b).

with the intent to cause or knowing that he is likely to cause wrongful loss or damage to the public or any other person destroys or deletes or alters any information residing in a computer resource or diminishes its value or utility or affects it injuriously by any means, commits hacking. (emphasis supplied)³⁴ Thus, an ISP may be held liable under the aforesaid provisions of the Act, if it accesses information for the purpose of unauthorized reproduction or with the intent to alter any information or diminish its value or utility.

Further, the Act provides defences to a Network Service Provider³⁵ for any third party information³⁶ or data made available by him if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.³⁷

B. The Indian Copyright Act, 1957

In general, a copyright is said to have been infringed when any person does, in relation to work, anything that the owner of the copyright has an exclusive right to do under the Copyright Act. However, according to section 63 of *The Indian Copyright Act, 1957*, in order to charge the infringer with the offence of copyright infringement, the infringer must be any person who knowingly *infringes or abets* the infringement of the copyright in a work. (emphasis supplied)

Therefore it can be concluded that the offence of copyright infringement on the internet falls within the scope of this section even though the *Indian Copyright Act, 1957* does not specifically mention the infringement on the internet. The authors find it important to draw reference to the word 'knowledge' in the aforesaid section. Knowledge is a necessary ingredient in order to commit the offence of or to abet the offence of copyright infringement. In the absence of essential statutory procedures concerning notices to ISPs for copyright infringement, can a particular

³⁴ *The Information Technology Act, 2000*, section 66.

³⁵ Section 79: 'Explanation: for the purposes of this section- (a) "network service provider" means an intermediary.'

³⁶ Section 79: 'Explanation: for the purposes of this section- (b) "Third party information" means any information dealt with by a network service provider in his capacity as an intermediary.'

³⁷ *The Information Technology Act, 2000*, section 79.

notice by an Author 'A' stating that his copyrighted article called 'XYZ' is being unauthorisedly circulated, amount to 'knowledge' on the part of the ISP? The authors state that knowledge of the infringing material/activity is impossible as the speed at which the information is disseminated is too swift. Also, the practical difficulties of 'frivolous claims' must be kept in mind before expecting the ISPs to take action against infringing materials.

C. *The Indian Penal Code, 1860*

An ISP may also be held liable under the *Indian Penal Code, 1860* as the publication of a copyrighted literary work by an ISP alleging copyright in the same, may tantamount to the offence of forgery. Forgery has been defined as act by a person who *makes any false documents or false electronic record* or part of a document or electronic record, with the intent to cause damage or injury to the public or to any person, or *to support any claim or title.*(emphasis supplied)³⁸A person is said to make a false document or electronic record, when a person dishonestly and fraudulently makes, signs, seals or executes a document or part of a document with the intention of causing it to be believed that such document or part of a document was made signed, sealed executed, transmitted or affixed by or *by the authority of a person by whom or by whose authority he knows that it was not made, signed, sealed, executed or affixed.* (emphasis supplied)³⁹ For example, if a website 'A' knowingly hosts an article which is copyrighted with person 'B', on its own server, the website 'A' has represented to the public that it has the requisite authority/permission from person 'B' to publish the article. In order to escape the offence of forgery, the person who commits the forgery must prove that he did not dishonestly or fraudulently pass off the copyrighted work as his own.

D. *The Element of Knowledge*

The question of what constitutes knowledge by an ISP has been discussed extensively by the US District Court in the case of *Gucci America v. Hall*

³⁸ The *Indian Penal Code, 1860*, section 463.

³⁹ The *Indian Penal Code, 1860*, section 464.

Associates,⁴⁰ wherein a suit was filed against the ISP, Hall associates for trademark infringement. The Court held that

‘The First Amendment concerns raised in Gucci and the need to show “actual malice” to recover damages necessitate a clearer standard of what qualifies as knowledge. Notice may not be sufficient to qualify as “knowledge” within the definition of trademark infringement. ... ISPs could be given “notice” of frivolous infringement claims, thus forcing them to take action where no infringement had in fact occurred. Calling for excessive proactive measures by ISPs to ferret out trademark infringement would also be burdensome, especially given the number of sites they host. This calls for caution in going after ISPs where infringers can put forth content easily and anonymously, as is often the case on the Internet.’

Although the above case does not deal with copyright infringement, it makes it very clear that in order to constitute the element of ‘knowledge’ there must be actual and constructive knowledge of infringement. Thus, it is clear that notice of an infringement to an ISP does not by itself constitute knowledge as there are often frivolous claims and it would be burdensome on the ISP to take action of all notices considering the number of sites they host.

V. THEORIES OF LIABILITY FOR COPYRIGHT INFRINGEMENT

In the absence of clear standards for the liability of an ISP for copyright infringement under Indian law, it is imperative to discuss this issue in relation to traditional copyright infringement theories and international case law on the same. The liability for copyright infringement rests on three theories- direct, vicarious and contributory infringement.

However the US Supreme Court has recently introduced a new theory known as ‘the inducement theory’ vide its judgement in *Metro-Goldwyn-Mayer Studios Inc. et al. v. Grokster, Ltd., et al.*,⁴¹ Under this theory, the

⁴⁰ 135 F. Supp. 2d 409 (SDNY 2001).

⁴¹ 125 S.Ct. 2764 (2005).

Court stated that a company is liable for contributory infringement if they intend to bring about infringement, by distributing a device suitable for infringing use and actual infringement occurs.⁴² The question arises as to which of the abovementioned standards should be applied in order to fix the responsibility of ISPs for copyright infringement.

A. Direct Copyright Infringement

Direct infringement occurs when a person violates any exclusive right of the copyright owner. The First US case to consider the issue of ISP liability was *Playboy v. Frena*,⁴³ wherein the Court held that the operator of a Bulletin Board Service, which allowed third parties to place digitized images of *Playboy* magazine, infringed the distribution and display rights of the copyright owner. In this case, 'intent' and 'knowledge' were not considered as relevant ingredients and the intermediary was subjected to a no-fault liability.

However, in the landmark case of *Religious Technology Centre v. Netcom On-Line Communications Services Inc.*,⁴⁴ the representatives of the Church of Scientology brought an infringement action against Netcom, America's largest ISP, whose customer had posted infringing copies of the works of L Ron Hubbard to a newsgroup. The Court rejected the strict liability approach followed in the *Playboy* case and held that the mere fact that Netcom's system incidentally makes temporary copies of the Plaintiff's work does not mean Netcom has caused the copying. The conclusion of the Court in this case was that an act of volition on the part of an ISP is a pre-requisite for copyright violation.⁴⁵ Thus, as regards direct copyright infringement, it is essential that the ISP must initiate the infringement or create or control the content of its service or must play an active role in the infringement.

⁴² Philip Larson, 'P2P Filesharing – The Supreme Court Speaks in *MGM v. Grokster*', available at <http://www.philiplarson.com/blog/?p=5> (last visited 2 October, 2006).

⁴³ 839 F Supp 1552 (MD Fla,1993).

⁴⁴ *Supra* n29.

⁴⁵ This reasoning was followed in a number of subsequent cases. See, *Sega Enterprises v. Maphia*, 948 F Supp 923 (ND Cal 1996).

