

INTELLECTUAL PROPERTY RIGHTS, BIOTECHNOLOGY AND THE THIRD WORLD

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CERTIFICATE

This is to certify that this dissertation entitled "**INTELLECTUAL PROPERTY RIGHTS, BIOTECHNOLOGY AND THE THIRD WORLD**" submitted by **KIRAN BHARGAVA** in partial fulfillment of the requirements for the award of the Degree of **MASTER OF PHILOSOPHY**, has not been previously submitted for any degree of this or any other University and this is her own work.

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ABBREVIATIONS

ASEAN	–	Association of South East Asian Nations
BJP	–	Bhartiya Janata Party
CPI (M)	–	Communist Party of India (Marxist)
DDT	–	Dunkel Draft Text
DSB	–	Dispute Settlement Body
EMRs	–	Exclusive Marketing Rights
EPO	–	European Patent Office
EU	–	European Union
GATT	–	General Agreement on Trade and Tariffs
GM Crop	–	Genetically Modified Crops
GMO's	–	Genitically Modified Orgnaisms
GURT	–	Genetic Use Restrictive Technique
IP	–	Intellectual Property
IPRs	–	Intellectual Property Rights
ITO	–	International Trade Organization
LMO's	–	Living Modified Organisms
MTO	–	Multilateral Trade Organisation
PBRs	–	Plant Breeders' Rights
PLT	–	Patent Law Treaty
TRIPS	–	Trade-Related Aspects of Intellectual Property Rights
UN	–	United Nations
UNCTAD	–	United Nations Conference on Trade and Development
UPOV	–	Union Pour la Protections des Obtentions Gevetales (International Union for the Protection of New Varieties of Plants)
US	–	United States of America
USTR	–	United States Trade Representative
WHO	–	World Health Organisatiion
WIPO	–	World Intellectual Property Organisation
WTO	–	World Trade Organization

PREFACE

The present century is hailed as a “knowledge century” where knowledge rather than tangibles is seen as a dominant mode of production. It has come to centre stage particularly due to propriety value attached to it. With the onset of the latest phase of globalisation, parallel process of harmonization is also at work. One such move is universalisation of Intellectual Property Rights (henceforth referred as IPR) which is generating major implication for the world political and economic system. Initially, IPR were visualised as a legal-economic dispatch, which later assumed sociological and anthropological dimensions. Finally ushering in, as a highly contested political issue. With the recent developments in the arena of biotechnology, the issue of patent has raised fundamental questions not just about politics and economy or morality and law, but it also involves much deeper issues, for it has changed our fundamental vision of ‘nature’ and our relationship with it. The issues of livelihood and food security, sustainable development and biosafety are intrinsically linked, as nature in context of biotechnology is not seen as intrinsic entity but has acquired the role of a new unconventional raw material to serve human ends. These issues have been in forefront since last two decades. The developed countries tried to bring the issue of IPR on agenda, the different forums. Initially, the third world countries posed a united front but with the onset of Uruguay Round of GATT, the divided front failed to live up to the aspirations of the people. It had to abide by the packaged deal of WTO. This brought forth various contagious issues into focus particularly, the debate regarding TRIPs and its impact upon the third world, in the light of the ‘third technological revolution’ in the field of biotechnology. In this regard, the issues pertaining to the value of traditional knowledge systems, rights of indigenous communities and the informal innovators are of particular political interest. Of late, the issue

has turned emotive with issues of culture, nationalism and sovereign right of nations being raised.

The chapterisation scheme is as:

Chapter 1 presents an overview of the issues involved. It tries to locate the politics involved in the conduct of international trade and the international organization and tries to place the issues of propriety knowledge into the framework of Intellectual Property Rights. It tries to locate the historical trajectory and political economy of the patents through various conventions and treaties. With particular emphasis on WIPO, CBD and TRIPs. It builds on an understanding of politics behind the process of harmonization in the world.

Chapter 2 looks at the history of biotechnology leading to biotechnological revolution. Watson's and Crick's discovery of the double helix DNA had generated immense interest. It gained impetus particularly, in the aftermath of Diamond vs. Chakravorty case, when for the first time life forms were seen as patentable entities. This becomes significant to India in the light of recent Supreme Court verdict in Damminaco case. Biotechnology is intimately related to biodiversity, in the form of 'germplasm', which serves as the raw material for the former. Developments in the technical front have implications for the issue of biodiversity and technology transfer. It is also linked with the questions pertaining to the rights of indigenous communities and the traditional knowledge systems. The study further looks into the highly contestable issue of patenting of life forms, GMO, GM crops.

Chapter 3 deals with the Third World and its location on various fronts. It tries to identify broad areas of contestation between the developed countries and the third world in the arena of IP protection vis-à-vis biotechnology. It analyses as to how an economic agenda assumes political overtones. It critically evaluates the change in the stand of

various Third World countries, which represented a more pragmatic but fragmented approach. It looks into the causes of this discord and provides insights about their stand and approach on certain vital and emerging issues. It looks at the relationship of biotechnology and biodiversity from the point of view of the third world.

Chapter 4 deals with reports of various organizations and agencies, views of the civil society with regards to implications of IP on third world. It tries to figure out the rationale behind reforming of patent laws in post colonial era. Various debates regarding the issue have been analysed through the illustration of India. The effort has been to trace the trajectory of Indian Patent Laws and various debates surrounding it.

Chapter 5 analyses the challenges emerging before the third world due to the interlinkages of the issues of intellectual property rights and biotechnology. It ponders upon the available options and the way ahead.

CHAPTER – I

INTELLECTUAL PROPERTY RIGHTS

With the onset of neo-liberal agenda on a global scale, international trade has come to be synonymously used with development.¹The hallmark of the present era has been the pace at which knowledge is generated and appropriated. Today knowledge has become the kingpin for development. Ganguli, describes it as:

“The continual process of learning, creating ‘new knowledge’ and further transforming it into ‘value-added knowledge’ with appropriate ‘proprietary protection’ and ‘fair distribution to its benefits’ has become fundamental to knowledge driven industries”².

The interesting dimension is that it is not knowledge per se but the propriety knowledge that is seen as the engine of growth. Proprietary knowledge is the knowledge that is protected through the instrument of intellectual property rights. (Henceforth, IPR).

The paradigm of IPR took a new turn in 1986 with the beginning of the Uruguay Round. This was the special ministerial session of contracting parties to the General Agreement on Tariffs and Trade at Punta del Este in September 1986, which launched the multilateral trade negotiations. It also included an agreement on the “Trade Related Aspects of Intellectual Property Rights’ (TRIPs) as a subject of negotiations. Marcia A Hamilton,³ opines that the Agreement’s “heading ‘trade-related’ makes it appear as

¹ Developing Countries in World Trade, Trade and Development Report, Yemen, Commission on Trade and Development, United Nations, 2002, p.1.

² P. Ganguly, Intellectual Property Rights: Unleashing The Knowledge Economy, Delhi, Tata Macgraw Hill, 2001, p.1.

³ Marci A Hamilton, “The TRIPs Agreement: Imperialistic, Outdated and Overprotective”, Vanderbilt Journal of Transnational Law, 1996, p. 614.

though it is simply business. But actually to understand TRIPS, it is important to embrace an interdisciplinary approach to widen the lens to include culture, politics, and human rights.” With the advances in technology, the issue of “trade relatedness” of IPR has produced wider implications.

The mandate for TRIPs states that “to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall clarify GATT provisions and elaborate as appropriate new rules and disciplines”⁴. The developed countries argued that issues related to Intellectual Property Rights should form part of the negotiations as inadequate protection to IPRs results in trade distortions. While the developing countries argued that IPR is not a trade related issue, therefore GATT was not the right forum to discuss IPR. They insisted that GATT should discuss only the trade related aspects and keep the task of setting norms and standards for the World Intellectual Property Organisation (WIPO).

In the international system, the law is used not only as a policy instrument but it also serves varied purposes. It is used to accommodate some of the nuances of the complex, fluid character of globalisation wherein, the legal diversity is often regarded as difference, leading to ‘systems friction’⁵. To avoid this they resort to interlegality⁶. At times it may lead to clashes in perspective while at others, it may lead to

⁴ Niranjana Rao, “Trade Related Aspects of Intellectual Property Rights: Question of Patents”, Mumbai, *Economic and Political Weekly*, p. 1053.

⁵ Christopher Arup, *The New world Trade Organization Agreements*, Cambridge, Cambridge University Press, 2000, p. 5.

⁶ Term used by Bonaventura da Sousa Santos cited in Christopher Arup (2000), *op. cit.*, p. 5.

intermingling or creation of new hybrid legalities.⁷ These inter legalities based on interactions are rooted into geopolitical needs of various countries⁸. Globalization has led to rediscovery of political economy as an approach to understand contemporary world politics⁹

Patnayak¹⁰ says that with the end of 'end of history' and rise of the 'trading state' the need to re-structure the world economic system has become pertinent. This existing international economic order in terms of international economic regimes has been defined by Ruggie as "governing arrangements, constructed by states, to co-ordinate their expectations and organize aspects of their behaviour in economic issues and trade relations." For this purpose various multilateral agencies are trying to act as mediators between the conflicting parties. Their role within the framework of this complex interdependence has been lucidly defined by Koehane. He states that the International regime serves as regulator of international system, which helps in reducing the cost of transactions amongst interacting nations. The third world visualises the virtual existence of these independent global regime as a threat to their economic sovereignty. The integration of national economy into global economy has led to destabilization of many economies and political regimes. It is argued that transition from GATT to WTO in 1995 was perhaps the most important development for the global economic system in the twentieth century. As emergence of WTO lent a new meaning to the term globalization, which was until then in realms of intellectual discourse!¹¹

⁷ Ibid.

⁸ Ibid., p. 6.

⁹ Kegley and Witcoff, World Politics, Trend and Transformation, London, St. Martin Press/WORTH, 2000, p. 208.

¹⁰ J.K. Patnayak, India and the GATT: Origin, Growth and Development, New Delhi, A.P.H. Publication and Corporation, 1996, p. 7.

¹¹ Amit Dasgupta, "WTO and New Issues", Paper Presentation at the Session on WTO, Kathamandu, Feb. 4, 2001.

The setting up of WTO was not only a milestone in the process of multilateral negotiations but it was symbolically significant too. It reflected an inherent change in the view point of various players in the international system. This shift in approach was particularly evident during the TRIPs negotiations. Marci A Hamilton¹² says that “signing of TRIPs led to significant section of world to question the political and social organization of power.”

WTO agreements are linked with the neo-liberal agenda of regulatory reform, which promotes harmonization and effective regulation. It is popularly claimed that the process of globalisation leads to localism and decentralization but actually the institutions like WTO end up giving more regulatory powers to the state. Yet it is seen as an attempt leading to the erosion of national sovereignty, particularly economic sovereignty. Keayla¹³ states that, the challenge posed by the WTO to the national economy is compounded by the process of globalization. WTO aims at paving down and restricting the role of state to its primary functions of law and order only. The state is being asked to shed its interventionist and directional role and activities intended for promotion of socio-economic goals in the name of efficiency and productivity. There are contending claims of geopolitical realities of nations juxtaposed against global economic forces.

While highlighting the inequity involved in the system, in such politically fluid situation, Arup¹⁴ says that, for some globalisation brings back the framework of political economy of world systems theory, leading to the rise of corporate conglomerates and technocratic elite. While others contend that this system may lead to new kind of 'feudalism' based on abstract

¹² Marci Hamilton, (1996), op. cit., p. 619.

¹³ Keayla, GATT:A Threat To Economic Sovereignty, Delhi, National Working Group on Patent laws, 1993, p. 1.

¹⁴ Christopher Arup (2000), op. cit., p. 19.

values and social capital. Thus, dividing the world in a new kind of 'center' and 'periphery' form of polarization.

The issue of Intellectual Property Rights in its present avatar, came to the forefront with the signing of TRIPs agreement. It is one of the major agreement under WTO, included in Annexure Three of the Marrakesh Agreement. To look into the politics of TRIPs it is pertinent to know the historical trajectory of this global regime. In the post- Second World War reconstruction effort, the Brettonwoods Conference in 1944, recommended the setting up of International Trade Organisation (ITO), to deal with the problems of international trade, it could not come into force. Therefore there was a need to look for an option to conduct international trade, so in 1947, GATT (General Agreement on Trade and Tariff) came into being. GATT was modelled on a pre-war United States Agreement Programme that came into force in 1934 with US Reciprocal Agreements Programme (RTAA). According to Grimwade¹⁵, "It's overt intention was to use US tariff as a weapon to gain access to other markets." But with the establishment of GATT, these bilateral measures took a multilateral turn. According to Mckinney¹⁶ no one intended GATT to evolve into an organization. To corroborate his view, he cites certain examples viz. GATT participants were not referred as members but as 'negotiating parties'. GATT provision contained the clause of 'grandfather right' i.e. the provisions where members were free to frame their own laws.

Later, the Havana Conference recommended setting up of ITO but US Senate refused to ratify it as it preferred not to lose its sovereignty over the trade issues and particularly and insisted on continuation of the provisions of Article 301 in the Trade Act. Therefore, GATT continued to be the principle agency conducting the affairs of international trade. This

¹⁵ Nigel Grimwade, *International Trade Policy: A Contemporary Analysis*, London, Routledge, 1996, p. 5.

¹⁶ Joseph A. McKinney, 'The World Trade Regime: Past Success and Future Challenges,' *International Journal*, XLIX, Summer 1994, p. 448.

was heavily in favour of the industrialized nations and eventually came to be known as 'rich man's club'. GATT basically performed two functions. First, it governed the international trade and secondly it provided a forum for multilateral negotiations. But in 70's, it began to expand its area of operation.

Gottfried Haberler Committee reviewed the functioning of GATT trading systems in 1958 and concluded that the developing countries were facing an iniquitous system.¹⁷

Efforts were made by developing countries on the forum of UN to search for alternatives. Its committee in 1963 recommended for setting up UNCTAD, which was widely seen as a forum for developing countries.¹⁸ Later, the developed countries tried to bring in the issue of IPR in the Tokyo Round of GATT, which lasted from 1973 to 1979, but the attempt failed. GATT launched its most ambitious Uruguay Round that lasted from 1986 to 1993 leading to signing of the Markesh Agreement in April 1994, which led to the establishment of the WTO. Experts opine that WTO extended the GATT structure in a manner consistent with what was once envisaged for the failed ITO.¹⁹

Kenney²⁰, opines that "The unforeseen disintegration of the Soviet Union led to a situation wherein nations were in desperate need of joining the international trading system. The use of multilateral and unilateral measures against the opponents also facilitated the process leading to the signing of TRIPs agreement. With the enforcement of TRIPs, the issue of IPR has reached 'behind the border'²¹ into the social and political fields that were not related to trade. In extending the notion of 'trade,' efforts

¹⁷ V. Ramchandriah, GATT Accord: India's Strategic Response, New Delhi, Common Wealth Press, 1994, p. 97.

¹⁸ S.Sen, "From GATT to WTO", Mumbai, Economic and Political Weekly, 22 October 1994, p. 2802.

¹⁹ Kegley and Witcoff, op. cit., p. 224.

²⁰ Joseph A. Mckinney, (1994), op. cit., pp. 449-450.

²¹ Term used by Christopher Arup cited in Cristopher Arup, op. cit.,(2000),p. 5.

have been made to bring domestic laws and legal frameworks in compliance with the various multilateral agreements. When the law itself is used to achieve specific ends it involves the issues of economics, politics and culture.

Many critics see the process of harmonization as universalisation of a particular domestic order. Bhargava²² opines that TRIPs intends to internationalise what so far had been in the domestic domain. It established the norms and criteria for IP protection, broadened the scope of protection encompassing lifeforms. Thus, it was seen as a mechanism not to increase the overall world trade but to fulfil the needs of particular constituencies.