B. Contributory and Vicarious Copyright Infringement

Vicarious liability arises when a person fails to prevent infringement when he can and has a right to do so and is directly benefited by such infringement.⁴⁶ Contributory liability arises when a person participates in the act of direct infringement and has knowledge of the infringing activity. The liability for Contributory Infringement, imposed on an ISP, is dependent upon the degree of knowledge and participation of the ISP in the transmission of the copyrighted material over the Internet. It is essential to analyse certain important cases in order to examine the active or passive role played by an ISP in different technological set-ups. The authors consider it pertinent to point out that most of the landmark cases in the recent past on copyright infringement deal with the peer-to-peer file sharing network.

1. Napster Case

Napster allowed its users to search for music files stored on other users' computers, and to transfer exact copies of such music files from one computer to another through a network known as 'peer-to-peer'.⁴⁷ In the case of *A & M Records, Inc. v. Napster, Inc.*,⁴⁸ Napster was held liable for contributory copyright infringement as it knowingly encouraged and assisted its users to infringe the record companies' copyrights, thereby materially contributing to the infringing activity. Although Napster did not take in any revenue, it planned to monetize its customer base by advertisement, targeted mail, commission and direct marketing of CDs

In this case, the level of involvement and participation of Napster was to a higher degree as they had actual and constructive knowledge of the infringement and they could not qualify as '*passive carriers*'. As regards the vicarious copyright infringement, the panel concluded that Napster

⁴⁶ Subhrrag Mukherjee, 'Liability of Internet Service Providers for Copyright Violation on the Internet', available at http://www.legalservicesindia.com/articles/isp_in_us.html (last visited 2 October 2006).

⁴⁷ Summary of the case of *A & M Records, Inc. v. Napster, Inc.*, available at <http://www.ce9.uscourts.gov/Web/OCELibra.nsf/0/cc61d7c45e059bd4882569f100620da0?OpenDocument> (last visited 2 October 2006).

⁴⁸ 114 F. Supp. 2d 896 (N.D. Cal. 2000).

has a direct financial interest in its users' infringing activity and retains the ability to police its system for infringing activity.

2. KaZaa Case

The KaZaa service offered its users a computer program⁴⁹ for the exchange of various types of text, image and sound files by the individual users of the Internet, which allowed the users to offer information independently but also to locate and download information from other individual users (peers). The main distinction between Napster and KaZaa was that the former was hosting a central database of the locations downloadable files on the user computers, whereas the KaZaa software created a new local database for each user every time he connected and without any further involvement from KaZaa.⁵⁰ When the question of liability arose⁵¹ it was held that could not be held guilty of inciting or authorizing users of its software to infringe copyright as the software was also capable of being used for legitimate file exchange.

3. The Betamax Case

In *Sony Corp v. Universal City Studios*,⁵² a case brought by the movie industry against the Sony Betamax VCR alleging that Sony was contributorily liable for the infringement that occurred when VCR owners taped copyrighted programs. In the above case, the Court found that the VCR was capable of several non infringing uses, including the time-shifting of television broadcasts by home viewers.⁵³ Moreover, there was no evidence that Sony had desired to bring about taping in violation of copyright or taken active steps to increase its profits from unlawful taping. Therefore, the Supreme Court held that because the technology was capable of substantial non infringing purposes, the manufacturers could

⁴⁹ The software distributed by KaZaa via its website is also called peer-to-peer technology..

⁵⁰ Reed *supra* n. 2, 99.

⁵¹ *KaZaa BV v. Vereniging Buma & Stichting Stemra*, Amsterdam Court of Appeal, Case 1370/01 SKG, 28 March 2002.

⁵² 464 U.S. 417 (1984).

⁵³ Fred von Lohmann, 'What Peer-to-Peer Developers Need to Know about Copyright Law', available at http://www.eff.org/IP/P2P/p2p_copyright_wp.php (last visited 2 October 2006).

not be held liable. This judgment has now come to be famously known as the Betamax case and the defense of 'substantial non infringing purposes' is famously known as the Betamax defense.

C. Inducement Theory

With the advent of P2P file sharing, one of the biggest controversies has been the liability of the distributors of file-sharing software, since the copyright owners have sued software distributors under theories of secondary liability for facilitating and inducing their users to commit infringement. In the case of *Metro-Goldwyn-Mayer Studios Inc. et al. v. Grokster, Ltd., et al.*,⁵⁴ the US Supreme Court had the chance to clear the mist on this subject, but the Hon'ble Court succeeded in confusing the scenario even further by introducing a new theory of infringement known as the Inducement theory.

In the above case, a group of movie studios and other copyright holders sued the respondents for their user's copyright infringements through peer-to-peer networks, alleging that respondents knowingly and intentionally distributed their software to enable users to infringe copyrighted works. The Ninth Circuit Court in applying the Betamax defense found that the respondent's software was capable of substantial non-infringing uses and owing to its decentralized architecture the respondents did not materially contribute to their user's infringement as the users themselves searched for, retrieved, and stored the infringing files. Finally, the court held that respondents could not vicariously be held liable because they did not monitor or control the software's use, neither did they have an agreed-upon right or ability to supervise its use, nor did they have an independent duty to police infringement.

However, the US Supreme Court in the same case introduced a new theory known as the inducement theory and held that a software distributor that promotes the use of its tool to infringe copyright 'as shown by clear expression or other affirmative steps taken to foster infringement' is liable for the resulting infringement of their users. The Court noted a number of areas that suggested that Grokster had induced infringement including i) advertising and instructing how to infringe, ii) targeting former Napster

⁵⁴ United States Court of Appeal for the Ninth Circuit, No. 04-480. Decided on June 27, 2005.

users known to infringe, iii) failing to take steps to prevent infringement, iv) profiting from infringement, and v) simply distributing a tool capable of infringement, and held that Grokster was not merely a passive recipient of information about infringing use rather, it encouraged its user to download copyrighted works.⁵⁵

The Court reconciled this new rule with the protection Sony provided under the Betamax defence by holding that Grokster's unlawful objective was 'unmistakeable.' By contrast, Sony did not try to profit from unlawful taping, nor did it intend for its users to unlawfully tape shows, and Sony did not take affirmative steps to encourage its users to use VCRs to infringe copyrights.

Grokster was held liable under the inducement theory and the question of contributory and vicarious liabilities were left open and were remanded to the lower courts to decide. The majority also declined to address the conflict about when *knowledge of infringement* may be imputed to a P2P software distributor. Therefore the issue of 'knowledge' of infringing conduct with respect to a P2P network also remains obscure.

1. How Does Grokster Differ From Napster?

Grokster's client application licensed the FastTrack network technology.⁵⁶ StreamCast developed a similar product but relied on the Gnutella network. Therefore, Grokster and StreamCast were all new client software applications that were used to connect to the FastTrack and Gnutella's decentralized P2P networks to enable their users to share files. These networks differed from Napster in two primary ways: one that users could search for any file type (they were not restricted to MP3s like in Napster), and the second that the network was decentralized (no centralized index servers). The decentralized network architecture prevented any single

⁵⁵ Philip Larson, 'P2P Filesharing – The Supreme Court Speaks in *MGM v. Grokster*' available at <http://www.philiplarson.com/blog/?p=5> (last visited 2 October 2006).

⁵⁶ FastTrack is a so-called second generation P2P protocol. It uses supernodes to improve scalability. The supernode functionality is built into the client; if a powerful computer with a fast network connection runs the client software, it will automatically become a supernode, effectively acting as a temporary indexing server for other, slower clients.

broken link, such as Napster's index servers, from bringing down the network. Grokster removed the need for centralized index servers through its use of supernodes. Whenever a powerful computer with a high speed connection running Grokster connected to the FastTrack network, it automatically became a supernode and acted as a temporary indexing server for other clients on the network.