Reichman²³ says that "Imposition of foreign legal standards on unwilling states in the name of 'harmonization' remains today what Ladas deemed it in 1975, namely, "a polite form of economic imperialism." While others observe that "globalisation does not produce convergence or homogeneity in law"²⁴ but has an agenda of its own. In this context, Hamilton²⁵ opines that "if TRIPs succeed across signatory countries, it would be most effective vehicle of western imperialism in history". IP is socially recognised. Though, she writes in context of copyright, but it can be extended to IP as a whole. Hamilton says that for accepting western version of IP it is also pertinent to accept following western ethos of:

1. Individualism: This notion involves the belief that individual's creative effort is valuable.
2. Reward: Society should single out original products by granting their owners proprietary rights where quality rather than effort matters.

²² P.M. Bhargava, "Conventions In Place of Patent Law," *Mainstream*, 8 (1) March 7, 1990, pp. 31-34.

²³ J.H Reichman, "Intellectual Property in International Trade: Opportunities and Risks of a GATT connection" *Vanderbilt Journal of Transnational Law*, 1989, p.813.

²⁴ Cristopher Arup, (2000), op. cit., p. 7.

²⁵ Hamilton (1996), op. cit., p. 617.

3. Commodification: Products are capable of being disassociated with their producers.

Hamilton²⁶ opines that by strongly supporting the TRIPS Agreement, the United States is exporting and imposing Protestant-based capitalism. In Western intellectual property system individualism is the sine qua non for a society to recognize and honour personal liberty. TRIP'S is nothing less than "freedom imperialism".

In terms of polity, analyst states that agreements place the nation-state in a paradoxical situation. Once acceded to the agreement, they are forced through international institutions to abide by the provision of treaties which take away substantial amount of decision-making power of the state. For better management state is expected to initiate the process of decentralization, which again reduces the scope of decision making power in the domestic sphere. Thus, the role of state has itself come under a lot of stress.

In this neo-liberal regime, the regulative role of government is increasing to adjust the removal of 'private obstacles' from their national territory for better market access for global trade. (The role of state) particularly in developing countries has also come under review for two reasons. Firstly, due to the increasing power of International organisation and the binding nature of treaties. Secondly, due to the increased role of non-state actors like the civil society, business lobby, media etc. which are engaged in forming global alliances against the pursuit of this regulative agenda.

Thus, through the regulative powers of state have increased in domestic arena but at the same time, its freedom to make rational choices as an international entity has been curbed. As in the case of acceding to GATT. Even though there was lack of consensus on many issues among the

²⁶ Marci A Hamilton (1997), op. cit.

negotiating parties, yet they had to sign the Markesh agreement, for it was a package deal as envisaged by the Dunkel Draft text.

Globalisation thus widely reduces state's element of choice. Yet, it is endorsed by the local elite as it fulfils its agenda by invoking globalisation as a rationale. Yet, at the same instance, it also provokes many groups to seek protection through the apparatus of nation state. As witnessed in the case of indigenous knowledge sources being patented outside, the state is expected to fight for their cause. But Global economics and technologies increase a sense of risk and contingency in people's lives. At the core of all IP theory lies the basic observation that information has economic value both for the individual and the society. The problems inherited are due to the distinctive attribute of all intellectual productions. The characteristics of possibility of secondary production i.e. resale value, generates discontinuous marginal utility. It is costly to develop but inexpensive to imitate. The supporters for protection of IP claim that if IP is not protected it will systematically lead to underinvestment in creation of knowledge. Particularly patents are intended to introduce excludability from public good and information. According to liberals, state must provide a socially necessary incentive to innovators by establishing and enforcing temporary monopolies for invention. Though the idea of IP in domestic sphere is contestable but it becomes all the more contestable when it is extended and forced upon the world system. Some justify it and claim that this is due to the process of globalisation, which enhances interface within the global community.

It is pertinent here to deal with the meaning and constituents of intellectual property.

INTELLECTUAL PROPERTY

WIPO describes Intellectual Property as “a creation of Human intellect.”²⁷ Legally defining it, Cornish says, “Intellectual Property Rights protects application of ideas and information that are of commercial value.”²⁸

Generally, ‘property’ is of three types viz. movable, immovable and intellectual. The ‘intellectual property’ relates to “pieces of information which can be incorporated in tangible objects. At the same time an unlimited number of copies can also be produced at different locations. The property is not in those copies but in the information reflected in those copies”²⁹. Kash and Kingston, trace its origin in Enlightenment wherein, invention was seen as “an extension of the personality” of the individual and thus, as their intellectual property.³⁰ IPRs are claimed to have been a driving force behind the rapid industrial growth in the developed world. They primarily evolved to protect mechanical and chemical innovations for which identification of novelty, the inventive step and innovator is relatively clear and identifiable.

Classification of Intellectual Property:- The term “intellectual property” has been given official recognition by the international community with the establishment of WIPO, one of the sixteen specialized agencies of United Nations. The convention establishing the World Intellectual Property Organization (WIPO), concluded in Stockholm on July 14, 1967.

WIPO classifies intellectual property into two major branches:

- a) Industrial Property and
- b) Copyright Law.

²⁷ www.wipo.org

²⁸ W.R Cornish, Intellectual Property, Delhi, Universal Law Publishing Co. Pvt. Ltd, 2001, p. 5.

²⁹ Reddy, Intellectual Property Rights And The Law, Hyderabad, Gogia Law Agency, 2001, p. 3.

³⁰ Kash and Willaim Kingston, “Patent in a World of Complex Technologies”, Science and Public Policy, Beech Tree Publishing, Vol. 28, No. 1, Feb. 2001, p. 15.

'Proprieties Industrial', a term of French origin, meaning industrial property encompasses patents (technological information), trademarks (symbolic information), industrial designs and trade secrets.

Copyright law and neighbouring rights (expressive information) cover literary, artistic, musical, photographic, audio and visual works³¹. Article 2(8) of WIPO provides that 'intellectual property' shall include rights relating to:

1. Literary, artistic and scientific works.
2. Performances of performing artists, phonograms and broadcasts.
3. Inventions in all fields of human endeavour.
4. Scientific discoveries.
5. Industrial designs.
6. Trademarks, service marks and commercial names and designations.
7. Protection against unfair competition.

And all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

The objects mentioned under (1) belong to the copyright branch of intellectual property. The objects mentioned in (2) are usually called 'neighbouring rights' that is, rights neighbouring on copyright. The objects mentioned under (3), (5), and (6) constitute the industrial property branch of intellectual property.³²

THE VARIOUS CONCEPTS AND THEIR HISTORICAL TRAJECTORY

Copyright: The scholars of ancient Greece and Roman Empire were the first to be concerned about being recognized as a creator of their work. It

³¹ What is intellectual property ?, www.bountyquest.com

³² WIPO, Licensing Guide for Developing Countries, Geneva, 1977, pp. 15-16.

was only after the invention of the printing press in late fifteenth century that the issue of piracy was raised. As number of press increased, the emperor exercised the royal prerogative to regulate and protect the book trade. The first decree regarding copyright was Licensing Act of 1662. It established a register which was maintained by Stationer's company. Its political orientation was clear as it also had power to seize books suspected of containing matters hostile to church and government. In 1709, the first copyright act, in the world was passed by UK's parliament. Statute of Anne, introduced two concepts viz.:

- An author being the owner of the copyright.
- The principle of a fixed term of protection for published work.³³

At international level in 1886 the Conference of Power framed the Berne Convention for the protection of literary and artistic work. The International Copyright Act was passed in 1886 and rectified in 1887. It abolished the requirement for register. It included an exclusive right to import or produce translations. System of copyright evolved with the advancement of technology. A case in point is UK where the Copyright Act, 1911 was extended to include records, perforated rolls, sound recording and work of architecture. Here tangibility was a primary consideration. The copyright act of 1956 extended to incorporate the new technological advances in the field of films and broadcasting. The importance of copyright is that they protect only the form in which an idea is fixed and not the substance of an idea, which lies in the territory of patent protection.³⁴ Even the rights accorded to owners of industrial design are protected under industrial design.

Trademarks: They are understood to date back to at least 3500 years when the potter's marks were used in identifying the source. It is a crucial

³³ A History of Copyright (www.intellectual-property.gov.uk)

³⁴ A.K. Kaul (ed.), Laws Of Copyright, Delhi, Faculty Of Law, 2001, pp. 4-5.

element of branding a product. It indicates the origin or source thereby serving consumer-protection function by establishing a link between a provider and service.³⁵

The important consideration is the use of mark in commerce as connected to the product and not the mark itself. Therefore, there can be cases where a mark can be used by different companies to represent different goods³⁶. When it is used to identify services it is called service marks³⁷. Many treaties exist in this regard.

Heald³⁸ emphasizes that trademark protection “prevents marketplace confusion that is detrimental to the interests of consumers in very nation” and “increases consume wealth by improving consumer information.”

Trade secrets: A trade secret is any information, design, device, manufacturing process, composition, technique, or chemical formula that is physically known and provides the know how with business advantage. They are potentially unlimited in nature³⁹. Till others discover the information independently or by analysing or dissenting a product through reverse engineering etc. It has to be appreciated that trade secrets per se cannot be legally protected as they are secrets, what is enforceable will be consequential effects of breach of trust or legal contracts.

Patents: This form of intellectual property is at the core of controversy. This work largely deals with this particular variant of IntellectualProperty. Its epistemology can be traced back to the Latin word ‘patene’ which means ‘to open’. Usually patent is used in two senses:

(a) The document that’s called patent or letters of patent.

³⁵ Introduction to IPR (www.usino.state.com)

³⁶ What is IPR? (www.bountyquest.com)

³⁷ WIPO Licensing Guide, op. cit., 1977.

³⁸ Reichman, “Compliance with the TRIPs agreement: Introduction to a scholarly Debate”, Vanderbilt Journal of Transnational Law, Vol. 29, May 1996, No. 3, p. 387.

³⁹ What is IPR? (www.bountyquest.com)

(b) The other is in the context of protection that a patent concerns.⁴⁰

World Intellectual Property Organisation (WIPO)⁴¹ defines patent as a 'document issued by a government office, which describes the invention and creates a legal situation in which the patented invention can normally only be exploited (made, used, sold, imported) with the authorisation of the patentee. The protection for the innovation is limited in time (generally, 15 to 20 years. Cornish⁴² says, "Patents are granted in respect of inventions i.e. technological improvements, with some scintilla of inventiveness of what is previously known".

A patent provides the patent holder, or patentee the right to exclude others from making, using, selling, offering for sale or importing the invention for fixed period of time from the date the inventor files the application. The patent system is based on the principle that, as a matter of public policy, it is desirable to encourage the making and exploitation of inventions⁴³. It is also seen as a government sponsored monopoly design to reward the invention by providing the inventor with the incentive for risking time, effort, and money in developing the technology. The patent system assumes that long term monopoly rights to an invention provide a powerful economic incentive to invention. It needs state's stimulation as it is assumed that the market would not provide adequate incentives⁴⁴. Thus it provides:

1. It provides the inventor with the 'first to market' advantage.
2. It allows preventing competition in early stage of commercialisation effort.⁴⁵

⁴⁰ KRG Nair and A Kumar (ed.), Intellectual Property Rights, New Delhi, Allied Publications Limited.

⁴¹ WIPO Licensing Guide, op. cit., 1977, p. 57.

⁴² W.R Cornish, Intellectual Property, Delhi, Universal Law Publishing Co. Pvt. Ltd., 2001, p. 6.

⁴³ AK Kaul(ed.), Laws Of Copyright, Delhi, Faculty Of Law, 2001, p. 8.

⁴⁴ Kash and Willaim Kingston, "Patent in a World of Complex Technologies", Science and Public Policy, Beech Tree Publishing, Vol. 28, No. 1, Feb. 2001, p. 14.

⁴⁵ AK Kaul(ed.), Laws Of Copyright, Delhi, Faculty Of Law, 2001, p. 8..

The system provides a bargain between the government and the inventor. The inventor is required to make a full disclosure of the invention to a government patent office, which is sufficient for other skilled workers to practice the invention, and this disclosure is eventually made available to the public. In exchange, the inventor is given the exclusive right to the invention for a fixed term.

According to Cornish⁴⁶, a patent can be characterized as a negative right, as it gives that inventor or patent owner the right to exclude others from making, using or selling the invention. It does not necessarily give the patent owner the right to make invention. It not only debar initiators but even independent devisers of the same idea upto a certain period.

The history of patents is long. It dates back to Ancient Greeks who granted cooks a monopoly for one year to exploit new recipes. The Roman emperor Zeno (480A.D) rejected the concept of monopoly all together.⁴⁷

In the recent past, the major effort was in 1623 through a parliamentary act in Great Britain called Statute of Monopolies Act of 1623. It proposed granting exclusive rights for new inventions for the term of 14 years. French patent law of 1791 stipulated that the monopoly of an inventor was a 'natural right' while Austria (1794) accepted patents but rejected the concept of natural rights and called it a statutory right i.e. benefits created by the state through law. There are debates regarding property as an entitlement, i.e. a natural right or property as a privilege or a creation of positive law serving instrumentalist purposes. Regarding the nature and philosophy of property rights, Oddi⁴⁸ opines that "the tension is highlighted when natural rights are extended beyond tangible property to intangibles including ideas, invention, or expression." Others opine that IPR are not rights but are privileges.

⁴⁶ W.R Cornish, *Intellectual Property*, Delhi, Universal Law Publishing Co. Pvt. Ltd, 2001, p. 5.

⁴⁷ The Laws of Life, Sweden, *Development Dialogue*, 1988 (1-2), p. 251.

⁴⁸ A. Samuel Oddi, "TRIPS-Natural Rights and a 'Polite Form of Economic Imperialism' " in *Vanderbilt Journal of Transnational Law*, vol. 29:415, 1996, p. 427.

Modern patent system was catalysed with the onset of Industrial Revolution, when exploitation of invention for commercial benefit became fairly common. The aim was to protect the interest of the inventor and encourage the development of newer and better products so that the society ultimately benefits. Another important component was that once the right was recognised, the new knowledge was open to public scrutiny. The inventor, knowing that his interest is protected, did not feel the need to cloak the invention in secrecy. But the widely held notions of knowledge as a common good and being passed from generation to generation made this transition a bit problematic. In Netherlands, though the patent bill was created in 1809 but it was repealed in 1869 by the Parliament. In Switzerland the issue was far more contentious. The referendums rejected it five times viz. 1849, 1854 and twice in 1863. It finally succeeded in 1887.

The trajectory of the patent laws is as⁴⁹:

First introduction in the fifteenth century.	Italy	
First known grant by a state to the inventor.	Republic of Florence	1421
Patents Ordinance	Venice	1474
Granting rights and privileges to the inventors by Queen Elizabeth I	Great Britain	
Statute of monopolies proposing grant of exclusive rights to inventors for new inventions for a period of 14 days.	Great Britain	1623

It was only towards the end of early eighteenth century and during the nineteenth century that more comprehensive patent statutes got formalized in various countries.

⁴⁹ Source: The New Encyclopaedia Britannica, 15th edition, vol. 30, page 1071, Cited in Prabudh Ganguli , Gearing Up For Patents Hyderabad, Universities Press,1998, p. 13.

Statutes of patents⁵⁰

USA	1970	Prussia	1815
France	1791	Brazil	1840
Netherlands	1809	Chile	1846
Austria	1810	Great Britain	1852
Russia	1812	India	1856

There are three popular models of patent:

Inventive Model: It gives legal protection to inventors .It is endorsed by most of the countries and is recognised within TRIPs though most popular, it still remains the most controversial. This work mainly deals with this model.

A few countries utilise other means like utility model and inventors certificate etc.

Utility model: It is merely a name given to certain inventions in mechanical field. It includes articles of manufacture, composition of matter, improvement in manufacture or anything produced by humans. China, Japan and Germany followed it. It differs from invention granted through patent viz.

(a) In invention under utility model, the technical programme i.e. inventive step required is lesser.

(b) Term of protection provided is generally shorter here.

⁵⁰ Ibid, p. 13.