2. Grokster In India

The authors are of the view that if the Grokster case were to be tried in India, Grokster would be held liable on the principle of knowledge. Grokster, even under Indian law could not be held liable for reproducing the work or making copies, or translation or adaptation of the work, but, under section 63 of the Copyright Act, Grokster can be held liable for 'knowingly' *abetting* (emphasis supplied) the infringement of the copyright in a work since it was knowingly inducing its users to use its software as an alternative to Napster and it failed to take steps to stop the infringement and furthermore profited from the infringement. The Supernodes that are used in Grokster have the ability to monitor traffic/searches and identify uploaders by frequency of hits/bandwidth. The issue remains in the practical difficulty of policing such uploads. A recent example of such practical difficulty is when the Department of Technology of the Indian Government decided to censor all blogs because the Government apprehended that the Forum was being misused and was a threat to national security. In an attempt to block a few blogs, it was considered practically feasible to block the ISP rather than individually blocking the specific blogs.

D. *The Likely Target*

The *DCMA, 1998* provides immunity to an ISP and it has been recognised in various judgements that the information is disseminated at great speed and it is nearly impossible for an ISP to regulate the information content. The authors contend that the ISPs are made likely targets because in most cases, even if individuals who download or upload infringing materials are traced, they may not have the resources to pay the damages sought for by the copyright owners, or which would be worth claiming,

in order to justify the costs and expenses of a legal battle. In such a scenario, the owner of the copyright may choose to proceed against a bigger fish, such as an ISP, on grounds that it has been negligent in policing its network, through which the infringing individual has gained access to the internet.⁵⁷ Also, in comparison to an independent publisher or author, an ISP is in a much better position to supervise how its subscribers make use of the Internet. All these factors make the ISPs especially culpable in the eyes of the law.⁵⁸

On the other hand, the ISPs contend that they are only *passive carriers*, just like telecommunications companies, and therefore should be given some degree of immunity from copyright infringement liability. This argument was upheld in the case of *Alexander Lunney v. Prodigy Services Company*,⁵⁹ wherein the name of a minor, Alexander Lunney was usurped by an unknown impostor, who opened a number of accounts in Lunney's name with Prodigy Services Company (Prodigy) and posted two vulgar messages in Lunney's name on a Prodigy's bulletin board and also sent a threatening, profane electronic mail (e-mail) message in Lunney's name to a third person. The father of Lunney sued Prodigy for defamation stating that Prodigy was derelict in allowing the accounts to be opened in his son's name, and was responsible for his having been stigmatized and defamed his son. The Hon'ble New York Appellate Court recognising Prodigy as an ISP held that Prodigy's role in transmitting e-mail was akin to that of a telephone company, which one neither wants nor expects to superintend the content of its subscribers' conversations. In this respect, an ISP, like a telephone company, is merely a conduit.⁶⁰

⁵⁷ See Rahul Matthan, *The Law Relating To Computers And The Internet* (Butterworths India 2000) 320.

⁵⁸ VK Unni 'Internet Service Provider's Liability for Copyright Infringement- How to Clear the Misty Indian Perspective', available at <http://www.richmond.edu/jolt/v8i2/article1.html> (last visited 2 October 2006).

⁵⁹ (1999) 94 N.Y. 2d 242.

⁶⁰ A conduit, under common law lacks the ability to screen and control defamatory speech that may occur over systems and therefore they are least culpable an ordinarily immune from liability. Held in the case of *Stephan J Barret v. Ilena Rosenthal* 114 Cal App 4th 1379.

The authors state that though the facts of the above stated judgement relate to defamation, the ratio that emerges from the judgment is that an ISP lacks the power to monitor and screen all the information that it disseminates and it is merely a conduit.

Furthermore, the ISPs contend that placing undue liability on an ISP for copyright infringements could have a crippling effect on the growth of the Internet.⁶¹ The World Wide Web, with its millions of users has made the policing of the content a complex task and it would be ludicrous to suggest that a service provider should constantly monitor all the content on all the websites as then, it would never be able to escape liability for copyright infringement and would result in an undesirable censorship over the content by the service provider.

E. Delusory Defences to Escape Liability

1. Disclaimer On The Website

The display of a disclaimer notice on the website to the effect that the website makes no claims as to the copyright over the material available on the site does not exempt the website or the ISP from liability. While this notice cautions persons intending to duplicate and use the materials available on the website that they will be liable for prosecution by the original owners of the material if the material is used without authorization, the notice in no way protects the website or the ISP from prosecution. In fact, the notice tantamounts to an admission of guilt that would prevent the website or the ISP from raising the plea of innocent infringement.⁶²

2. Acknowledgement Of Copyright Of Authors On The Web Pages

The Acknowledgement of the copyright of the authors of their works on the website also does not provide any immunity against prosecution as there is no substitute for an actual license from the owner of the copyright.⁶³

⁶¹ Unni *supra* n58

⁶² See Rahul Matthan, *The Law Relating To Computers And The Internet* (Butterworths India 2000) 304.

⁶³ *Ibid.*

3. Hyperlinking

The mere creation of hyperlinks from one website to access another website that contains infringing material is also deemed to be an infringement of copyright. In other words, even if the contents of a webpage do not infringe the copyright, the links to pages that infringe copyrighted material are vicariously liable for infringement.

VI. CONCLUSION

The Internet is an international network of interconnected computers that enables millions of people to communicate with one another in 'cyberspace' and to access vast amounts of information from around the world.⁶⁴ Countries across the world have recognised the need to classify the ISPs into categories and to accordingly recognise their rights and liabilities. In Australia, under *the Copyright Amendment (Digital Agenda) Act, 2000*, an ISP alleged of infringing copyright is protected as long as the ISP does not determine the content of the communication and limits its role to only providing the server the allegedly infringing material being distributed to the public. In the United States of America, under the DMCA, a copyright owner can notify the website's host ISP of a particular infringement and demand the ISP to remove the infringing material from its servers, and the ISP can escape monetary liability by promptly removing the same.

The grey area concerning the issue of ISP liability in India has to be addressed considering the traditional meaning of the term 'knowledge', which may implicate an ISP even when it is not practically possible for the ISP to monitor all the content passing through its server. However, the juxtaposition of the theoretical and practical aspects of the knowledge and involvement of an ISP in an internet transaction raises many interesting questions which need to be answered by passing adequate legislation on this aspect. An analogy is often drawn between an ISP, which maintains a system that automatically transmits users material but is itself indifferent to the material's content, and the owner of a copy machine who makes

⁶⁴ *Reno v. American Civil Liberties Union et al* 117 S. Ct. 2329, 2334 (1997).

its use available to the public.⁶⁵ However in actuality an ISP is not only acting in a capacity of plain carrier but it plays multifarious roles such as a search engine or for temporary storage. The multifarious roles of an ISP are yet to be categorised in India and thus the issue of their resulting liabilities remains vague. The Legislature at the time of amending the copyright law has not addressed this situation. In light of the aforesaid, an urgent need for legislation is required in India, along the lines of the DMCA, which enumerates the different kinds of ISPs and contains provisions specifying the rights, liabilities, obligations of the ISPs. Additionally, existing legislation like *The Indian Copyright Act, 1957* should also be amended enumerating clear standards of liability on the ISP's as well as the other key players, specifying the circumstances under which protection is available to the ISP with specific mention of the liability of P2P software developers, especially since the international standard that have emerged on this aspect remain unclear.

⁶⁵ *Costar Group, Inc. v. LoopNet, Inc.* 373 F.3d 544, 549 (4th Cir. 2004).

TAP, TAP, WHO'S LISTENING – PRYING INTO PRIVACY.†

*Vishal Kanade**

I. INTRODUCTION

The issue of telephone tapping has always been a very controversial issue in India. Recently however, it was the accusation made by Mr Amar Singh, a political leader and a Parliamentarian, that his telephone had been tapped by the Government that raised several uncomfortable questions about the present legal position on telephone tapping in India. The issue of telephone tapping has resurfaced in India on a number of occasions owing to political scandals and unauthorised telephonic intercepts carried out by law enforcement agencies. As a matter of fact, there have been several controversies caused by telephone tapping internationally as well. The 'Watergate' scandal and the recent 'domestic intelligence surveillance program' adopted by the United States are some such examples.

These national and international incidents have time and again reinforced the concerns of civil liberties groups and human rights organizations regarding the effect of such measures on the right to privacy of citizens. The debate on the validity of the State to intrude in the realm of private life of citizens to prevent and pre-empt crime has assumed even greater significance in view of atrocities committed by way of terrorism.

Telephone Tapping or wire tapping can simply be defined as the monitoring of the telephone conversation by a third party.¹ It received its name as the monitoring device in view of the fact that the wires of the telephone lines were being monitored and tapped a small amount of the

† This article reflects the position of law as on 15 January 2006.

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¹ 'Phone-Tapping Serious Invasion Of Privacy', *The Times of India*, (Mumbai, India, 9 January 2006) page 13.

electrical signal carrying the conversation.² This sort of surveillance in the form of wiretapping directly impacts the right of privacy of citizens. This right has been recognised as an inalienable right of every individual by the highest court of our country and has been incorporated in several international covenants such as the *International Covenant on Civil and Political Rights*.

This article seeks to examine the issue of telephone tapping in India and its impact on the right to privacy of citizens. The author also wishes to emphasise that the laws of the land as they stand today, are not equipped to keep pace with the rapid strides in technology that have taken place over the years.

II. TECHNOLOGICAL REVOLUTION

Today, there is also an additional dimension to the issue of telephone tapping and electronic surveillance that one has to consider. That is, the exponential growth and availability of state of the art technology that can facilitate invasion of privacy of an individual.

An innocent looking watch or a sleek looking executive pen might be nothing else but a voice recording device. Such snooping and eavesdropping equipment, which earlier was seen only in 'James Bond' movies, is now available in the public domain. One such example is the website in USA known as 'Locatecll.com'. This website for 110 US \$ provides information including calling records of any cell phone number that is given to them. Although this website caters to an American audience, the fact that such technology is freely available and user friendly, even a ten year old can avail of it.

The 'Amar Singh tapping' incident emphasises that we have entered an era, where the civil society faces the threat of invasion of its privacy not only from 'Big Brother' but also from any Tom, Dick and stupid Harry with adequate knowledge and the right kind of equipment. It is this development that has underscored the importance of protection of privacy rights of citizens of India.

There are several ways by which telephonic conversation could be

² *Ibid.*

monitored. Landline telephonic communication can be tapped at the telephone exchange, or on the caller's transmission line leading to the exchange.³ There are also what are known as 'laser-devices' which when pointed in the direction at the windows of the room from which the person is speaking, from the minute vibrations of the glass windowpanes, that can construct all the sounds in that room.⁴

Cell phones are becoming increasingly popular throughout the country as is evident from the fact that mobile connections have long outnumbered the landline connections in our country.⁵ However, owing to the technology that is available in the market today, the threat of cell phone tapping is ever increasing. Today, the new form of tapping is known as 'off the air' type of cell phone interception. Although none of the off-air intercept systems are made in India, their manufacturers have representatives and authorised agents in several cities in India according to a news report.⁶

Today, we also see that technological developments in the communication sector are taking place at an exponential rate. One such instance is the Voice over Internet Protocol,⁷ which enables telephone conversations to be transmitted over the Internet. There is also a new form of communication called 'digital communication'. Digital communications services generally convert telephone conversations and other transmissions to a digital code that is impossible to 'listen in' on.⁸ In 1994 the US Congress passed the *Communications Assistance for Law Enforcement Act*, also known as the *Digital Telephony Act*. The Act's purpose is to provide law enforcement officials with assurance that they will be able to 'tap' or have access to the content of any communications incorporating new digital technology.⁹ However, there is no such parallel legislation in India.

³ Ravi Prasad, 'Big Brother Is Listening', *The Indian Express*, (Mumbai, India, 14 January 2006) p 9.

⁴ *Ibid.*

⁵ Manoj Mitta, 'Look Who's Listening', *The Times of India*, (Mumbai, India, 15 January 2006) p 7.

⁶ *Ibid.*

⁷ Mitta *Supra* n. 5.

⁸ Wiretapping/Eavesdropping on Telephone Conversations: at <http://www.privacyrights.org/fs/fs9-wrtp.htm> (last visited 15 January 2006).

⁹ *Ibid.*

Clearly the existing provisions of law never contemplated such kind of a situation and the law in force in the country is not in a position to tackle the threat posed by such kind of technology.

III. THE ISSUE OF PRIVACY

Despite the law on telephone tapping and its evidentiary value, the inescapable fact is that tapping poses a real and serious threat to the right of privacy of a citizen. In India, civil liberty organizations and non-governmental bodies have since a long time campaigned for the protection of right of privacy against several instances of unwarranted Government surveillance in the form of telephone tapping.

What was most shocking about the entire 'Amar Singh tapping' incident was the statement made by the Union Home Secretary that the tapping took place without any participation of Government agencies and that it was entirely carried out by private individuals.¹⁰ Needless to say, if one of the most prominent politicians in India can be made a victim of telephone tapping by individuals and private detectives without any involvement of the Government, then ordinary citizens have plenty to worry about.

A. Law Of Privacy In India

In India, 'right to privacy' by itself was not identified under the Constitution. However, it has been recognised by the Apex Court as a fundamental right. The leading case on this point was the *Kharak Singh v. The State of UP*,¹¹ (Kharak Singh case) where the Supreme Court read 'right to privacy' as part of the right to life under Article 21 of the Constitution. As a matter of fact, in the Kharak Singh case, Article 21 of the Constitution was interpreted by all the seven learned Judges ie majority and the minority opinions to include that 'right to privacy' as a part of the right to 'protection of life and personal liberty' guaranteed under the said Article.

Numerous international covenants give specific reference to privacy as a right. *The International Covenant on Civil and Political Rights* (adopted 16

¹⁰ 'Probe Into Ric's Role In Phone-Tapping Row', *The Times of India*, (Mumbai, India, 15 January 2006) p 1.

¹¹ AIR 1963 SC 1295, para 38.

December 1966, entered into force 23 March 1976), the *UN Convention on Migrant Workers* (adopted 18 December 1990, entered into force 1 July 2003) and the *UN Convention on Protection of the Child* (adopted 20 November 1989, entered into force 2 September 1990) have recognised the right to privacy. Article 17 of the *International Covenant of Civil and Political Rights, 1966*, to which India is a signatory, states that 'No one shall be subjected to arbitrary or unlawful interference with his privacy, family, human or correspondence, nor to lawful attacks on his honour and reputation.'