Inventor Certificate: In the socialist regimes the innovations were recognized as inventor certificates. The provisions existed in laws of Algeria, Bulgaria, Czechoslovakia, Cuba, North Korea, Mongolia, former USSR and Vietnam. The state had an exclusive right of exploitation of the invention and the inventor had a right of fixed remuneration.⁵¹

In Third World countries the patent system was introduced by the colonial power. It was introduced in India in the year 1858, later it came to be regarded as the grand father of every colonial patent law.⁵²

In its modern avatar patents have been defined by three criteria of novelty, involves and inventive step (i.e. it is not obvious) and is industrially applicable.⁵³ Within the debate there are two rationale in defence of IPR i.e. “monopoly profit incentive” and “exchange of secrets thesis” wherein the latter holds it as society’s part of bargain with the inventor⁵⁴

Oddi⁵⁵ points out irony of over emphasising the natural rights thesis, which is the foundation of US domestic IP laws. He says that such high level of justification is impossible. “Either under the older ‘social welfare’ theory or under more recent theories, such as Grady and Alexander’s ‘rent dissipation theory’, Merges and Nelson’s ‘race to invent’ theory, or Kitch’s ‘prospect theory.’” Kash and Kingston⁵⁶ also try to break the myth that patent as monopoly rights are essential to revive the cost of labour. They point out when the inventor want wide application of their technology,

⁵¹ Lakshman Kadrigemer, “Objectives of Industrial Property, Reasons for Granting Patent” in The Role of Government Industrial Property Authorities and the Legal Profession in Administering Industrial Property Right in Asia and Pacific, Thailand, WIPO, 1983.

⁵² Surendra J. Patel, “Intellectual Property Rights In Uruguay Round”, Mumbai, Economic and Political Weekly, 1997, p. 24.

⁵³ WIPOs Lisencing Guide, op. cit., p. 27.

⁵⁴ Brain Belcher and Hawtin, “A Patent on Life: Ownership of Plant And Animal Research” in Nair and Kumar (ed.) Intellectual Property Rights, New Delhi, Allied Publication Limited, p. 266.

⁵⁵ Samuel Oddi, “TRIPS-Natural Rights and a ‘polite form of economic imperialism’ ” in Vanderbilt Journal of Transnational Law, Vol. 29:415, 1996.

⁵⁶ Kash and Willaim Kingston (2001), op. cit., p. 17.

they encourage others to use their patents by offering low or no cost licensees.

While Adelman⁵⁷ argues that a universal patent system will, benefit the world community by eliminating the free-rider's disincentives to innovate in all market structures and by increasing the supply of needed inventions that would otherwise not have been made. He says even if "those who pay monopoly prices for products that for one reason or another would have been invented in the absence of a patent system, (are) apparent losers... they also benefit from products that are off-patent, but which may not have been developed in the absence of a patent system." One of the paramount problem of IP is to establish a balance between what is revealed in the patent application and to decide how not to provide rights so that they do not exceed beyond the revealed information.

Reichman⁵⁸ opines that modern day patents are based upon the instrumentalist view.

The 3 major premises for IPR are:

- (1) It is assumed that such creative activities/inventions are elastic in supply and will not get generated in economically adequate measure for public use without economic incentives.
- (2) Without some sort of monopoly power granted, for sometime, to those generating such activities, adequate economic benefits will not accrue to them.

⁵⁷ Adelman and Baldia, "Prospects and Limits of the Patent provision in the TRIPs Agreement: The Case of India", *Vanderbilt Journal of International Law*, Vol. 29, 1996.

⁵⁸ J.H. Reichman (1996), *op. cit.*, p. 392.

- (3) IPR regulation ensures such special economic benefits to those individuals/organisations indulging in creative activity using their special talents.

Though the issue of intellectual property rights is surrounded by major controversies, yet it has become inevitable in present times⁵⁹ Professor Machlup in late 50's summed up the stalemate in these words, "if we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it." With the increase in transnational activities, it became essential to establish some minimum standards of uniformity, to conduct international operations.

Today at the international level, more than twenty conventions have been signed on the issue of intellectual property. The latest being the Patent Law Treaty of 2001. Some important treaties regarding patents are as follows:

The Paris Convention: This was the first step towards harmonisation in international arena. It was adopted in 1883, since then, it has been amended several times. It has been politically negotiated to keep pace with the technological and legal developments. It covered Industrial Property and provided for National Treatment, Right of Priority and Common Rules. Its most important clauses from the view of the third world were that importation does not amount to working of patent and Article 5A (2) provided for the provision of 'compulsory licensing'.⁶⁰

⁵⁹ Machlup cited in Reichman, (1996), *ibid*, p. 393.

⁶⁰ D.M. Nachane, "Intellectual Property Rights in the Uruguay Rounds: An Indian Perspective", *Mumbai, Economic and Political Weekly*, February 1995.

Patent Co-operation Treaty: It aimed at harmonizing the international arena in terms of the procedure related to filing, search and examination of the patent application.

Budapest Treaty for the deposition of microorganisms for the purpose of patent protection was concluded in 1977 and enforced in 1980. It was established to accommodate new developments on the front of biotechnology and the new interpretation about the subject matter of patent. With the provision of patenting of life, new concerns emerged. As written disclosures were not enough in this case for filling of patents, so supplementary clause for deposition of microorganisms was added. It also paved way for Cartagena Protocol On Biosafety.

World Intellectual Property Organization (henceforth WIPO): It succeeded International Bureau that administered Paris and Berne Convention through the 1967 Stockholm WIPO Convention, it came into being in 1970. It worked as an umbrella to administer various international treaties related to IPR. Further, through an agreement in 1974, it became one of the sixteen specialised agencies of the UN. Currently, it administers twenty-four such treaties. Regarding its functions the WIPO bulletin, states "WIPO is responsible for taking appropriate action... for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries to accelerate their... development".⁶¹

Prior to Uruguay Round, WIPO had encouraged and assisted the adoption of many international conventions to set the minimum standards in various components of IPR. It subsumed various international conventions and treaties within it. These were administered, negotiated and revised by WIPO but there was a perception that WIPO lacked effective powers to

⁶¹ Nair and Kumar (ed.) (1994), op. cit., p. 2.



discipline signatories in case of non-compliance. Grinwade⁶² argues that had WIPO been successful in establishing a set of rules and minimum level of IP protection in all countries, the issue would not have assumed such great proportion in GATT negotiations. Prior to TRIPs, it was the most important fora for IP issues. Many argue that WTO has undermined the role of WIPO. But Correa and Musngu article argue that, "...while the 'politics' of intellectual property have mainly taken place at the WTO, new intellectual property standards continued to be set under the auspices of WIPO".

TRIPs (Agreement On Trade Related Aspects Of Intellectual Property Rights]

This is identified as one of the most important and controversial agreements under the WTO. Infact the mid-term review of Uruguay Round was almost on the verge of breakdown due to rift on the issues of TRIPs. Reichman⁶³ opines that "(TRIPs was) the most ambitious international intellectual property conventions ever attempted". As for the first time in history these provisions "make it likely that states will lodge actions against other states before duly constituted international bodies, with a view to indicating the privacy on intellectual property rights of their citizens against unauthorised uses that occur outside the domestic territorial jurisdictions"⁶⁴. The mandate of the Negotiating Group regarding TRIPs reads: "...reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not

⁶² Nigel Grimwade, International Trade Policy: A Contemporary Analysis, London and New York, Routledge, 1996, p. 312.

⁶³ Reichman, (1996), op. cit., p. 366.

⁶⁴ Ibid, p. 367.

themselves become barriers to legitimate trade⁶⁵, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rule and disciplines.” So, GATT framed a set of rules and procedures for intellectual property protection called TRIPs), which was mandatorily adopted as a standard by all the GATT members. The agreement covered enormously wide arena. It included provisions for Most Favoured Nations, National Coverage and Mandatory Patenting.

To be patentable the invention must be ‘novel’ and ‘inventive’. The test of inventiveness is whether it is obvious to a person skilled in the relevant field. The TRIPs agreement defines the scope of “Patentable Subject Matter” Under Article 27, it states that“...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application...”

The limit to scope of patentability, is the issue which has generated most debates. Keeping in mind the sensitivity Article 27 Clause [2] the TRIPs agreement provides that “Member may exclude from patentability the inventions, the prevention within their territory of the commercial exploitation ...to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment”.

The agreement also provided for scope of exclusion from the clause of patentability. Article27(3) states that

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

⁶⁵ Also in Preamble of TRIPs Agreement, see Appendices, p. I.

[b] Plants and animals other than micro organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes...”

One of the very crucial issues during the negotiation process was concerned with establishing the relationship of TRIPs with the existing structures. It was decided that all signatories of TRIPs would automatically become the members of Paris Convention. With the incoming of TRIPs the flexibilities enjoyed by countries under Paris Convention ceased to exist.

It is pertinent to analyse the inherent divergences between the approaches of the two treaties.

Though the two systems were based on the principle of 'National Treatment' but their interpretation were different. In the Paris Convention it was related to 'persons' whatever rights and obligations were provided in patent law for nationals, were also applicable on the foreigners. While under GATT it relates to 'goods' i.e. no discrimination shall be made on the basis of origin of goods i.e. produced domestically or imported.⁶⁶ It is feared that this provision may give advantages to the established corporates and reduce opportunities for domestic firm. It is seen as detrimental to the pursuit of national interest by the state. It may lead to slow down of technological advancement, increase foreign dependence, reduce local production and leading to increase in unemployment which can produce major socio-political upheavals. Under TRIPs, it is binding for national governments to protect foreign firms from the threat of unauthorised use of intellectual property. This is seen as a strong re regulatory mechanism provided to the state.

⁶⁶ Nachane (1995), op. cit.

In the particular context of biotechnology, it is pertinent to look at property rights for plants. International convention for the protection of new varieties of plants (UPOV) provides for plant breeder's right (PBR), a form of property right in plant technology. The 1991 UPOV act defined the breeder "as a person who breed, discovered and developed a variety". The system of PBR is much more specific than the patent, as it is available only for a product and not for the processes. It provides ownership rights for the whole plant and not for the constituent parts. To claim PBR's it must fulfil the following three criteria: distinct, homogeneous and stable (across generation). The 1978 model provided for 'breeder's privilege'. While 1991 Act strengthened breeder's right' over access to the resource. The important provision was that UPOV prohibited members from extending both PBR and patent protection to a plant variety. But the 1995 act lifted the ban on double protection. TRIPS too provides for the proprietary in the plant technology Its Article 27, clause 3, provides that, "... members shall provide for the protection of plant varieties either by patents or by an effective sui generis system...".

Thus, initially the aim of various agreements was to set minimum standards for operational efficiency. With the shift towards initiating the process of harmonisation, the basic issue of trade law has assumed political flavour. It has particular implications for the third world when it is tied with the technology. It is important to see patents vis-à-vis technological development as it is intrinsically linked with transfer of technology. Technological innovations have always been provided stimuli by government policies. A study points out that roughly 50% of productivity growth in advanced countries comes from such innovation.⁶⁷ As the 1999 World Development indicators show that "Balance of Technology trade"⁶⁸ is heavily tilted in favour of a few nations whose

⁶⁷ Kash and Willaim Kingston, (2001), p. 11.

⁶⁸ Patnaik, (1996), op. cit.

expenditure on R&D as percentage of GNP has been high. Maskus⁶⁹ point out that US is overwhelmingly the main supplier of technological ideas to other countries. Though this proposition in itself is controversial.

As Deardorff⁷⁰ argues that even if it is believed that domestic IP protection is necessary to ensure optimal quantity of invented goods, yet it does not mean it is efficient to extend such protection to the rest of the world. He also argues that greater the area of protection lesser is the marginal benefit. There are others who point out that in England, lack of IP protection from contending and emerging power is identified as a cause of its fall as an industrial super power in nineteenth century.

IP protection is seen by some as a hindrance in technological fields. Heller and Eisenberg⁷¹ opines that “patent are more often disadvantages for complex technologies because they inhibit the rapid diffusion and use of new technology. In the case of complex technology where patent monopoly was a minor issue. In the post second world war era, the three most important technology i.e., automobile, aircraft and radio, grew on the basis of pooled patents. This process had begun in 1856 with sewing machine industry. In it member firms transferred all the patents to the pool. It was seen as an anti competitive behaviour but proved to be a great technological advantage leading to cost efficiency.

Today, in the field of life sciences, development is taking place at great speed. Facilitated by the very nature of biotechnology, controversies are generated about the issues of ownership, which has given rise to a patent litigation. It is giving rise to a new ‘scientist-lawyer complex’. U.S. Advisory Committee pointed out that “it has become an increasingly inefficient,

⁶⁹ Kash and William Kingston, op. cit., pp. 13-14.

⁷⁰ Alam V Deardorff, “Should Patents be Extended to all Developing Countries?” in Robert Stern (ed.) The Multilateral Trading System: Analysis and Options for change, New York, Harvester, Wheatsheaf, 1993.

⁷¹ Heller and Eisenberg cited in Kash and William Kingston (2001), op. cit., p. 15.

ineffective and undesirable means of resolving patent related disputes.”⁷² The committee pointed out that due to increasing cost and delay, the central purpose of patent i.e. an effective incentive for development and commercialisation of new technology is seriously eroded. It is pointed out that patent litigation is used as a corporate tool to intimidate other competitors and stop their entry. This ‘saturation patenting’ is contrary to the very aim of IPR i.e., “the progress of science and technology.” Patents are also used as trading currency/ bargaining chips. Firms in complex technologies, patent several sub components in order to gain strong position in the cross of cross licensing it is very crucial to patent strategy of a company. This trend in patent activity has been amply reflected by Ganguli.⁷³ He calculates that worldwide there has been marginal growth of just 6.4% in number of first file name of patents while subsequent corresponding has grown at 280%.

Kash and Kingston⁷⁴ opine that such patent should not be granted as they are based on incremental innovations which is, ‘obvious to one skilled in the art.

Today IPRs are seen as an effective means of benchmarking intellectual assets and innovative capabilities of an organization. But others maintain that patent system allows the legal appropriation of knowledge from public domain. Mashelkar⁷⁵ points out that the process of globalisation is threatening the ‘collective knowledge’ of society by turning it into propriety knowledge for commercial profits through patents. The importance of patents in industrial and technological fields can be identified when Mehrotra⁷⁶, says that, the level of patenting activity is often treated as an index of the industrial capability. The patentee is given the right in view of

⁷² *ibid.*

⁷³ Prabudha Ganguli, *Intellectual Property Right: Unleashing The Knowledge Economy* Delhi, Mac Graw Hill, 2001, p. 38.

⁷⁴ Kash and Kingston (2001), *op. cit.*, p. 17.

⁷⁵ Prabudha Ganguli (1998), *op. cit.*, p. 1.

⁷⁶ N.N. Mehrotra, “Patents Act and Technological Self Reliance: The Indian Pharmaceutical Industry”, *Mumbai, Economic and Political Weekly*, May 1989.

freely making available the technical details of the invention. Not only does it help in increasing the knowledge base of the society but also induce investment climate leading to industrialization. This may be true about the developed countries, the third world still remains on the margins of such system. Theoretically, rights of ownership starts with the inventor but usually it is granted to the employer. Due to the capital and resource intensive nature of the research, Vandana Shiva opines that “Patent is not a reward of labour but of capital”. Ganguli introduces “Patent Globalization Index” to measure globalization of patent which has increased from 1.69 in 1991 to 6.04 in 1997.⁷⁷

Thus the role of patent has come a long way from a mere royal prerogative to being a corporate strategy. Unlike the use of patent pool in 50’s for development of big technology. Today it is a weapon for bargain and coercion. With the onset of biotechnological revolution, patent has become a political instrument.

⁷⁷ Prabudha Ganguli, Intellectual Property Right: Unleashing the Knowledge Economy, Delhi, Tata Macgraw Hill, 2001, p. 42.

CHAPTER – II

DEVELOPMENT OF BIOTECHNOLOGY

AND POLITICAL RESPONSE

In the present century, the onset of fourth industrial revolution, humanity has reached a threshold. As the level of scientific advances have reached a stage where man no longer is a mere product of nature but is also creator of it. In this context, new issues of knowledge and politics have emerged. The creation and diffusion of technology is at the heart of the modern economic growth. The technological revolution occurred in varied and diverse areas but developments on the front of biotechnology¹ have been the most significant. Biotechnology, by accident or by design has always been used by humans since time immemorial. Technology, combined with the issue of intellectual property is not just about law and science but has political and socio-economic implications. As technological transformation of society was not a spontaneous eruption of creativity, it was the explosive climax of several millennia of cumulative human progress. Its antecedents were entire histories of civilizations living in making² Infact, on the basis of evolution Patel categorizes history into three main epochs:³

- a) Biological evolution stretching over two million years.
- b) Cultural mostly agricultural evolution covering twelve thousand years.
- c) Industrial revolution covering two hundred years. Industrial revolution, accelerated the speed of innovation. The latest phase

¹ Biotechnology is a general term and in its broadest sense to the variety of techniques involving living organism as a means of production.

² Surendra J Patel, Technological Transformation In Third World: The Historical Process, Avebury, UN University, 1995, p19.

³ Ibid. p. 22

of industrial revolution is marked by biotechnological revolution.

Broadly on the basis of technique it can be classified as traditional biotechnology and modern biotechnology. Auramovic Mila traces its trajectory on the basis of its chequered history as:⁴

- a) The first generation phase of biotechnology: It was based on empirical practice with minimum scientific or technological inputs. It dates back to the stone age and uses biological organisms such as bacteria, yeast and traditional methods of fermentation to produce food and drink.
- b) The second generation: Developing on the rudimentary knowledge, the interwar period witnessed developments in fermentation technology using cell culture and sterile manufacturing facilities to yield new products. The milestone being the discovery of penicillin in 1928. This resulted into huge interest in the field of microbiology. The properties and characteristics of microorganisms were identified, which led to successful use of mutation and selection of strains technique to achieve substantial improvement in yields which enhanced production efficiency. The seminal development being the use of hybrid crop varieties in US Corn Belt in the early 30s.
- c) The third generation: It began with Watson and Crick's discovery, which opened Pandora's box of hopes and opportunities. The "third wave" technology was more generic than any other since industrial revolution.⁵ Biotechnology⁶, in particular was greeted with great euphoria as it was identified as a solution to fundamental plaguing problems of mankind viz. death, disease hunger and pollution.

⁴ Auramovic Mila, *An Affordable Development? Biotechnology, Economics And Third World.*, London, ZED books, 1996, pp. 7-8.

⁵ Susantha Coonatilake, *Towards a Global Science: Mining Civilizational Knowledge*, New Delhi, Vistaar Publications, p.181.

⁶ WHO defines Biotechnology as "the integration of natural sciences and engineering sciences, in order to achieve the application of organism, parts thereof and molecular analogues for products or services. CBD defines modern biotechnology as any technological application that uses biological system, living organism or derivatives thereof to make or modify products or processes for specific uses."

Major milestones in the evolution of biotechnology since its inception are:

7000 BC	Sumerians brew beer.
4000BC	Egyptians leaven bread with yeast.
3,000 BC	South American people select and breed potatoes as staple crop.
1861	Pasteur discovers that fermentation is performed by microorganisms.
1865	Gregor Mendel, the father of genetics, presents his laws of inheritance.
1900	Rediscovery of Mendel's theory.
1939	Plant cells grown in suspension.
1940	Oswald Avery isolates pure DNA.
1941	Danish microbiologist A. Justin coins term "genetic engineering".
1950s	First plants from tissue culture regenerated.
1953	James Watson and Francis Crick describe double helix structure of DNA
1973	Stanley Cohen and Herbert Boyer discover recombinant DNA technology, considered to be the birth of modern biotechnology.
1973	First gene transfer with rDNA technique from one bacterium to another.
1976	Genetech first company to commercialise rDNA technology.
1981	First transgenic animal .
1982	The first genetically engineered product, human insulin, is approved for sale in US.
1989	First animal, Onco Mouse patented.
1989	PGS announces the cloning of male sterility gene to develop commercial hybrid for all crops.
1990	The first food products modified by biotechnology, an enzyme is marketed.
1990	Several companies announce "gene gun" to engineer any crop genetically.

From the rudimentary beginnings, today, modern biotechnology has reached a phase where it is engaged in the process of genetic engineering⁷

⁷ The technique that allows the scientist to change the character of living organism by transforming genes from one organism, across specie barrier to another to create a genetically modified organism which is not possible in nature.

life forms and has the potential to produce designer babies. In the inter war period, to define the forthcoming age of biochemicals, Karl Ereky coined the term Biotechnology.

But it was in early 1970s California that biotechnology first exploded in early 1970's. The electronics industry in Silicon Valley, prepared the ground for the biotechnology, by providing the infrastructure to business professionals and venture capitalists, who were familiar with high technology industries. Furthermore state boosted several universities with world class life science facilities. However, early concerns were expressed about the power of the new techniques, in the mid 70's, and for a few years there was a noisy debate and controversy about whether the new knowledge and techniques would unleash new threats. Vandana Shiva traces origin of controversy about Genetic Engineering (henceforth GE) since this instance. She identifies two phases of controversy about GE, first emerged when rDNA technologies were in experimental phase. They used crippled organisms, which were meant not to survive in the environment. The university scientists through Asilomar Declaration in 1972 called for moratorium on rDNA research. She calls the second phase as 'Wall Street Phase' when, scientists left universities to open Biotech firms and safety standards were sacrificed for biotechnology miracle. It led to a kind of shift of biotech knowledge from the public institutions to the private domain. The debate turned multi faced with the US Supreme Court's, 1980 decision in Diamond vs. Chakravarty case. When for the first time patenting of life forms was allowed. The controversial technology gained new dimension with the introduction of IP protection to the lifeform. Apart from moral and ethical issues, it should also be seen in light of prevailing international order, as it was an issue of paramount concern for the third world.

In the 1970's the trend of R&D in biotechnology soon graduated and diversified in enormous fields of application. Even its most vociferous

critics accepted the contribution of biotechnology in creating new materials such as biodegradable plastics, polymers and biopesticides. They regarded it as environmentally compatible technology. Its medicinal and therapeutic uses were widely acclaimed. It made and still continues to make major contributions in arena of treatment. Insulin is now manufactured from genetically modified bacteria, which is inserted with human insulin-producing genes. Any risks associated with these treatments appear to be acceptable in the presence of life threatening situation.

The technology has generated controversy cutting across the boundaries of science, law and politics, particularly with the involvement of issues of intellectual property on life forms, which is dealt with later. Buttle⁸ has broadly grouped the application of biotechnology into four domains:

- (1) Industrial tissue culture.
- (2) Dairying and animal husbandry.
- (3) Plant genetic manipulation and breeding.
- (4) Genetic manipulation in micro organisms.

This chapter deals with the particular application of biotechnology in the field of genetics. There is no exact agreed definition of biotechnology, despite several attempts. Recently OECD redefined it as “an application of scientific and engineering principals to the process of material by biological agents to provide goods and services”. In this regard, the definition used by Cartagena protocol on bio safety in Article 3 of Terms Of Use is most suited to this analysis.

Article 3 (i) “Modern Biotechnology” means the application of:

⁸ Nachane, “Intellectual Property Rights in Uruguay Round: An Indian Perspective”, Mumbai, Economic and Political Weekly, Feb. 1995, p. 258.

- (a) *In vitro* nucleic acid technique, including rDNA (recombinant deoxyribonucleic acid) and direct injection of nucleic acid into cells or organelles or
- (b) Fusion of cells beyond the taxonomic family to overcome natural physiological reproductive or recombination barrier and that are not techniques used in traditional breeding and selection.

The chapter takes the layman's understanding of the process and identifies it as 'genetic engineering'. In this context, the chapter revolves around the understanding of the interplay between biotechnology and biodiversity and attempts to trace the challenges and implications it presents before the IP regime.

The concerns are situated around few core issues viz.

- a) The most critical issue is that biotechnology aims at redefining the way in which we look at nature. It considers the mechanical reductionist view of life (which is also supplemented by modern IP regime). It de-emphasises natural history model of nature for molecular structural explanations of natural characteristics.⁹
- b) Second concern is primarily related to the issue of 'risk' and 'threat perception' involved in production of Genetically Modified Organisms and its impact upon the environment. It became all the more significant when genetic engineering technique was used in food products. It is seen in context of agronomy, food security and its impact upon the food chain and biological diversity.
- c) Biotechnology uses a new kind of unconventional raw material in the form of germplasm. It is found in enormous proportions in the biologically diverse south. This issue regarding the material

⁹ Les Levido and Joyce Tait, "The Greening of Biotechnology: GMO's as Environment Friendly Products" in Shiva and Moser (ed.) *Biopolitics*, Madras, Orient Longman, 1996, p. 124.

aspect of ownership and control over natural resources, with issues of IP involved, virtually assumed the proportion of technology rich vs. genetically rich countries.

- d) In the later part, the chapter revolves around the understanding of patents vis-a-vis biotechnology and probes into various controversies regarding it.

I

Technology is not just a science but is the reflection of larger socio political context. Biotechnology is its best illustration. Its application in the field of genetics through the mode of genetic engineering has influenced our basic assumption in life about life. GE has certainly generated lot of political milieu. Levidow and Tait¹⁰ have attempted to trace the politics behind the nomenclature of the term to indicate the technology. Through the example of UK they elucidate how the terminology was changed at various points of time to make it more acceptable in public domain. Initially, Royal Commission on Environmental Pollution used the term 'Genetic Engineering.' But in tune with its nature the Department of Environment used the term 'manipulation'. While in the course of first proposal for Deliberative Release Directive, this term was replaced by 'Genetically Modified'. Since then it has been used in official discourses. But the term GE is widely used by scientists, environmentalists and the civil society. This gained wide approval as 'modification' suggested gradual evolutionary change. Critics point out inherent fallacies in usage of the term Genetic Engineering as Vanadana Shiva¹¹ contemplates that GE is based upon the reductionist approach where organisms are viewed as machine. The

¹⁰ Ibid, p. 127.

¹¹ Vanadana Shiva "Beyond Reductionism in Shiva and Moser (ed) Biopolitics, Madras, Orient Longman, 1996, p. 267.

world is seen in the form of atomised fragments which associate mechanically to make larger system. Infact through it, she tries to make a larger point about microbiology as whole. "GE brings us to second order of 'Genetic Reductionism', where genes are perceived in isolation from its environment".

Levido and Tait¹² also endorse the view and opine that Genetic Engineering suggests a potentially omnipotent physico - chemical approach to biology of life. In fact they seem to echo the words of Microbiologists Muller¹³ who in 1926 declared that "gene can be viewed as a biological atom, solely responsible for physiological and morphological properties of life forms". Levido and Tait¹⁴ take a critical view of it to suggest that "molecular biology schema trie(s) to describe all organisms as self assembling, self maintaining, self reproducing, information processing machines". Burke¹⁵ takes analytical stand and opines that, GE suggests 'a nasty foreign technique, which is disturbing natural world'.

Shiva¹⁶ opines that modern biotechnology should be seen in the paradigm of engineering rather than ecology as "it tries to offer technological fixes to complex problems and later these problems are seen as 'unanticipated side effects' and 'negative externalities'."

The basic issue involved in this debate is the way in which science perceives nature. Particularly the way in which biotechnology has changed our vision about biodiversity. Vandana Shiva¹⁷ opines that category of biodiversity is a construct of biotechnological era. Previously, living resources were described in concrete terms as plant, animal etc. She

¹² Les Levido and Joyce Tait, (1996), op. cit., p. 127.

¹³ Cited in Vanadana Shiva (1996), op. cit., p. 268.

¹⁴ Les Levido and Joyce Tait, (1996), op. cit., p. 24.

¹⁵ Cited in Les Levido and Joyce Tait, Ibid., p. 127.

¹⁶ "IPR, Biotechnology and Third World: Towards a New System of Value", www.twinside.org.

¹⁷ Biodiversity as category, is a product of biotechnology. The former is essential raw material for latter. The "environment" is displaced and destabilized by the biological pollution and risks posed by biotechnology. See Vanadana Shiva "Beyond Reductionism in Shiva and Moser (ed) (1996), op. cit., p. 267.

claims that a systemic approach to biodiversity –biotechnology complex¹⁸ is essential for analysis else our critical perspectives can become locked into fragmented and fragmenting politics that protects and reinforces the status quo. While others opine that the practical application of biotechnology in area of GE “makes nature’s biological heritage plastic”¹⁹. Not only does it try to invade nature’s realm but it also tempers with the ‘products of nature’ and in the long term can produce intended and unintended effects of varying proportions.

II

This brings us to another problem about the issues of safety. This dimension has certainly acquired political colours in particular context to its application in agriculture. Environmentalists certainly perceive these moves as a threat to the natural course of life and hence demand a cautious and wary approach particularly in relation of the third world as it is the ‘center of origin’ of most species.

Cautioning about the uncertainties of Genetic Engineering Kollek²⁰ says that biological significance of Genetic Information to a great extent depends upon the context. Resultantly, gene or gene product may have different biological meaning in different context. To illustrate the case in point of Canada (with regards to GM Soya and Corn) can be given, wherein introduction of GM and their interaction with local species is assumed to have not much adverse impact on the local ecology. The reason cited is that Canada is not the centre of origin of these varieties. The same understanding cannot be applied to the third world, as it is the centre of origin of most species and how these species will interact with the genetically modified counterparts remains a contagious issue.

¹⁸ Ibid, p. 268.

¹⁹ Susantha, Coonatilake, op. cit., p. 183.

²⁰ Regime Kollek, “The Limits of Experimental Knowledge” in Shiva and Moser (ed.) *Biopolitics*, Madras, Orient Longman, 1996, p. 102.

Kollek²¹ corroborates the above view and says that, “when the gene enters in the new genetic context it is not possible to determine its significance and interaction in the new context. This is particularly important in context of third world which is centre of origin of most species”.

This is equally applicable to, the new gene introduced in the existing species; Dowkin²² tries to explain this interaction, wherein he states that the manufacture of a body is cooperative venture of such intricacy that it is almost impossible to disentangle the contribution of one gene from that of another. A given body will have many different effects on quite different parts of the body. A given part of the body will be influenced by many genes, and the effect of any one gene depends on interaction with others. Some genes act as master genes controlling the operation of a cluster of other genes. This is the factor which has generated most apprehensions, as doubt occurs to what will happen if the target gene acquires the role of master gene. But supporters of genetically modified technology prefer this technique to traditional alternative forms. The argument that they propound is that DNA offers greater safety as “genetic changes from rDNA technique will often have inherently greater predictability due to the greater precision that that rDNA technique accords to a particular modifications”²³. They extend the argument to claim that “GMOs are more analogous to domesticated organisms that have been bred for man’s use from the wild specie”²⁴.

Before analyzing the linkages between GMO and biodiversity, it is pertinent to know its precise definition. Though the Rio document does not specifically mention either Genetically Engineered Organism or Genetically Modified Organisms(henceforth GEO,GMO) but introduced the

²¹ Ibid.

²² Richard Dawkins, *Selfish Gene*, Oxford, Oxford University Press, 1989, pp. 152-155.

²³ Quoted from Sussmam – in Les Levido and Joyce Tait (1996), *op. cit.*, p. 124.

²⁴ Ibid, p. 125.

term 'Living Modified Organism²⁵' (LMO) as a biological entity. It is believed to be generally derived from the US regulation that define any bred organism as "genetically modified". In nutshell, it relied on a process oriented definition.

GMOs have been released in the environment relatively recently and their geographical expanse and studies regarding their ecological impact are so far relatively constrained. So, the documented information about their impact upon environment and biodiversity is sparse.