In the case of *R Rajagopal and another v. State of Tamil Nadu*,¹² the Supreme Court held that the right to privacy is a right to be let alone. The Apex Court further observed that a citizen has a right to safeguard the privacy of his own, his family, marriage, procreation, motherhood, childbearing and education among other matters.¹³

In today's day and age, where the world is described as a global village, there is enormous reliance of the masses on telephonic communication. So much so, that it has become an indispensable part of urban life in India.

In the case of *Olmstead v. United States*,¹⁴ the minority view that was expressed on the issue of privacy and telephone tapping was that:

'The evil incident to invasion of the privacy of the telephone is far greater than that involved in tampering with the mails. Whenever a telephone line is tapped, the privacy of the persons at both ends of the line is invaded, and all conversations between them upon any subject, and although proper, confidential, and privileged, may be overheard. Moreover, the tapping of one man's telephone line involves the tapping of the telephone of every other person whom he may call, or who may call him. As a means of espionage, writs of assistance and general warrants are but puny instruments of tyranny and oppression when compared

¹² (1994) 6 SCC 632, para 28.

¹³ (1994) 6 SCC 632, para 9.

¹⁴ 277 U.S. 438 (1928).

with wire tapping.’

The Apex Court has acknowledged this fact and held that protection of privacy while on the phone is of paramount importance, unless that conversation is being intercepted in accordance with the procedure established by law. With regard to telephone tapping the Apex Court in the *People’s Union for Civil Liberties v. Union of India*,¹⁵ (the PUCL case) observed that:

‘[T]he right to hold a telephone conversation in the privacy of ones home or office without interference can certainly be claimed as “right to privacy”. Conversations on the telephone are often of an intimate and confidential character. Telephone-conversation is a part of modern man’s life. It is considered so important that more and more people are carrying mobile telephone instruments in their pockets. Telephone conversation is an important facet of a man’s private life. Right to privacy would certainly include telephone-conversation in the privacy of one’s home or office. Telephone tapping would, thus, infract Article 21 of the Constitution of India unless it is permitted under the procedure established by law.’

It is indeed the solemn duty of the Government considering several judicial precedents, law of the land and international covenants to take steps to protect this unalienable right of the citizens of this country.

B. The Scope For Abuse

The recent ‘Amar Singh Tapping’ incident indicates that only forged letters were used by a group of private detectives because of which the service provider itself tapped the telephone line. The most disturbing aspect of telephone tapping in India today is the fact, that it is not only the Government or the some elements within the service providers who have the ability to tap, but also certain private individuals who have

¹⁵ AIR 1997 SC 568, para 19.

access to such kind of technology.

The Indian Express publishing transcripts of telephone conversations of prominent businessmen like Bombay Dyeing chairman, Nusli Wadia, Mahindra and Mahindra chairman, Keshub Mahindra,¹⁶ is just an indication to the fact that the threat of corporate espionage is very much real and in existence in India.

Apart from corporate espionage, the use of such technology is also a matter of grave concern for ordinary citizens who use telecom services. Just as 'Data Theft' is an important issue with regard to credit cards, where crucial information about the subscriber can be obtained by the interested parties, telephonic conversations can be tapped to obtain information about individual citizens. People at times have the most intimate of conversations on their phones. It is this information that can be used or rather misused.

IV. LAW OF THE LAND

A. *The Indian Telegraph Act*

Phone tapping in India is almost as old as the introduction of telephones in India, in the early 1880s.¹⁷ After independence, there have been several episodes of telephone tapping, which involved Presidents, Prime Ministers, political figures and on one occasion, even a Chief of Army Staff.¹⁸ In spite of such incidents, the law on the subject of tapping has been by and large static. The *Indian Telegraph Act, 1885* (the Act) contains provisions, which authorise the Government to intercept telephonic communication. Section 5(2) of the Act deals with the issue of phone tapping. This section was part of an amendment that was brought to the Act in 1972.

Section 5(2) of the Act provides that in event of the occurrence of a public emergency or in the interest of public safety, the Central Government or the State Government can intercept messages if they are

¹⁶ Syed Ashraf, 'Corporates Beware! Your Phones Might Be Tapped', 1997, available at <http://www.rediff.com/business/oct/07assam.htm> (last visited on 15 January 2006).

¹⁷ Prasad *Supra* n. 2.

¹⁸ Avijit Ghosh, 'Tales Of Tapping', *The Times of India*, (Mumbai, India, 15 January 2006).

satisfied that it is necessary or expedient to do so in the interest of:

- Sovereignty and integrity of India.
- The security of the State.
- Friendly relations with foreign states.
- Public order.
- For preventing incitement to the commission of an offence.

There are several Government agencies, which are authorised to tap telephonic conversations and eavesdrop on telephone lines. The Central Bureau of Investigation (CBI) Report that was submitted to the Supreme Court in the *PUCL case* indicated that under the provisions of law, the Intelligence Bureau, Director General, Narcotics Control Bureau, Revenue Intelligence and Central Economic Intelligence Bureau and the Director, Enforcement Directorate have been authorised by the Central Government to intercept telephonic communication. In addition, the State Governments also give authorisation to the Police and Intelligence agencies to exercise the powers under the Act.¹⁹

As per the provisions of the Act, in case of a conversation between two individuals, it is permissible if one of the individual tape-records the conversation. However, if a third party tries and tapes that conversation it is an offence under the Act. Section 25 of the Act states that if any person intending to intercept or acquaint himself with the contents of any message damages, removes, tampers with or touches any battery, machinery, telegraph line, post or other thing whatsoever, being part of, or used in, or about any telegraph, or in the working, thereof, he shall be punished with imprisonment for a term which may extend to three years, or with fine, or with both. The Act under section 4 gives complete authority and monopoly to the Central Government to establish and maintain telegraphs. Sub-section 1 of section 4 permits the Central Government to grant a license to any person on such conditions and consideration for

¹⁹ AIR 1997 SC 568, para 6.

establishing and maintaining telegraph within any part of India. Moreover, section 7(2)(b) of the Act gives rule-making power to the Central Government and mentions that the Government should formulate precautions to be taken to prevent improper interception and disclosure of messages.

B. Regulation Of Telecom Services

The Telecom Regulatory Authority of India (TRAI) was established under the *Telecom Regulatory Authority of India Act, 1997* to regulate the telecommunication services and other incidental matters. In that sense, TRAI has a major role in ensuring that the private telecom services providers do not contravene the provisions of the license that is granted to them by the Government under section 4 of the Act. Section 11(1)(b)(i) of the *Telecom Regulatory Authority of India Act, 1997* provides that TRAI has the power to 'ensure compliance of terms and conditions of the license'. This section, thus, empowers TRAI to take concrete action to ensure that private telecom service providers strictly follow all the clauses in their agreement including provisions of the license that deal with the interception of messages.²⁰

Section 11(1)(a)(iii) of *Telecom Regulatory Authority of India Act, 1997* provides that TRAI can make recommendations on revocation of license for non-compliance of terms and conditions of license.

C. Judicial Scrutiny

In the early nineties, there were several incidents of illegal tapping of politicians belonging to the opposition parties carried out by the Central Bureau of Investigation. A report was published in the 'Mainstream' Volume XXIX, dated 26 March 1991, titled 'Tapping of Politicians phones'.²¹ Based on this report, the People's Union of Civil Liberties, a voluntary organization, filed public interest litigation in the Supreme Court to read down the provisions of the Act vis-à-vis tapping and introduce procedural safeguards to prevent tapping of telephones. The Supreme

²⁰ Prasad *Supra* n. 2.

²¹ AIR 1997 SC 568, para 2.

Court laid down a detailed procedure to prevent abuse of the provisions of the Act and thus, the landmark *PUCL case*,²² for the first time concretely addressed the issue of telephone tapping. The Apex Court provided for guidelines for regulating telephone tapping by the Government, though not describing it as unconstitutional altogether.

The Apex Court observed that such safeguards were imperative considering the 'Mainstream' report whose authenticity was not questioned by the learned counsel for the Union of India.²³ The report indicated that various authorised agencies were not maintaining the files regarding interception of telephones properly, whereas one agency was not maintaining even the logbooks of interception. The reasons for keeping a telephone number on watch had also not been maintained properly.

The Apex Court rightly took the view that although section 5(2) could not be struck down, as it would jeopardise public interest and security of the State. However, adequate machinery to safeguard the right of privacy and prevention of abuse of power under the Act had to be introduced.

The Supreme Court in the *PUCL case* laid down the following guidelines to be followed during phone tapping. Firstly, that an order for telephone tapping in terms of section 5(2) of the Act shall not be issued except by the Home Secretary of Government of India and Home Secretaries of the State Governments. In an urgent case, the power may be delegated to an officer of the Home Department of Central Government, but as regards State Governments, this power cannot be delegated to officer below the rank of a Joint Secretary. Secondly, the order shall require the person to whom it is addressed to intercept in the course of their transmission by means of a public telecommunication system.²⁴

The Supreme Court also laid down that while considering whether the order under section 5(2) of the Act is necessary, it would also have to be considered whether the information which is necessary to acquire by tapping could be reasonably obtained by other means. Furthermore, the Court held that, the order under section 5(2) of the Act, unless renewed,

²² AIR 1997 SC 568.

²³ AIR 1997 SC 568, para 4.

²⁴ AIR 1997 SC 568, para 35.

would cease to have effect at the end of two months from the date of issue and the total period for the operation shall not exceed six months. The authority carrying out the tapping would also have to maintain detailed records on the tapping exercise and that each copy of the intercepted material shall be destroyed as soon as its retention is no longer necessary.

The Apex Court also directed the Government to constitute a Review Committee consisting of Cabinet Secretary, the Law Secretary and the Secretary of Telecommunication at the level of the Central Government. At the State level, such Review Committee would consist of Chief Secretary, Law Secretary and another member, other than Home Secretary, appointed by the State Government.

The Review Committee was as per the directions of the Supreme Court, on its own within 2 months from the passing of the order of the authority concerned, to investigate whether the order under section 5(2) of the Act was relevant and if there was contravention of section 5(2), then order the destruction of the copies of the intercepted material. Thereafter, the Government under section 7(2)(b) of the Act incorporated these directions on phone-tapping. It is indeed unfortunate that our country laid down such safeguards after 50 years of independence and only after judicial intervention by the Supreme Court.

D. The Evidentiary Value Of Taped Conversation

Interception of telephonic communication is an important tool for the law enforcement and intelligence agencies for obtaining conviction of the accused from the Courts. It is within the court of law that the evidentiary value of the tapped conversation has come under scrutiny in several cases.

One of the most noteworthy of such cases is the *RM Malkani v. State of Maharashtra*,²⁵ (Malkani case). This case revolved around the question of admissibility of taped telephonic conversation for the purpose of conviction of the accused. The Apex Court in this case held that such

²⁵ AIR 1973 SC 157.

evidence was admissible as evidence. The Supreme Court in the *Malkani case* pointed out that in several cases such as *N Sri Rama Reddy etc v. Shri VV Giri*,²⁶ and *S. Pratap Singh v. The State of Punjab*,²⁷ the conversation or dialogue recorded on a tape-recording machine had been accepted as admissible evidence. The Apex Court also held that such taped conversation would not amount self-incrimination and therefore, did not violate Article 20(3) of the Constitution.²⁸

The *Malkani case*, laid down the principle, that just as a photograph taken without the knowledge of the person photographed could become relevant and admissible, so does a tape record of a conversation unnoticed by the talkers.²⁹ The Apex Court further held that:

‘A contemporaneous tape record of a relevant conversation is a relevant fact and is admissible under Section 8 of the Evidence Act. It is *res gestae*. It is also comparable to a photograph of the incident. The tape-recorded conversation is therefore a relevant fact and is admissible under Section 7 of the Evidence Act.’

At this juncture, while dwelling on the point of relevancy and admissibility, it will be useful to have a look at section 29 of the *Indian Evidence Act, 1872* which states that:

‘If such a confession is otherwise relevant it does not become irrelevant merely because it was made under a promise of secrecy, or in consequence of a deception practised on the accused person for the purpose of obtaining it, or when he was drunk, or because it was made in answer to questions which he need not have answered, whatever may have been the form of questions, or because he was not warned that he was not bound to make such confession, and that evidence of it might be given against him’

It thus follows that a confession made during a telephonic conversation,

²⁶ AIR 1971 SC 1162.

²⁷ AIR 1964 SC 72.

²⁸ AIR 1973 SC 157 para 30.

²⁹ AIR 1973 SC 157, para 26.

which is intercepted, can be adduced as admissible evidence.

In the case of *N. Sri Rama Reddy v. VV Giri*,³⁰ the Supreme Court held that previous statements made by a person and recorded on tape can be used not only to corroborate evidence given by witness in Court but also to contradict evidence given before Court while testing veracity of witness and to impeach his impartiality in accordance with provisions of the *Indian Evidence Act, 1872*.

The Supreme Court further propounded the principle that taped conversation is admissible even if the person against whom it is used has no intimation of the fact that the conversation is being recorded.³¹ In doing so, the Supreme Court has adopted the common law principle of admissibility of evidence that is 'it matters not how you get it if you steal it even, it would be admissible in evidence'.

However, at the same time, the Supreme Court also took a cautious view with regard to the admissibility of such taped conversation. In its wisdom, the Apex Court in the *Malkani case* held that taped conversation would not be admissible as evidence in certain circumstances. The Supreme Court observed that a relevant tape-recorded conversation is admissible provided, three important conditions are satisfied:

- Firstly, the conversation should be relevant to the matters in issue;
- Secondly, there should be identification of the voice;
- Thirdly, the accuracy of the tape-recorded conversation has to be proved by eliminating the possibility of erasing the tape record.³²

The Supreme Court in the same case also laid down the approach that the Courts should take in cases where such taped conversation is sought to be adduced as evidence. The Apex Court held:

'The Court will take care in two directions in admitting such

³⁰ AIR 1971 SC 1162, para 24.

³¹ AIR 1973 SC 157, para 30.

³² AIR 1973 SC 157, para 23.

evidence. First, the Court will find out that it is genuine and free from tampering or mutilation. Secondly, the Court may also secure scrupulous conduct and behaviour on behalf of the Police. The reason is that the Police Officer is more likely to behave properly if improperly obtained evidence is liable to be viewed with care and caution by the Judge. In every case the position of the accused, the nature of the investigation and the gravity of the offence must be judged in the light of the material facts and the surrounding circumstances.³³

From the ratio that has been laid down in the *Malkani case*, it is evident that the authenticity and accuracy of the taped conversation is a *sine qua non* for its admissibility before the court of law. After the *PUCL case*, the procedure laid down by the Apex Court for the purpose of interception of telephonic conversation further streamlines the law relating to admissibility of tapped telephonic conversation. Today, if the law enforcement agencies wish to rely on tapped conversation as evidence, they have to follow the procedure prescribed by the *PUCL case* and furthermore satisfy the Court that the taped conversation is free from tampering and its accuracy is impeccable.