The problem is compounded by the fact as Inghan²⁶ puts it, that little has been done to know ecology of the genes so there is limited knowledge about the consequences of horizontal gene transfer. He cautions that before releasing any engineered organism into the real world from chilled laboratory situation, it must be treated as a potential hazards as organisms are capable of reproduction. He suspects that there is severe limitation in quantification and suggests that there is a need for cautious approach as pathology of GMO is not clear. A vigorous strain, once released into the natural environment can have a subsequent history, which is hard to predict and harder to influence. The problem is compounded in case of transgenic²⁷. It is claimed that transgenic by definition are based on the concept of species pollution. Since they are formed by crossing species boundaries mixing genes of species that do not breed naturally. This changes the integrity and uniqueness of the species. It is feared that it can change interactions between species, leading to domination of certain species and the displacement of others.

There is a need for adopting precautionary approach. It is pointed out that genes do not exist in isolation but interact, hence they are described as

²⁵ According to Cartagena Protocol On Biosafety Article 3 (g) LMO means "any living organism that posses a novel combination of genetic material , obtained through the use of modern biotechnology" while Article 3(h) defines it as "any biological entity capable of transferring or replicating genetic material, including sterile organisms , viruses and viroids".

²⁶ Elaine Ingham, cited in Vandana Shiva, Biopollution and Biosafety, Haridwar, Navdanya Publications, 2000, p. 12.

²⁷ The case where genes are transferred from one entity to other.

fluid. So it is assumed to have the capacity to 'jump'²⁸ i.e. they can exit and reinsert themselves in different locations in the genome. The case of havoc created by the introduced species, is also often cited. In this context, the main concern relating to GMO's impact upon environment relates to :

- (i) The environmentalist fear that in case of escalation of the co-evolutionary war²⁹ between GMOs and the pests, it is feared that pest may develop immunity and develop into super pests.
- (ii) Concerns are raised about their interactions with the wild species. Doubts are raised particularly about the GM cropspecies with their wild counterparts may lead to their transformation into super weeds.
- (iii) Stress tolerant GMOs may reduce extension of natural ecosystem to the extent where no agriculture was done before.
- (iv) Suspicion is raised about its impact upon the niche and the entire food chain, of which it is a part.

It is also pointed out that in this case, lack of evidence of harm can not be interpreted as lack of harm. Therefore there is a need for adoption of precautionary approach i.e. releasing GMOs into the environment. Infact, every GMO that is produced, has the potential as they are living organisms so they have the power to reproduce. The issue certainly involves the concerns for bio safety. Several attempts have been made at international level to consider this aspect. The first treaty regarding safe handling of LMO's was the **Budapest Treaty**, This was in the context of applications that were filed for patent, mandatory requirement for which was the deposition of micro organism.

²⁸ Jumping Gene or teransposons were first discovered by Babara McClintock.

²⁹ Evolution between two or more interacting species in which evolutionary changes one species influence the evolution of other species.

The concerns of biosafety have been evident in deliberations of various international forums and treaties.

The Rio Declaration On Environment And Development in principle 15 states that the “precautionary approach shall be widely applied by the states according to their capacities”.

The spirit is also reflected in **Paragraph 16.29** of the Agenda 21, which calls for “...a need for further development of international agreed principles on risk assessment and management of all aspects of biotechnology”. It also brings to notes that “....several fundamental principles underlie many of these safety procedures, including primary considerations of organism, building on the principle of familiarity, applied in a flexible framework, taking into account national requirements and recognising that the logical progressions is to start with a step by step and case by case approach. A more comprehensive approach should be used, based on the experiences of the first period, leading interalia, to streamlining and categorizing; complimentary considerations of risk assessment and risk management; and their contained use or release to the environment”.

Since the issue of LMO deals with the issue of biotechnology, it also entails questions about transfer of technology. Regarding this **Convention On Biological Diversity** through- **Article 19.3** cautions and sets appropriate procedures and lays down that “.....advanced informed agreement , in the field of safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effect on conservation and sustainable use of biological diversity”.

The similar fate that almost all environmental treaties face in US, President Bush Sr. in a post-Rio policy measure, blunt the call for biosafety and declared the principle of ‘substantive equivalence’. Analyst state that ‘substantive equivalence’ is a pseduo scientific concept and say

that the attempt “is a political judgement masquerading as if it is scientific.” The dichotomy produced due to developments in international politics is amply reflected in various treaties. In this context, supporting the claim Neumayer³⁰ argues that Article 2.2 of SPS agreement under WTO which is based on scientific principle, goes considerably against the precautionary principle embodied in principle 15 of Rio declaration.

The concerns, to some extent were settled with the signing of **Cartagana Protocol On Biosafety**. It recognizes the risks posed by GMO to human health and environment. It aims to ensure sufficient level of protection, so that the transfer of LMOs do not entail adverse impact on conservation and use of biodiversity.

This brings us to another dimension of GE i.e. its application in the field of agriculture. There are varied uses of biotechnology in agriculture. Here focus is on the introduction of GM crop. In the 80’s biotechnology promised great benefits to both the producers and consumers of agricultural products. The first plant with genetically transformation appeared in 1982 and first patent was granted in 1985. This gave rise to a new line of crops called GM crops. Its applications are also associated with potential risk. The risks and benefits vary from product to product and is perceived differently in different countries. The main public concern relates to the ethical misgivings, anxieties about food and environmental safety and fears about concentration of economic power and technological dependence, which could deepen the technological divide between the developed and developing countries.

It is relevant to note here that the GM crop basically fall in four categories:

1. Herbicide Resistance GM crop.

³⁰ Eric Neumayer, Greening Trade and Investment: Environment protection without Environment Protectionism, London, Earthscan Publications, 2001, pp. 166-67.

2. Those resistant to viral, bacterial and fungal infection it is done mostly through the introduction of genetic material of the other specie into the plant.
3. Insect/pest resistance usually through the introduction of Bt.gene from *bacillus thuringiensis*.
4. Those resistance to adverse agro-climatic conditions like high salinity.³¹

In the early 90's the corporate world hailed the use of GM technology in the arena of agriculture as the 'green ecofriendly' technology which had the capability to reduce chemical based pesticides. The use of pesticide had come under heavy criticism with the publication of Rachel Carson's seminal work 'Silent Springs'. So, this green technology's was potential to eliminate the problem of world hunger was appreciated. It is argued that there is no cause of concern in GM crop.³² They insist that, technically speaking HYB were GMO too. The only difference being that the former were produced by traditional methods while modern methods included identification or particular gene that was to be inserted. The supporter of the new technologies claimed that all of us have been consuming GMO all our lives without knowing as the transfers of genes occurred in thousands years in nature³³.

By 1986, the leaders of the developed countries meeting in the OECD council stated on the bases of expert consensus, that "there is no scientific bases for specific legislation to regulate the use of recombinant DNA organisms, while this statement remained the bases of US policy, US regulated vaccines/drugs/foods/seeds etc. under the already existing statutes with minor adaptation of existing procedures.

³¹ Jose Sarukhan, "GMO's Precautionary Principle", Chennai, Hindu Survey of Agriculture, 2000, p. 157.

³² KRG Nair and Ashok Kumar (ed.), Intellectual Property Rights, New Delhi, Allied Publishers Limited, 1994.

³³ Vandana Shiva and Ingunn Moser (1996), op. cit., p. 4.

In Europe, this debate proved more contentious due to its environmental impact. There were concerns for improved testing facilities and safety protocols. Chief concern was that on consumption of GM crop, DNA of the GMOs could pass intact into the host (human and animal) and generate disastrous implications. While scientists claim there was no reason to believe DNA from other organisms will behave in some way that is different from rest of DNA in food.

Secondly, particular alarm was raised due to the presence of an antibiotic resistance marker gene in the GM crops as it could have adverse impact on human health.³⁴ Analysts suggest that the base sequence of novel protein should be known so that in case of emergency, the donor organism is identifiable.

Today the politics of GM crops has become a highly contagious issue particularly in EU. It has produced new foes and friends at the international level. Today, the two most aggressive proponents of biotechnology are situated in politically dramatically opposite spheres-US and China. While the issue has produced rift between old allies EU and US which had lead to cooling of the euphoria about application of technology.

Though the area under the cultivation of GM crop has risen by a factor of 30 over the period of five years but its geographical sphere still remains very limited. The polarity of the issue is clearly evident by the fact that four countries account for 99% of global GM crop area. Infact, the field trials of GM crops in EU have plummeted by 87% since 1998 to mere 33 in 2002, in contrast in US its between 900 to 1100 a year³⁵.

This is mainly attributed to the efforts made on the part of civil society, which has been engaged in its endeavour to save seeds from being

³⁴ GMOs are developed by linking the target gene (e.g. for insect resistance) to a genes of an easily identifiable (marker) trial, in the debate on genetically modified organisms: Relevance for South, Overseas Development Institute (www.odi.org.uk/index.html).

³⁵ Nature Biotechnology, Volume 21, May2003, p. 5.

concentrated in the hand of few corporate. As along with the paramount ecological concerns, the issue involves the concerns for equity.

The main reason sighted by Joint Review Committee constituted by European Union for the fall in GM trails was the unclear legal situations and low public acceptance of GM products and an uncertain market situation which arose due to the 1999 moratorium declared by the EU.

Europe's current political antagonism about GMO's has been reflected in severing of its ties with US on this front. The political nature of controversy between Europe and US is amply reflected in the statement of US Agriculture Secretary Glickman, who confirmed the support of the administration and stated that US will stand behind GM crop. The political issue took emotive overtones as he commented that "Europe has a much greater sensitivity to the culture of food as opposed to the science of food, but in the modern world we just have to keep the pressure on the science"³⁶.

It is alleged that US wanted to shift the issue of GMO to WTO wherein Europe too was with the third world. They viewed that it was essentially not a trade issue. In October 1999, the Seattle Ministerial Text called for 'disciplines to ensure that trade in products of agricultural biotechnology is based on transparent, predictable and timely process'³⁷. Critics have pointed out that it is US which does not follow transparent measures, when it refused to abide by the issue of GM labelling. Since EU directives now requires all food and animal food products to be clearly labelled as genetically modified. US alleges that this is an unacceptable technical trade barrier which in long run may negatively affect the attitudes and actions of other countries and attempts to challenge it on the fora of WTO.

The corporates are particularly concerned about this EU ruling due to the impact it entails to the third world. They particularly site the example of

³⁶ Vandana Shiva, *Biopollution and Biosafety*, Haridwar, Navdanya Publications, 2000, p. 9.

³⁷ *Nature Biotechnology* (2003), op. cit., p. 6.

Zambia, which in October 2003 refused 6,3000 ton of GM corn from US intended to provide relief to the current famine in Southern Africa. The Agricultural Minister of Zambia³⁸ reasons that “the corn could contaminate Zambia’s agriculture, which could the loss of its cash crop export markets in Europe”. This is the clear evidence of the paradoxes faced by the third world vis-a-vis agricultural biotechnology. Due to the historical baggages and severe crises third world are forced to seek aid. But the developed countries take advantages as aid is forced upon them in form of ‘tied aid’. The technology, which could have helped them, cannot be used by them, due to export orientation of their agriculture.

Brown and Ravetz³⁹ point out that basic problem in biotechnology is “the difference in perception, it is associated with the attitude towards the unknown. It tends to reflect optimism among laboratory scientist and caution among others. The nature of GMO controversy is amply reflected by the editorial in New Scientist. Its sums up the whole controversy. It states that “in case of GM crops, opponents will not accept any level of risk. The controversy is really an ideological and political battle in a wider war against free trade, globalisation and multinationalism.”⁴⁰

The first GMO was released in 1992. Since then, genetic engineering (GE) has elicited allies and foes from varying ideological standpoints. It is particularly evident in case of the nature of political debates surrounding the genetically modified crops.

III

Initially, positive role was assigned to biotechnology due to its potential in conserving biodiversity. In this context Vandana Shiva reasons, that as the “green revolution” miracle fades away, out as ecological disaster,

³⁸ Ibid.

³⁹ Jerry Ravets and Jennifer Brown “Biotechnology: Anticipatory Risk Management” in Brown Jennifer (ed.), Environmental Threats: Perception Analysis and Management, London, Belhaven Press, p. 387.

⁴⁰ New Scientist editorial, 22 May 1999, p. 3.

biotechnology revolution is being heralded as an ecological miracle for agriculture. Since it offered chemicals free, hazard free solution to the ecological problem created by chemical intensive farming. Secondly, biotechnology is also benefited from its falling under the category of biological which carries connotations of 'being ecologically safe'. It is also referred as 'Ecology Plus'. But gradually it graduated as hindrance for the existing biodiversity.

Biodiversity, is one of the paramount concerns for biotechnology as the former serves as its raw material in form of germplasm. Every industrial activity and production process requires some kind of material base. For the biotechnology industry in the north the germplasm presented in south provided the raw material. This is the bone of contention between the developed countries and the third world. Vandana Shiva points out, that the modern plant breeding and biotechnology have made genetic resources extremely valuable, as they serve as raw materials for the biotechnological industry. But she points out the dichotomy and claims that the status of germ plasm creates arbitrary inequality and separates 'production' and 'conservation' as activities. She points out that the germplasm serves as a 'product' 'a finished commodity' form some but for others it is raw material. She opines that 'value addition' in one domain results in 'value robbed' in other domain, which in turn translates into biodiversity erosion and poverty.

Infact, Juma⁴¹ traces the historical roots of the process, to the era of colonization and opines that colonialism could have been meaningless without access to genetic resources as the source of agricultural growth. Others identify the modern process of biotechnology in the light of an attempt to re-colonise the third world.⁴² Joaquim Gascon i Bruslenga⁴³

⁴¹ Carlos Juma, The Gene Hunter: Biotechnology and Scramble for Seeds, New Jersey, Princeton University Press, 1989, p. 3.

⁴² Joaquim Gascon i Bruslenga, "Biotechnology and the third world". (www.twinside.org)

⁴³ Ibid.

opines that biotechnology is an extractive industry as it continues to depend upon germplasm which serves as strategic raw material and is present in diverse form in south.

This debate can be traced back to the days of beginning of the biotechnological revolution which aimed at changing the genetic nature of the organism. This seemingly technological achievement had taken political overtones. In the domestic arena the debate was about the pros and cons of the biotechnology, its increasing frontiers, and about the aspects of safety. But in the international arena, the core issue was that for biotechnological development the industrialised countries needed the germplasm. This germplasm was present in the south in form of biodiversity. This biodiversity became the raw material for the biotechnology. Thus, the world was again divided on new line of 'gene-rich' and 'technology-rich' countries.

With the involvement of issues of intellectual property rights protection, a number of unresolved questions were raised regarding the ownership and control of genetic resources, as the access to the germplasm was paramount. It was collected from the south but was stored in the international research institutes located in north. Regarding the controversy Hobberlink⁴⁴ opines out that biological and genetic raw material found in developing countries has been created, modified, maintained and conserved by numerous generations of indigenous communities, biotechnology comes, insert a gene and claim it as its own. This claim over ownership of germplasm led to the "seedwars" in FAO in the 1980's⁴⁵.

Through various conventions and treaties the developed countries tried to convert the natural wealth of south as the 'common heritage' while

⁴⁴ Henk Hobberlink, Biotechnology and the Future of World Agriculture: The Fourth Resource, London, Zed Books Limited, 1991, pp. 24-28.

⁴⁵ Juma (1989), op. cit., p. 153.

through the issues of intellectual property rights it tried to extract huge royalties from the developing countries. This also had huge implications, as the search for germplasm also involves the issues of indigenous knowledge systems. This forced the third world to adopt a more pragmatic approach, so that they can defeat the malafied designs of the first world. It led the third world to change its position in favour of treating this 'common heritage' as the issue of 'national sovereignty'. This issue will be dealt with in greater detail in chapter 3 in the light of IPR issues.