In the case of *State of Maharashtra v. Jaysingh Wadhu Singh*,³⁴ the Bombay High Court upheld the acquittal of a dismissed Sessions Judge by the Special Maharashtra Control of Organised Crime Act (MCOCA) Court. The dismissed Sessions Judge named JW Singh, who was charged with having links with the underworld. The prosecution relied on tapped telephonic conversations that allegedly took place between the Sessions Judge and an underworld operative. The High Court approved of the findings of the Special MCOCA Court Judge that the interception of telephone conversation was in contravention of the provisions of the Act.³⁵ Similarly in the case of *State v. Mohd Afzal and Others*,³⁶ (Parliament attack case), one of the accused was acquitted on the ground that the

³³ AIR 1973 SC 157, para 26.

³⁴ 2003 (8) LJSoft (URC) 11.

³⁵ 2003 (8) LJSoft (URC) 11, para 6.

³⁶ 2003 (3) JCC 1669, para 419.

telephonic conversation that the prosecution was relying on was prima facie tampered with.

In view of these judgments, it has to be said that the Indian courts have adopted a pragmatic and judicially sound approach towards telephone tapping. The Courts in India have not struck down telephone tapping as unconstitutional, but at the same time have given directions, which would prevent the state from misusing its powers. The judiciary has, thus, ensured that the substantive law as laid down in section 5(2) of the Act has procedural backing so that the exercise of power was fair and reasonable.

V. INTERNATIONAL POSITION ON TELEPHONIC INTERCEPTION.

A. *Legislation In The United Kingdom.*

The traditional common law doctrine as was propounded in the *R v. Leatham*,³⁷ was 'it matters not how you get it if you steal it even, it would be admissible in evidence'. In the case of *R v. Effik*,³⁸ evidence unlawfully obtained by police by way of unauthorized interception of telephone conversation was held to be admissible by the English Courts. However, *R v. Effik* was overruled by *R v Preston*,³⁹ and thereafter, concrete legislation governed the interception of communication.

In 1984, an individual by the name of Mr Malone, successfully brought an action against the UK in the European Court of Human Rights under Article 8.⁴⁰ Article 8 of the European Convention on Human Rights deals with the 'Right to respect for private and family life'. He had been the subject of a 'phone tap' by a legitimate investigating authority. His action succeeded because there was, at the time, no statutory framework in the UK for 'phone taps' and thus, such surveillance was not 'provided for by law' as required by sub-paragraph 2 of Article 8.

Thereafter, the then Government brought in the *Interception of*

³⁷ [1861] 8 Cox CC 498.

³⁸ (1994) 3 All ER 458 HL.

³⁹ [1994] 2 AC 130.

⁴⁰ Available at <http://www.hamiltons-solicitors.co.uk/archive-docs/rip.htm> (last visited on 15 January 2006).

Communications Act, 1985, which came into force in 1986. Its stated objective was to provide a clear statutory framework within which the interception of communications on public systems can be authorised and controlled in 'a manner commanding public confidence'⁴¹. The 1985 Act, however, did not apply to tele-communications systems outside the public network.

Subsequently, the UK Government introduced the *Regulation of Investigatory Powers Act, 2000 (RIP Act)*, which made private tapping a crime. Under the abovementioned Act, it is an offence for any person intentionally, and without lawful authority, to intercept any communication in the course of its transmission through a public telecommunication system and except in specified circumstances through a private telecommunication system.⁴² The Act also makes the controller of private telecom systems liable for any unauthorised tapping. The RIP Act regulates the interception of communications transmitted by a private network.⁴³ It also establishes a Tribunal, which can investigate whether there was a warrant and, if so, whether it was properly issued. RIP Act further provides that, if the 'Interception Warrant' has been improperly issued, then the Tribunal has power to order compensation and the destruction of the recorded material.

Thus, the UK has laws, which deals with the aspect of tapping through public telephonic systems and private telecommunication system.

B. Legislation In The United States.

There are several noteworthy American cases, which indicate the judicial trend in cases involving tapping in that country. In the case of *Olmstead v. United States*,⁴⁴ the Supreme Court allowed evidence adduced in the form of intercepted telephonic conversation, which was obtained in

⁴¹ *Ibid.*

⁴² 'Introduction Telephone Tapping', available at www.yourrights.org.uk/your-rights/chapters/the-right-to-privacy/telephone-tapping-and-interception-of-communications/index.shtml (last visited on 15 January 2006).

⁴³ Ashraf *Supra* n. 15.

⁴⁴ 277 US 438 at 466.

contravention of the laws of Washington State. However, subsequent American judgments have not condoned such surveillance. In the case of *Berger v. New York*,⁴⁵ much of the evidence was obtained with court-ordered eavesdropping devices in the offices of the suspects.

On appeal of conviction, the New York State appellate court upheld a New York statute permitting eavesdropping in the home and office. However, the Supreme Court found that the statute was too broad and its pervasive nature violated the fourth and fourteenth Amendments. The Supreme Court held that the broadly sweeping statute was without the necessary judicial checks and protective measures to ensure protection of individuals' rights. Therefore, the court reversed the holding of the New York State appellate court.

Similarly in the case of *Katz v. United States*,⁴⁶ an eavesdropping device was attached outside of a public phone booth used by the accused. Based on recordings of his end of the conversation, the accused was convicted. On appeal, the accused challenged his conviction arguing that the recordings could not be used as evidence against him. The Court of Appeals rejected this point, noting the absence of a physical intrusion into the phone booth itself. The question before the Supreme Court was whether the Fourth Amendment protection against unreasonable searches and seizures requires the police to obtain a search warrant in order to wiretap a public pay phone. The Court ruled that the accused was entitled to Fourth Amendment protection for his conversations and that a physical intrusion into the area he occupied was unnecessary to bring the Amendment into play. The Judiciary in the United States has, thus traditionally taken a position in favour of the right to privacy of its citizens.

The Congress in the United States in 1978 established the Foreign Intelligence Surveillance Court⁴⁷ as a special court and authorized the Chief Justice of the United States to designate seven federal district court

⁴⁵ 388 US 41 (1967), available at http://www.law.cornell.edu/supct/html/historics/USSC_CR_0388_0041_ZS.html (last visited on 15 January 2006).

⁴⁶ 389 U.S. 347 (1967), available at <http://www.oyez.org/oyez/resource/case/198/> (last visited 15 January 2006).

⁴⁷ 'Foreign Intelligence Surveillance Court,' available at http://www.fjc.gov/history/home.nsf/page/fisc_bdy (last visited on 15 January 2006).

judges to review applications for warrants related to national security investigations. The provisions for the court were part of the *Foreign Intelligence Surveillance Act* (92 Stat. 1783) (FISA), which required the government, before it commenced certain kinds of intelligence gathering operations within the United States, to obtain a judicial warrant similar to that required in criminal investigations. Under FISA procedures, all hearings and decisions are conducted in secret⁴⁸.

However, after 11 September 2001, there was a drastic shift in the policy of the Government by which more sweeping powers were given to the law enforcement agencies to conduct surveillance operations. The *USA Patriot Act, 2001* (115 Stat. 272) expanded the time period for which the Foreign Intelligence Surveillance Court could authorize surveillance and increased the number of judges serving the court from seven to eleven.⁴⁹ Thus, there exists a separate judicial body, which overlooks telephonic interception carried out by the US Government.

VI. RECOMMENDATION

Till recently, most of these tapping episodes were confined to the Government agencies using the available Government-controlled resources to carry out such operations. The boom in the telecom sector has brought in several private entities, which play a major role in providing telecom service to millions of subscribers all over the country. It is this influx of private entities and other private parties, which has radically changed the ground situation, whereby the Government no longer has complete monopoly and therefore complete control over the telecom sector.

There is, thus, an urgent need to ensure that the activities of private

⁴⁸ 'Support Oversight Of The Secret FISA Court,' 2003, available at <http://www.aclu.org/natsec/spying/14454res20030510.html> (last visited on 15 January 2006).

⁴⁹ *Supra* n. 45.

telecom service providers are completely regulated by the Government. Realising this, the Indian Government, to its credit, came out with the 'Communication Convergence Bill, 2001' (CCB). The CCB was introduced for promoting and developing the entire communications sector and to facilitate and develop the carriage and content of communications including broadcasting, telecommunications and multi media. The Bill proposes to repeal five laws, that is the *Indian Telegraph Act, 1885*, *Cable TV Networks Act, 1995*, *Indian Wireless Telegraphy Act, 1933*, the *Telegraph Wires (Unlawful Possession) Act, 1950*, and the *Telecom Regulatory Authority of India Act, 1997*.⁵⁰

Section 63 of the CCB deals with interception of communication and punishment for unlawful interception. The authorisation for tapping is based on exactly the same grounds as has been mentioned under the *Indian Telegraph Act, 1885*. The only difference being that service providers have been enjoined to assist the Government agencies in interception failing which, they can be punished with imprisonment up to seven years. In addition, any person responsible for unauthorised interception is liable for punishment up to five years or with fine which may extend up to ten lakh rupees and for a second and subsequent offence with imprisonment which may extend to five years and with fine which may extend up to fifty lakh rupees, or with both.

The main objective of the Bill is to facilitate and enable access to a national communications infrastructure, to provide a wide choice of services to consumers, set up a regulatory framework that can tackle the convergence of technologies and spell out the powers and role of a single licensing

⁵⁰ Communication Convergence Bill, 2001, clause 93(1), the Bill is available at <http://www.bsnl.in/Telecomguide.asp?intNewsId=30444&strNewsMore=more htm> (last visited on 15 January 2006).

and regulatory authority for all the three sectors. Regrettably, this Bill has been pending in the Parliament for the past six years and till it comes into force, the existing law will have to be amended to prevent invasion of privacy of the citizens of the country.⁵¹

One such amendment in the existing law can be on the lines of RIP Act of UK, which regulates both tapping through the public controlled telephonic systems and private controlled telephonic systems. This will address the issue of the private telecom service providers and their ability to illegally intercept telephonic conversation.

In the wake of the 'Amar Singh tapping' controversy the Government has also issued guidelines with regard to the contentious issue of phone tapping. This can only be termed as a step in the right direction. All service providers have been asked to appoint round-the-clock nodal officers, who will acknowledge requests within two hours of intimation from security and law enforcement agencies. The set of guidelines issued by Department of Telecom (DoT) state that the service provider shall arrange to issue acknowledgement letters within two hours for each of the intimations to the security and law enforcement agencies concerned, in a sealed cover, on receipt of such intimations for interception. The access service providers have been asked to use 'encryption Algorithm such as A 5/2 for GSM network' meaning thereby that a coded mail would be sent to the security agencies, who would decipher it. However, in emergency cases where prior approval of the relevant competent authority has not been obtained, the nodal officers of the telecom companies would take a post confirmation approval within three days of such a request. Such requests would have to be given by the head or second senior most officer, not below the rank of Inspector General of Police. In order to maintain checks and balances in tapping a phone,

⁵¹ *Ibid.*

officers in the rank of Superintendent of Police or equivalent instead of officer of Deputy Inspector General or equivalent, are authorised to authenticate orders issued by the Home Secretary.

Another modification that has to be introduced is to make the recommendation of the TRAI to revoke the license granted by the Government under section 11(1) (a)(iii) of *Telecom Regulatory Authority of India Act, 1997* mandatory, which is not the case as of now. The Government also needs to lay down laws, which will prohibit use of modern eavesdropping devices, which are available in the market. The Government also has to take steps to regulate the activities of private bodies such as, private detective agencies, which have the necessary technical expertise and resources to carry out surveillance activities.

In order to ensure that there is no abuse of the power to tap telephonic conversations, the Review Committee that was established after the *PUCJ* judgment should also consist of members from the Judiciary. The present Review Committee basically consists only of bureaucrats unlike the American Court, which consist of judicial members. There have been allegations made against successive Governments in India, to the effect that the political party in power had engaged in phone tapping of opposition party members. Introduction of judges from the higher courts or members of the judicial services will lend more credibility to such a body as compared to a body consisting only of bureaucrats.

Finally, one must also not overlook the fact that introduction of safeguards should not act as an impediment for the State agencies to carry out their routine functions. Terrorism has proved to be a menace for the society. India has faced terrorism for more than two decades now. Phone tapping can and has proved to be a vital tool with which terrorist designs can be successfully foiled.

In the case of *Regina v. P and others*,⁵² the House of Lords in the United Kingdom held that, 'Any developed society has to have a scheme for the surveillance of those who are liable to attack or prey upon the society or its members. Such schemes have throughout history included the interception of communications and in modern times this has included telecommunications.'

The *Maharashtra Control of Organised Crime Act, 1999*, included specific provisions, which allowed telephone tapping of suspected terrorists and also admitted such taped conversation as evidence. These provisions were, however, struck down by the Bombay High Court in the case of *Bharat Shah v. The State of Maharashtra*,⁵³ on the ground of legislative incompetence. The Bombay High Court held that only the Parliament could draft a provision, which allowed telephonic tapping. The world has already witnessed several incidents of terrorist atrocities and the devastating consequences of terrorist actions. The Central Government can include provisions akin to the provisions that were struck down from *Maharashtra Control of Organised Crime Act, 1999* in a legislation specifically designed to tackle terrorism along with appropriate judicial oversight, and provisions on the line of RIP Act of UK which also provides for compensation for wrongful telephone tapping.

VII. CONCLUSION

For every use of a technology, there is scope for equal and opposite abuse. In this day and age, technology is being increasingly used for the execution of terrorism, white-collar crimes, and corporate and industrial espionage. Therefore, in order to tackle these crimes, the Governments will continue tapping as a potent instrument of state power. The Supreme

⁵² Available at <http://www.publications.parliament.uk/pa/ld200001/ldjudgmt/jd001211/pappl-1.htm> (last visited date 15 January 2006).

⁵³ (2002) 1 BOM LR 527.

Court in the *PUCL case* has rightly affirmed that every state is bound to maintain its intelligence apparatus for conducting surveillance on its citizens. The challenge that we face today is to ensure that in doing so, the Government does not transgress its powers and wrongfully invade the privacy of its citizens. In addition to this, the Government has to introduce appropriate legislative mechanism to tackle the use of state of the art technology that facilitates invasion of privacy. The need of the hour is incorporation of various safety mechanisms and proper implementation of the existing provisions of law.

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