Bowring⁴⁶ points out to the northern policy of 'banking' the diverse germplasm created and conserved by now doomed, southern agricultural communities, now which tries to liberate the production of potential lucrative cash crop from the ecological conditions, 'monopolised' by the third world. He tries to place it within the larger political framework and opines that this is done in order "to avoid the limitations and uncertainties of geopolitical instability... which they have to grapple with". It appears that the first world has taken lesson from the first oil shock and this time with regards to the germ plasm they stand on a firm footing.

This attempt is particularly evident in terms of the increased efforts on the part of organised interests to promote the use of GM crops. Introduction of GE techniques in agriculture assumes significance in the light of the experiences and the fallout of First Green Revolution across the globe. Though it enhanced food productivity, it also produced grave repercussion. The green revolution was mainly attributed to the distribution of HYB seeds provided by public distribution agencies. These miracle seeds proved to be high responsive varieties and reduced the use of traditional varieties. Vandana Shiva opines that the miracle seeds were not perfect, as the opportunist insects and viruses mutated and unlocked the genetic resistance of the new seeds. This was manifested by the rise of

⁴⁶ Finn Bowling, "Manufacturing Scarcity: Food Biotechnology and the Life Sciences Industry", Capital and Class, London, Vol. 79, Spring 2003, p. 291.

previously insignificant pests or diseases. These resulted into major crop epidemics which occurred due to the mass vulnerability which was the outcome of introduction of monocultures. This development of monoculture across varieties and across species was also attributed to the market mechanism, which proved disastrous.

The focus of modern agriculture is on mass production. Large-scale uses of monoculture make crops vulnerable to single pests. Juma⁴⁷ goes behind the philosophy of monoculture to argue that, mass production requires standardized components, and procedures, to make products which are “responsive to economies of scale”. Green revolution made factories out of the fields. Shiva opines that biodiversity loss has been the consequence of monoculture paradigm in which biodiversity is consumed while the monocultures are protected through centralized control. Juma⁴⁸, sees green revolution “analogue of the production paradigm in industry.” It is also linked to the loss of biodiversity, which is leading to genetic erosion.⁴⁹ The HYV crops required ideal conditions and they focused on particular staple crop, which also created local elites who controlled the local resources. It produced inter and intra regional implications. The social cultural and political implications of green revolution are well documented and are to be borne in mind while considering the case for introduction of biotechnology in agriculture.

Shiva analyses that new biotechnology follow the path of hybridisation and changes the location of power which is associated with the seed. She quotes Kloppenburg⁵⁰ who opines that “it decouples seeds as “seeds” from seeds as ‘grain’ and thereby facilitate the transformation of seed from a

⁴⁷ Quoted in “Intellectual Property Rights, Biotechnology and Third World – Towards a new system of values” (www.twinside.org).

⁴⁸ Quoted in Ibid.

⁴⁹ The State of the World’s Plant Genetic Resources for Food and Agriculture, Food and Agriculture Organisation of the UN, Rome, 1998, p. 53.

⁵⁰ Cited in Vandana Shiva, ‘Biotechnological Development and the Conservation of Biodiversity’ in Vandana Shiva & Ingann Moser (ed.), (1996), op. cit., p. 199.

‘use value’ to an ‘exchange value’ ”. In the long term the productivity of the hybrid seed decrease but today with the emergence of seed – chemical industrial complex, biotechnology has posed a serious considerations before the farmers in terms of seeds. With the developments on the fronts of GM technology the problem has assumed new proportions. The analysts argue that with the introduction of GURT crops the farmer’s links with their seeds would be severed. They will have to buy seeds yearly and since modern day agriculture research is concentrated in the hands of few private MNCs, only the rich farmers can afford it. Secondly, the decisions regarding the entire food chain of the world would get concentrated in few hands.

Agro-biotechnology is intrinsically linked to the issues of food security as seeds are its main targets, which are also the tool for farmers. The developments of monoculture also led to the displacement of the traditional activity that entailed loss of indigenous varieties and traditional knowledge systems. The relationship of farmer with seed is intrinsic. Kothari⁵¹ points out that due to these links the activity is referred as agriculture and the effort of the industry is to convert it into agronomy. In modern day economy three popular modes of seed acquisition exists:

- (a) Informal system is characterized by farmers activity of saving seeds, bargaining with neighbour or with farmers of nearby villages.
- (b) Transitional system where some farmer specialises in the production of seeds for the local market.
- (c) Commercial system where seeds are provided by private companies/public institutions.

⁵¹ Ashish Kothari, ‘Cultural and Biological Diversity’, Folio, Chennai, The Hindu, 20 May, 2001, p. 17.

Increase in the commercialisation of seeds has posed a challenge to the traditional system. RAFI⁵² estimates that twenty years ago there were thousands of small seeds company but today top ten global seeds company controlled one third of the global trade and it also cautions that critical decisions are being made by fewer and fewer people. Today, 75% production in India is based on with less than ten varieties.

The first and for most fall out of monoculture is that it poses a potential threat not only to biodiversity in long run, but in short term to it has negative implications. In the recent survey of FAO regarding the estimation of genetic loss the main cause identified was the replacement of local varieties by improved or exotic varieties and species. It cautions that gene and gene complex found in diverse farmer varieties is absent in the modern varieties. Secondly the numbers of varieties decreased when commercial varieties were introduced in the traditional farming system. FAO cautions regarding this ongoing trend, it identifies value in genetic diversity generally but particularly identifies three 'Values' in terms of crop diversity:⁵³

- (1) Portfolio value: In this capacity genetic diversity provides stability for farming system at local, national and global level.
- (2) Option Value: It serves as an insurance against future adverse conditions and may later provide useful strains and characteristics
- (3) Exploration Value: It provides a treasure chest of potentially valuable yet unknown recourses.

FAO⁵⁴ also points out to the benefits of the farmer's varieties and evaluates that farmers variety are better adopted to poor condition. Landraces provide more reliable crop yield. Inter cropping suit

⁵² Cited in Hope J. Shand, "Biotechnology: Under whose control?", Chennai, The Hindu Survey of the Environment, 2000, p. 185.

⁵³ Food and Agriculture Organisation Report, Rome, Food and Agriculture Organisation, United Nation, 2002, p. 246.

⁵⁴ *Ibid*, p. 248.

microenvironment and has multiple usages. Fowler⁵⁵ questions the attitude of North and objects to the tendency of referring farmer's varieties as 'primitive' or 'stonage' and visualises it as blatantly unscientific, inaccurate and demeaning. Though he does not object to the term 'landrace' but indicates that it reflects the social relations, which is particularly true in case of the biotechnological development.

IV

This brings us to the issue of the linkages between the issues of patent and biotechnology. Nelson and Mazzoler⁵⁶ opine that patents play peculiar role in science-based⁵⁷ technological industry. They see modern biotechnology as an extreme case of science based industry, where patent race are common because multiple inventor not only see same broad unmet needs, but also often pick up knowledge of research advances that suggest peculiar avenues to follow.

They point out that in biotechnology main problem is imitation, which is compounded by the fact that the lifecycle of the product is of extremely short period. So, the rapid technological improvement and heavy investments, makes it imperative for biotechnology firms to have access to wide market.⁵⁸ The IP protection helps them to reccur benefits. Analyst point out that this trend of strong IP protection may lead to consequent weakening of the public good aspect of biotechnological research.⁵⁹ It is often assumed that technological innovation leads directly to economic performance but there are those who believe that property rights and well

⁵⁵ Cary Fowler, "Biotechnology Patents and the Third World" in Vandana and Moser (ed.), Biopolitics: A Feminist and Ecological Reader on Biotechnology, Madras, Orient Longman, 1996, p. 185.

⁵⁶ Mazzoler, R. and Richard R. Nelson, "Economic Theories about the benefits and cost of patent", Journal of Economic Issues, Vol. 32, No. 4, Bucknell University, Dec. 1998, p. 1045.

⁵⁷ Where the ability to create new products and process is strongly influenced by continuing flow of new sefic understanding and techniques, *ibid*, p. 1047.

⁵⁸ James D. Gaisford and William A. Kerr, Economic Analysis for International Trade Negotiations: The WTO and Agricultural, Cheltaham, Edward Eager, 2001, p. 157

⁵⁹ Carliene, Brenner, Integrating Biotechnology in Agriculture, OECD Department Centre, 1996, p. 91.

organised market leads to wealth creation, almost independent of innovation.⁶⁰ But Victor and Nelson⁶¹ point out the strong need of innovation in biotechnology industry. They argue that biotechnology is an industry founded on intellectual property rights, as the potential returns from investments made in biotechnology expect are to come from its ability to capture a considerable portion of value created by intellectual endeavours. Therefore, there arises a strong need for IP protection in biotechnology industry. This makes it a highly capital and knowledge based industry.

Along with the heavy cost, another cause of concern particularly for the third world is that bio-revolution is essentially private in character. Effective IP protection is seen as essential precondition for effective transfer of technology for the third world.⁶²

There are also concerns about the impact of technology upon the society. Shiva⁶³ says that introduction of ecologically and economically inappropriate science and technology leads to under development instead of development. Substantiating the view Bruslenga⁶⁴ points that forced imposition of technology in socio-economic and cultural environment, which is different from the place in which they were created, will almost result in either disastrous transfer of technology or radical change in social structure of the affected communities. It also results in rise of elite that are well positioned and may exclude others.

Bowling⁶⁵ stresses upon other impacts of privatisation of the system as a whole. Patented knowledge in the field biotechnology is not only deprivation of co-operative public health but also leads to deprivation in

⁶⁰ Victor and Nelsons (ed.), Technological Innovation and Economic Performance, Princeton, Princeton University Press, 2002.

⁶¹ James D. Gaisford and William A. Kerr (2001), op. cit., p. 158.

⁶² Op.cit., p. 264.

⁶³ Vandana Shiva and Ingunn Moser (ed.), (1996), op. cit., p. 195.

⁶⁴ Joaquim Gascon: Bruslenga, op. cit.

⁶⁵ Finn Bowling (2003), op. cit.

the agro-biotechnology sector. Some of the products of the biotechnology industry are also typically a product of indigenous knowledge system and of life forms which have been discovered, cultivated, selectively bred and husbanded by generations of non-western peasants and farmers who have worked on land over millennia. Therefore, seeking knowledge by the means of bio-prospecting and legitimising it through the instruments of patent is one of the prime concerns for the third world communities and states. Bowling⁶⁶ also questions the intention of the firms involved.

Others claim that patenting system in biotech industry is clearly ceasing to function as a reward and incentive for innovation, instead they are being used as threatening tactics to other researchers and competitors. Thus, there are clear indications of monopolistic tendencies on the part of the biotechnological firms. It is opined that most of the third world farmers are the original donors and custodian of most genetic resources and the western model of patent creates production, distribution and import monopolies. The right of business has been protected above all else.

In context of biotechnology industry and patents, the fundamental debate revolves around the issue of patentability of life forms.

Hobberlink⁶⁷ in this context opines that imitation is the problem of biotechnology industry and its raw material, i.e. genetic resources tend, to imitate itself continuously and without human intervention. The problem is compounded by the fact, that the traditional patent system was meant for industrial property. With maturing of plant breeding industry, there was pressure to protect it. He points out that 'life' never fitted comfortably into the rigid industrial patent scheme.⁶⁸ IPRs can be seen as the driving force behind the rapid industrial growth in the developed world as IPR's

⁶⁶ Ibid.

⁶⁷ Henk Hobberlink (1991), op. cit., p. 105.

⁶⁸ Ibid.

primarily evolved to protect mechanical and chemical innovations. In this case identification of novelty, the inventive step and the innovator is relatively straightforward⁶⁹.

It is argued that political problems were greater than the technical problems particularly in Europe. Since apart from socio and political factor, cultural factor also existed. But Jan Wendth⁷⁰ in particular context to that plant patents claim that it cannot even be granted even on the grounds of technical nitty-gritty'.

He points out three factors:

- 1) The criteria of Non obviousness and inventive step - both does not apply to new plant varieties as they are created by selection and crossing of already existing varieties.
- 2) Patent required exact description of the innovation and the process to obtain it which is often unknown.
- 3) Patent for new variety also hinder more dynamic development of agriculture sector as saving, re-use and exchange of seed becomes difficult.

Therefore, to consider these claims FAO was the first agency to recognise the concept of farmer's right. Through FAO International Undertaking On Plant Genetic Resources in 1983. It derived farmers right from their contribution to conserve and develop agro biodiversity. Yet, the national government were free to decide the scope of patent. Though instrument like UPOV existed to deal with property rights of plants.

FAO tries to sum up the controversy and states that "traditional farmers creates economic value but can not be benefited by it. As there is no market for the value they create, while other agents in the 'Plant Genetic

⁶⁹ Gadgil and Utkarsh "Intellectual Property Rights and Agricultural Technology", in Rajkapilla and Umakapila (ed.) *Indian Agriculture in The Changing Environment* Vol. 2, 2002, p. 69.

⁷⁰ Jan Wendt, "Biotechnology and Development: A balance between IPR protection and beneficiary", www.ric.fao.org.

Resource System' do benefit from the material that traditional farmer provide they do obtain specific rights over the germplasm that incorporates what traditional farmers have developed in the past". The Second Planetary Issue of 1990 Key Stone Dialogue (initiated in 1998) suggested and added specific recommendation on IPR. It could for recognition of role of information provided by traditional innovation system etc. It is pointed out that a major deficiency of the current regime is its failure to provide any recognition to the public domain foundations on which the innovation may be based particularly if it extends to biological domain.⁷¹

IUCN Environmental Law Centre states that "property systems rewards human ingenuity, but ignore the nature's handiwork of the value of raw material that is manipulated. They also fail to take into consideration the informal contribution of indigenous peoples and farmers to the maintenance and development of genetic diversity through years of cultivation and husbandry. The issue of inter-relationship between biodiversity and biotechnology becomes more complex when issues of intellectual property are involved, particularly in terms of GMOs/LMOs.

It is also essential to see dwell upon the varied approaches adopted by different agreement. While demonstrating the relationship between TRIPs and CBD about the clauses relating to the environmental protection while granting patents on life form, Goyal⁷² opines that TRIPs through article 27(2) and CBD through Article 7 and Article 8 provide for regulation of granting of IPRs to the innovation harmful to the genetic diversity. In effect patent can be denied for environmentally harmful innovation. He argues though there may be overlap between the two in practice but it differs on account of their approach to risk. CBD provides for 'precautionary

⁷¹ Gadgil and Utkarsh in Rajkapilla and Umakapila (ed.) (2002) op. cit., p. 172.

⁷² A. Goyal, "Harmful Biotechnolgoical Innovations and Genetic Erosion: Legal choice between precautionary Principle' and 'Necessary Principle', New Delhi, Indian Journal of International Law, Vol. 42, No. 1, Jaunary-March 2002, p. 48.

approach' while TRIPs provides for clauses on 'necessary' and 'serious prejudice to the environment'. The precautionary principle entails to establishing a duty to take such measures that anticipate and prevent the causes of environmental degradation even if there is no scientific proof that environment is being harmed. While as regards to necessary principle, appellate body in Reformulated Gasoline Case stated that 'a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purposes'⁷³.

It is also stated that under CBD there were two set of rights granted first dealt with the sovereign rights granted to the state over their genetic resources. The second relates to the technologies that were based on genetic material. Apart from it, CBD contained the right of traditional communities that were identified as custodian of the genetic resources.

The issue of IPRs acquired centre stage with the beginning of TRIPs negotiation. It acquired highly political overtones not only on the lines of north and south but also between EU and US. Analysts point out that in Europe the issue is whether the life forms are patentable or not, while in US the issue is if they are 'new' or not. TRIPs was signed amidst controversy. It aimed at the harmonization in patent laws on global level. Article 27.3 (b) of TRIPs Agreement deals with this issue. It states that 'plants, animals and essentially biological process of production' may be excluded from patentability. However 'micro-organisms and micro biological or known biological processes' must be patented. The grey area is that none of the terms are clearly defined. It seems as if the burden of defining what's is biological and what is micro-biological rests up on the lawyers rather than biologists.

⁷³ Ibid, p. 52.

Watal⁷⁴ points out “while there is uncertainty as to the definition of terms such as ‘non biological’ or ‘essentially biological’. But it was clear that ‘micro-biological processes’ are not excluded from patent protection. Legal experts point out that there is ample of scope to interpret what’s what. If limited view of micro-organism is considered, it involves only single cell organism. While in its broad interpretation, it includes biological material that is Self Replicating or replicable via host organism.⁷⁵ Watal⁷⁶ opines that since, TRIPs heavily draws from EPC (European Patent Convention) it could be assumed that “cell and parts thereof” are treated as micro-organism. She cites European Patent Office’s Enlarged Board of Appeals decision in Novartis case, which states “this[it] appears to be justified since modern biotechnology has developed from traditional micro-biology and cells are comparable to unicellular organisms.”

The second issue deals with the concerns of how to differentiate the terms ‘micro-biological process’ from “essentially micro-biological ones”. EU Directive restricts ‘essentially biological processes’ as they are akin to natural phenomena such as crossing and selection’ while ‘any process involving, performed upon or resulting in micro-biological materials’ defines the micro-biological processes.⁷⁷

Another controversial issue is regarding the differentiation between ‘discovery’ and ‘invention’. In this context, Belcher and Hawlin⁷⁸ state that patents are available on processes used in developing Micro Organism or to produce biological products. Such patents are often disciplined as ‘process patent’. So for a gene to qualify as something not found in

⁷⁴ Jayshree Watal, Intellectual Property Rights in the WTO and Developing Countries, New Delhi, Oxford University Press, 2002, p. 131

⁷⁵ R.A Mashelkar, “Indian Science and Technology in the wake of GATT”, in Bibak Debroy, Intellectual Property Rights, Delhi, B.R Publishing Corporation, 1998.

⁷⁶ Jayshree Watal (2002), op. cit., p. 132.

⁷⁷ Ibid, p. 148.

⁷⁸ KRG Nair and Ashok Kumar (ed.), Intellectual Property Rights, New Delhi, Allied Publishers Limited, 1994, p. 269.

nature, it must either be 'novel' or 'in and of itself' (i.e. created by the inventor) or 'transfer to a specie in which it is not found'.

In this context Watal says that TRIPs calls for 'strong' process patent, which in effect, is similar to 'product patent'. Watal opines that it is unclear if the rights of the patentee of the process will extend to the product, that is, if the process patent for a genetically engineered animal, will extend to the animal itself. She⁷⁹ points out distinction relevant to patentability is difficult to make in the field of biotechnology. As the distinction between the 'discovery' of something that exists in nature and the 'invention' that is the creation of something new involving a pre determined degree of human effort or intervention is difficult.

The problem of discovery and invention is particularly evident in terms of plant, though PVP provides lower degree of protection. It provides for two criteria i.e. distinctiveness and secondly it should not have been commercialised earlier. Watal⁸⁰ says that it leaves ample space for further discoveries of plant growing in the wild. She also opines that, in the issue of IPR and biotechnology, what is often neglected is the issue of Trade Secret (Article 39 of TRIPs). As breeder, often do not disclose the parent line, which may often be discovered independently by fair means by other breeder.

Critics also point out that mechanism of IPR is treated as a trade issue which is fundamentally a research issue. Barton⁸¹ points out that patents laws in most nations provide "research exemption" that allow the use of a patented innovation for experimental purposes one of the exception is US which does not have any such exemption and research is permissible only to satisfied academic curiosity and not for commercial purposes. Others opine that the controversy regarding the patent of genes generally focuses

⁷⁹ Jayshree Watal, (2002), op. cit., pp. 132-133.

⁸⁰ Ibid.

⁸¹ Barton J.H., 'Patenting Life', Scientific American, 1991.

on the barriers it poses for R&D, rather it should be focussed upon the question that should the genes at all be patented.

In fact, Vandana Shiva argues that GATT is not merely a trade treaty but also or “tactfully environment treaty”. She claims that TRIPs agreement is the highest level of legal regime aimed at protecting living organism as patentable matter. Since, it relates to plant, animal, LMO, in this way it attempts to rewrite our relationship with these species wherein they serve as a means to human end. It is opined that in changing scenario the situation can aggregate particularly with the research and development in aspects of genomic and cautions that this time it is “the genetic divide” that will separate these countries on the basis of their capacity to use information derived from the sequencing of the genome, from those that do not have it.

To bridge the divide, developing countries will have to formulate policies and strategies to enable them to be genuine partner in the genome revolution. It is also opined that with the identification of major part of genetic heritage of four billion years of biological history, deciphering it is probably only a few decades away.⁸² The progress in the field is seen with suspicion in many quarters of the third world, particularly due to the issue of their ownership.

⁸² Susantha Coonatilake, Towards Global Science: Mining Civilizational Knowledge, New Delhi, Vistaar Publication.

CHAPTER – III

IPR: IMPLICATIONS FOR THE THIRD WORLD

The chapter attempts to put forth the perspective of the Third World vis-à-vis the international structure of IPR regime with particular emphasis on biotechnology. The use of the term 'Third World' is particularly significant in terms of the historical connotations attached with it. Due to the unique economic, social and political front that it endeavoured to present to the world as an alternative of the "significant others". But today, with the demise of Soviet Union, many analysts refuse to accept its continuation as a term of reference. They argue that since third world was the creation of cold war paradigm, it has lost ground in post 1991 scenario.¹ In spite of the integration of the global economy and the near universal embrace of market forces, there still exist an inequitable hierarchical order that represents a thread of continuity from the past. The emerging international system which supposedly focused on the multilateral route, through the instruments of various treaties and conventions, is seen as an attempt for universalisation of a particular world order in the name of harmonisation. In particular, through the measures of IP protection and the 'genetic divide' it perpetuates. It is pertinent to have a brief overview of the debate regarding the term Third World.

THIRD WORLD

The term 'Third World' became one of the most overworked terms in the political discourse of 1960s and 1970s. Alfred Sauvy, a French economist is believed to have coined the term in 1952. The phrase became popular and widely acceptable as it helped replace the existing terms as 'backward

¹ Guy Arnold, The End of the Third World, London, St. Martin's Press, 1992, p. 14.

areas', 'underdeveloped countries', 'societies in transition' and 'peripheral countries'. It described the emerging states, which were qualitatively different from the 'First World,' composed of the older countries of Europe, Northern America and certain others, and the socialist countries of Eastern and Central Europe known as the 'Second World.' Mao sought to give the 'Third World' even more exclusive connotation. For him, two super powers, the U.S, and Soviet Union constituted the 'First World' and the satellites of the super power formed the 'Second World'. With the exception of Japan, the rest of Asia, Africa and Latin America constituted the 'Third World'². Although China participated in the First Afro-Asian conference in 1955 at Bandung, but Non-Aligned countries refused to accept China as a part of the Third World.

Muskhat³ opines that some authors attribute Pt. Nehru and other leaders for the concept of 'Third Force' in 1950. The idea of Third World contained within itself the parallel idea of "third way"⁴. It posed fundamental questions about the existing world order. Initially, both East and the West rejected the term Third World. But the term gained acceptability due to its political and socio-economic connotations. In political terms, it referred to the countries on the margins of the bi-polar world.

While Mushkat⁵ opines that the world states is easily defined by reference to its economic situation. The World Bank used it, with reference, to the low-income economies. Thus, it began to represent politically non-aligned, economically developing and the less industrialized nations of the world.

However, Willy Brandt⁶ in " North-South: A Programme for Survival" and Nyere heading the 'South Commission' rejected the notion of Third World

² A.N. Roy, The Third World in the Age of Globalization, Ne Delhi, Madhyam Books, 1997, p. 3.

³ Marion Muskhat, The Third World and World Peace, New York, St. Martin Press, 1982, p. 20.

⁴ Paul Cammack, David Pooland, William Tordoff, Third World Politics: A Comparative Introduction,P6.

⁵ Ibid, p. 21.

⁶ Andrew Heywood, Politics, Delhi, MacMillan, 2002, p. 141.

and preferred the use of term 'South' to represent developing countries and 'North' for industrialized countries. But it was a geographical expression with blurred boundaries. In the 1970s, the term to define international division was 'developed countries' and 'developing countries' which continues to be in popular usage till date, as the economic development has become the prime paradigm. Analysts may point out pitfalls with the usage of the term 'Third World' but it has certainly not outlived its analytical usefulness, particularly in the absence of any apt alternative.⁷ This study has interchangeably used the term, 'Third World', 'South' and the 'Developing Countries'.

THIRD WORLD IN WORLD POLITICS

In spite of the spatial and temporal differences amongst the countries of the Third World, the commonality arises from their 'shared histories' and 'shared experiences.' Particularly their common colonial bondage in the past and the desire to escape from dehumanising poverty and under development had led them to demand a more equitable and just 'New World Economic Order'. The Third World has been the kingpin of western affluence, right from the days of industrial revolution, when it helped the mother country in accumulation of capital. In the present times, when its oil serves as the basis of non-renewable energy based economy. Lately, with the onset of biotechnological revolution the developed nations are on the hunt for a new and unconventional raw material in the form of 'germplasm'. Third World as a concept found its expression in several demands through the fora of United Nations Conference on Trade and Development (UNCTAD) and New International Economic Order on the floor of UN General Assembly. Many authors point this as the factor that prompted the industrialized nations particularly, US to look for more viable alternative. As these institutions were allegedly, pre-occupied with

⁷ Guy Aroid, (1993), op. cit., p. 18.

the demands of the Third world. These structures also provided an appropriate forum for them to assert, bargain and confront the developed countries as a united group. Here, developed countries attempted to divide the third world by introducing categories of 'Least Developed Countries' on the basis of "concept of graduation"⁸. These forums helped in realization that unless the developing countries could organize and improve their bargaining power, their plea to restructure the international economic order was severely limited.

The issues of biodiversity, biotechnology and patents have long been in currency. They assumed new dimensions after Convention on Biodiversity (henceforth CBD) and the TRIPs agreement of WTO and the Cartagena Protocol on Biosafety (henceforth CPB). In the present context, with the end of cold war and the ever-continuing process of globalisation, there is a need to boost third world solidarity. Some analysts apprehend that the third world could now be subjected to a phase of re-colonisation, as the world seems to be ruled by one super power.⁹ Their leverage has steadily eroded on the fronts of political, economic, security and ideology. Ideological transformation has brought significant change, in their economic perspective and worldview, with economics being the main consideration. But unlike negotiation within UN, WIPO, UNCTAD, they can no longer negotiate collectively within the new international institutions as today alliances are forged around a precise pole of interest. While some analyst trace the root of the process, in UNCTAD VII's failure to go beyond the ritualistic benedictions of Uruguay Round talks, which were already in process. They critiqued that UNCTAD served as a unique mouthpiece and much less as a negotiating arm of the Third world vis-a-vis industrial north. It failed to be a rallying point of developing countries. Rather UNCTAD VII only issued a mandate to the UNCTAD secretariat to analyse the "appropriate problematica" involved in the Uruguay Round

⁸ G. Sundaram, "Will UNCTAD VII Be Different From Earlier Sessions" in *'The Hindu'*, Chennai, 23rd July 1987.

⁹ Martin Khokok Peng, *The Future of North South Relation*, Penang, Third World Network, 1992, P. 95.

negotiations¹⁰. Yet initially, countries of Third World broadly functioned as a unit, until the mid-term review of the Uruguay Round, which paved the way for transition from GATT to the multilateral WTO.

Grimvade¹¹ observes the change in the approach of developing countries. He opines that in past, "...in matters of international trade, developing countries were little more than onlookers who saw little value in taking an active part in the negotiating process. They argued... that their status warranted special and more favourable treatment and obtained it". According to him, a significant change took place in Uruguay Round where the developing countries played a more active part, as for the first time they made concessions in an effort to secure equivalent concessions from developed countries. IPR became a significant issue during the mid term Review of 1989. The inclusion of IPR created widespread unease, as the Third World feared that it would lead to absolute dominance of developed countries on trade and technology.¹² As the patent system would halt their process of technological transformation. So the issue of IPR became intrinsically involved with the issues of development of the third world¹³.

Due to its potential implications, the developing countries insisted that since IPR is not a trade related issue, it should legitimately remain under the purview of WIPO. As early as in 1961, India and Brazil called for the close examination of the adverse effects that the patent system can have on developing countries. Since the beginning the Third World was against the introduction of TRIPs in the Uruguay Round. They argued that TRIPs had marginal jurisdiction over the issue of IPR and thought WIPO to be a

¹⁰ G. Sundaran (1987), op. cit.

¹¹ Nigel Grimvade, International Trade Policy: A contemporary Analysis, London & New York, Routledge, 1996.

¹² Tarun Kabiraj, "Intellectual Property Rights, TRIPS and Technology Transfer" Economic and Political Weekly, Nov 14, 1999, p. 2990.

¹³ Surendra. J.Patel, "Intellectual Property Rights in the Uruguay Round", Mumbai, Economic and Political Weekly, May 6, 1989, p. 80.

more appropriate forum. During negotiations Third World realized that they lacked resource and expertise in such technical matters. They could also foresee that with new provisions:

- (a) They will have to introduce changes in domestic legislation, in accordance with the multilateral agreement.
- (b) It was seen as a hidden barrier, which might hamper and increase the cost of technology transfer.
- (c) Cost of production will increase immensely, not only in luxury goods but even for essentials items like food and medicine.

They were particularly concerned about IPRs linkages with Integrated Dispute Settlement Mechanism, as they wanted to keep this issue out of judicial realm. The leading countries of the third world initially confronted every move to bring non-trade issues on the agenda. But slowly, they began to deflect in different directions on various issues, both through the politics of coercion and allurements. Change in the stand taken by the leading countries, led to weakening of third world's position. This resulted in exchange of allegations wherein claims and counter claims were made about the betrayers. Particularly, India blamed Brazil for back tracking and cited change in its position regarding the issues of services as the main cause of their inability to achieve. While Brazil alleged India's for softening its stand on various issues.

In this context Rajiv Kumar particularly cites the role of receipt of structural adjustment loan from World Bank.¹⁴ The developments outside the negotiation process were of paramount importance in determining the positions of various countries during the negotiations. Predominantly, the extensive use of the provisions of Special 301 and Super 301 of the Trade

¹⁴ Rajiv Kumar, "The Walk Away From Leadership: India" in Daina Tussie and David Glover (ed.) The Developing Countries In World Trade, Boulder, Lynne Rienner Publishers, 1993, p. 157.

Act of 1974 (as amended in 1988) by US Trade representative (USTR) to enlist the offender countries in various 'Watch-list' for the purposes of trade sanctions. In April 1993, India, Brazil and Thailand were enlisted in 'Priority Foreign Countries' under Special 301 for not providing "adequate and effective" protection to US Intellectual Property¹⁵.

While in Latin America the efforts for generating disarray were mainly attributed to many bilateral and multilateral agreements. The hard efforts of the developed nations to disturb the third world unity were neither effortless nor useless. It is pointed out that by late 80's US growth had reached a plateau. Therefore, 'corporate' America needed stimulus, profits and more importantly, the market. Their interests were pursued by the political apparatus internationally. So the Uruguay Round, not only had far-reaching implications for the emerging world economic order but the negotiation process itself was of seminal importance as, it was here, that the attempts engineered to crack the third world solidarity were successful. Along with the explicit issues of equity and economics, the confrontation between the developed countries and the third world is focused around few core issues of biodiversity, biotechnology and patents.

MAJOR ISSUES

The issues of discord between the developed world and the third world can broadly be classified into as:

- a) Biodiversity: issues of ownership.
- b) Indigenous knowledge: piracy and biopiracy.
- c) Farmer's right: Issues of food security.
- d) Red biotechnology: Compulsory licensing.

¹⁵ Y. K. Alag, "The Dunkel Proposal and Indian's Strategic Interests" in Kumar and Garg (ed.) Intellectual Property Right, New Delhi, Allied Publishers Ltd., 1994, P. 124.

BIODIVERSITY: ISSUES OF OWNERSHIP

The core of issue in the words of Juma¹⁶ is "Who owns the germplasm?" Actually roots of the controversy can be traced back to 1930s, when U.S. cornbelt witnessed the first Green Revolution based on HYV seeds. North America was relatively poor in indigenous crop variety and its agriculture was based on narrow range of genetic resources. With the help of Latin American varieties, the hybrids were created, which significantly outyielded the best open pollinated varieties. This strategy strongly emphasised the use of Hybrid and development of monoculture, to increasing per acreage yield enormously. In order to solve the problems of low productivity this model was transported to numerous third world countries that produced huge intra and inter regional disparities leading to major socio-political and ecological upheavals. By the end of 70's immense progress on the front of life science technology and availability of venture capital funds, combined to give rise to the wild hunt for germplasm. Juma¹⁷ says, "The international controversy over the ownership of germplasm and other issues has been partly a result of agriculture research programme with which green revolution is associated." This contest culminated in form of "seed wars" in FAO in the 1980's.

This resulted in the establishment of International Gene Bank, which were mainly located in the North. These were used as depository to store the germplasm from the South. International Undertaking on Plant Genetic Resources was also signed. But the most important outcome from the point of view of the third world was the acceptance of their long-standing demand that like their genetic resources, the resources of the north should also come under 'common heritage'. The Resolution 8/83, provided

¹⁶ Juma, C., The Gene Hunter: Biotechnology and The Scramble for Seeds, New Jersey, Princeton University Press, 1989, p. 169.

¹⁷ Ibid.

for the inclusion of 'Elite and Proprietary Variety' of the North. Another important development was that the notion of farmer's right evolved on the basis of breeder's right, which had long-term implications.

The core of the issue was that genetic wealth of the world is concentrated almost exclusively in the tropics (developing countries), while the developed world has the technological tools needed to convert genes to product and money¹⁸. Anticipating the huge potential and opportunities the governments of industrialised countries gave a call to consider plant gene as 'global heritage' so as to fulfil their objective of 'full' and 'free' 'exchange of germplasm' while simultaneously they were patenting their own breeder varieties. They claimed that raw germplasm could not be given a price, as it is valuable only after investment of money and knowledge. It maintained that collection of raw germ plasm wouldn't deprive any body of anything.

The third world clearly realized that the germplasm collected free of cost from the wild in the South was being sold back to them as an expensive input. It was evident that north's cutting edge lied in their genetic engineering while of the south in its germplasm .The farmers began to loose control over their resources with the onset of modern Biotechnology. In 1983, International Undertaking On Plant Genetic Resources endorsed the principle of 'free exchange of genetic resources'. Thus in one stroke south's natural wealth became a common resource and the flow of germplasm towards the industrialized countries increased with the establishment of international boards for plant genetic resources (IBPGR).

Anticipating the 'tragedy of commons'¹⁹ the germplasm rich South was forced to take a common position in CBD negotiation, which, was a

¹⁸ Suman Sahai, GATT and WTO, Delhi, Gene Campaign, 2000.

¹⁹ The ruin that results when people are free to overexploit shared (common) resources without regulation of their equal access to them. Kegley and Witcoff, World Politics, London, St. Martin, 2000, p. 316.

paradigm shift from their original position i.e. now, rather than considering the biodiversity as a 'global common' they insisted upon it as an issue of 'national sovereignty'. In 1992, at Rio, CBD reaffirmed that countries have a sovereign rights over the genetic resources in their jurisdiction and called for the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. This access was based on the principle of 'informed consent' (article15.5). The clause on national sovereignty was controversial as it generated apprehensions about the massive power that was granted to the state. State was seen as the owner and conserver of the biodiversity. Such a notion neglected and undermined the role of tribals and other indigenous communities who have been involved in this process for centuries. Thus, people questioned the act of placing biodiversity in exclusive domain of state.

Article 16 of CBD dealt with the requirement of transfer of technology including biotechnology. Vandana Shiva²⁰ argues that 'global biodiversity' and 'global genetic resource' is not a global common as "biodiversity exists in specific countries and is used by specific communities." Martin Khor²¹with regard to the development in biotechnology argues that microorganisms are the basic 'raw materials' of the new biotechnologies. The 'Gene Rush' has thus become a new version of the old 'Gold Rush', in the scramble for future profits." Particularly, with the involvement of issues of intellectual property rights, potential for exploitation has accelerated and created new conflicts over biodiversity – between private and common ownership, between global and local use.²²

There has been a clear-cut asymmetry in assigning the value of genetic information which is processed in corporate laboratories and which is

²⁰ Vandana Shiva, 'Biodiversity Conservation, People's Knowledge and Intellectual Property Rights' in self edited 'Biodiversity Conservation', New Delhi, INTACH, 1994, p. 4.

²¹ Martin Khor, "A World Wide Fight Against Biopiracy And Patents On Life". (www.twinside.org.Ig/tittle/pat.ch.htm)

²² Vandana Shiva (1994), op. cit., p.4.

generated through indigenous sources of knowledge and farmers. This inherent bias has been aptly reflected by Vandana Shiva²³ who clearly points out the two types of inherent biases in the international IPR regime. Firstly, that the labour of Third World farmers has no value while labour of western scientist adds value. Secondly, value is a measure only in the marketing. While Suman Sahai²⁴ argues that a guarantee should be made so that genes stored in International Gene Bank cannot be protected by any system of IPR. In her view, the instrument of patents directed at genetic resources are as if, they are raw material of Biotechnology and opines that they can not be “owned” as private property because they are our ecological kin, not just “genetic mines”.

M.S. Swaminathan points out that, spread of patenting of biotechnology and more particularly of naturally occurring genes will hamper free exchange of germplasm and opines that the era of co-operation in developing varieties to strengthen food security is coming to an end. Due to reduction in publically funded research activities and the thrust of R&D shifting in the hands of few global corporate. Swaminathan²⁵ says, formally, only finished varieties (genotypes) were registered for benefit. But today scope has extended to individual genes and DNA sequences. He draws an analogy with U.S. court’s verdict that laws of nature, physical phenomenon etc. are not patentable. So naturally occurring genes should also not be patentable. Suman Sahai²⁶ argues if genetic resources are a common heritage they should not be privatised, if they are to be privatised, they must be acknowledged as the property of third world and paid for, like any other privately owned resource. Shiva²⁷ says, “there is no epistemological justification for treating some germplasm as value less

²³ Vandana Shiva, (1994), op. cit., p. 7.

²⁴ Suman Sahai “Farmers Right” Seminar, 418, June 1994. p.96.

²⁵ MS Swaminathan, “Genetic Diversity and the Indian Seed Industry”, in Bibek Debroy (ed.), Intellectual Property Rights, New Delhi, BR Publishing Corporation, 1998, p. 232.

²⁶ Suman Sahai (1994), op. cit., p. 96.

²⁷ Vandana Shiva (1994), op. cit, p. 8.

and common heritage and other germplasm as a valuable commodity and a private property.” She argues that “this distinction is not based on the nature of germplasm but on the nature of political and economic power”.

INDIGENOUS KNOWLEDGE: PIRACY AND BIO PIRACY

The industrialized countries blame the third world of piracy and trade in counterfeit products particularly on technological front. They claim that today, due to the very nature of technology like software and biotechnology, it is easy to imitate them which produces heavy damage for international trade. The pharmaceutical sector has been their main target due to the provision of process patents, which they allege not only facilitate, but also, promote reverse engineering. This reason is often cited by the industrial nations for enforcement of strict IP regime.

The third world blames the developed countries of indulging in bio-piracy. They proclaim that when any biologist comes to collect the germplasm, s/he comes in contact with the locals. Then transfer is not merely restricted to germplasm but often extends to include indigenous knowledge. The issues of linkages between biodiversity and biotechnology and IP emanate from the concept of bio-prospecting. The practice is heavily sought after by medical researchers and pharmaceutical companies. The discovery of new medicines based on indigenous knowledge enables them to invest less in R&D and reap early profits. Indigenous knowledge is sacrosanct amongst the local communities. As it is generated within the communities and is location and culture specific. It is the basis for their decision-making and survival strategies. It covers critical issues of primary production, human and animal life, and natural resources management.²⁸ Suman Sahai puts forward that Biopiracy is the

²⁸ About Indegenous Knowledge (www.nuffic.nl/ik-pages/about_ik.html.)

three dimensional theft of biodiversity and indigenous knowledge through the mechanisms of patents viz.

- It makes false claims of 'novelty' and 'invention', about the knowledge, which has evolved through ages. So it is an intellectual theft.
- It is theft, as it diverts scarce biological resources to monopoly control of corporations, and deprives local communities and indigenous practitioners.
- It creates market monopolies and excludes the original innovators from their rightful share of markets.²⁹

Products and patents are generated on the basis of traditional knowledge of the people of third world. Due to their lack of biotechnological advances, they fail to identify/separate that particular characteristic of the entity/gene which produces the responsible for a particular effect. It ends up in loss in the patent battle.

WTO rules instead of preventing this organized economic theft, protects the powerful and punish the victims. In United States- India dispute, the WTO forced India to change its patent laws and grant exclusive marketing rights to foreign corporations on the basis of foreign patents. Since many of these patents are based on biopiracy, the WTO is in fact promoting piracy through patents. Analyst believe the first step to curb massive bio piracy should be amendment to section 102 of U.S. Patent Act.

As a consequence of TRIPs the South's biodiversity and southern people's right to their diversity will be greatly reduced. As they will have to pay royalties for the use of their product, which have been biotechnologically tinkered by TNCs. For using these products they use will have to make

²⁹ Also in Panduranga Rao (ed.), WTO and Competitiveness, Delhi, Excel Books, 2001.

payments to the patentees, which will increase their debt burden. Jayashree Watal³⁰ opines that “given the ambiguous language of CBD and near absence of any national legislation on bio prospecting ... the commercialisation of biotechnological products and processes, based on genetic resources, obtained from developing countries, continue to be based on the principles of free market principle of demand and supply”. Indigenous people claim that wide scale looting of their knowledge and resources is taking place. Their knowledge is being appropriated without their consent with little or nothing in return. Bioprospecting is also threatening the existence of the indigenous cultures. In order to stop misappropriation of indigenous knowledge, reform in patent laws of the developed countries is sought.

Vandana Shiva³¹ opines “US needs to revoke patents based on indigenous knowledge and 'prior art'. In addition, the US also needs to change its patent laws, which sanction bio piracy by non-recognition of foreign 'prior art'. As they do not satisfy even one of the three essential criteria of: Novelty, Non-obviousness, and Utility. Most patents based on indigenous knowledge appropriation violate the criteria of novelty combined with non-obviousness. It ranges from direct piracy to minor tinkering through the biotechnological processes. It involves steps that are obvious to anyone who is trained in the techniques and disciplines involved. WTOs' multilateral rule-based system should ensure that the inequity and injustice that bio piracy exhibits is removed. It is opined that South as a collectivity needs to take their case to WTO to initiate proceedings against US to change its patent laws to give third world adequate protection against biopiracy. In order to solve the problems of piracy and misappropriation of indigenous knowledge of the South, one of the most

³⁰ Jayashree Watal, Intellectual Property Rights in WTO and the Developing Countries, New Delhi, Oxford University Press, 2002, p.174

³¹ Shiva, (1994), op. cit., p.57.

coherent demands was made by India in 1996, in the meeting of WTO Committee on Trade and Environment. It asked for the amendment of article 29 of TRIPs so that conditions can be imposed on the patentee to disclose the country of origin of bio resource or traditional knowledge.”³²

FOOD SECURITY / FARMERS RIGHTS

One of the main concerns of liberalization and opening up of the economy relates to the agricultural sector. It includes the issues of food security and the control over of seeds. Under UPOV though there are provisions of breeder’s right, there are provisions also for farmer’s right and farmer’s privileges. FAO defines farmers right, as“...those arising from the past, present and future contributions of the farmers in conserving, improving and making available plant genetic resources... particularly those at the centres of origin of diversity.” According to Suman Sahai.³³ Farmers right should refer to right to farming community of Third World who in created and maintained genetic resource of the world. It should also include right to control seed production, informed concern and payment if their varieties are used for commercial purposes.³⁴ Shiva credits the farmers and presents a strong case for their protection vis-à-vis the MNCs and opines that “centuries of innovation in the third world are totally devalued by giving monopoly rights of plant material to transnational corporations who make minor modifications compared to the evolutionary changes that nature and third world farmers have made.” She continues “IPR places the contribution of seed companies over and above the intellectual contribution of generations of third world farmers, over ten thousand years, in the areas of conservation, breeding, domestication and development of plant and animal genetic resources”. International

³² Jayshree Watal, (2002), op. cit., p. 175.

³³ Suman Sahai, Plant Variety Protection & Farmers Right Act 2001, New Delhi, Gene Campaign, 2001, pp. 2-3.

³⁴ Ibid.

Dialogue On Plant Genetic Resources says developing recognition and rewards system for informal innovation represents the concept of 'farmers right'.

The issues involved are of much deeper significance. On the one hand it is argued that when Biologist from MNCs go to the third world to collect plant germplasm they also collect knowledge. In this context it becomes difficult to define who are the real owners of this knowledge system. The ones who isolated the genes or the farmers and the indigenous knowledge structure who identified them.³⁵For thousands of years the farmers are engaged in the process of improvement of seeds. In Asia, farmers save substantial amount of harvest as seed for the next season. Tripps³⁶points out that the links of seed supply are embedded in the social fabric of farming community. In India farming community is the largest seed producer. It provides 85% of countries annual requirement of 60 lakh tones.³⁷ The corporate strategy of merger and acquisition of seed and chemical industries had opened a Pandora's box. In the 70's many chemical companies acquired seed companies to form life science corporations. It enabled them to control to productivity chain. An example is global seed giant Monsanto has developed a new variety of soyabean seed called the 'roundup ready'. Since this seed has a gene of 'roundup ready' herbicide inserted in it, they are resistant. Therefore farmers in order to gain maximum control should cultivate 'round up soyabean' and put round up herbicide.³⁸ Today 80% of GM seeds planted are Monsanto's intellectual property.³⁹ In the West agriculture is a commercial activity with less the 3% big farm owners involved, so they can sustain the

³⁵ Vandana Shiva (1994), op. cit.

³⁶ Tripps, Robert, Seed Provision and Agricultural Development, London,, Overseas Development Institute, 2001, p. 57.

³⁷ Suman Sahai, op. cit., pp. 4-5.

³⁸ K.R. Ravi Shankar, "Indian Agribusiness: Traumas of Free Trade Regime" in Pandurang Rao (ed.) World Trade Organisation and competitiveness, New Delhi, Excell Books, 2001, p. 434.

³⁹ Ahmad and Khan, "WTO, challenges and opportunities- a case of Indian Agriculture" in Pandurang Rao (ed.) WTO and competitiveness, New Delhi, Excell Books, 2001.

“genetic-corporate form of agriculture.”⁴⁰In third world agriculture is the activity for sustenance. But globalization, advances in technology and increasing importance of IPR are changing its character. TRIPs involved the provision of extension of IP protection to plant, it will result in increase in prices of seeds, greater domination of agriculture by MNCs and slower diffusion of new varieties. This is in sharp contrast to the Green Revolution where new varieties were provided by the publically funded institutes. TRIPs present enormous hardships for farmers as patenting of agricultural seeds forces farmers to buy seeds year after year. This will add to the third world debt. The patent allows the user only to use and not make the product. But since, the seeds make themselves, farmers saving and replanting them will amount to theft.⁴¹ It would be appropriate at this juncture to draw a parallel of the severe famine in Eastern India at the end of the eighteen-century. Most historians attribute it to the commercialisation of land and the inability of the farmers to save seeds.

It is strongly argued that there is need to take preventive action measures to protect farmers from the terminator technology and ensure that GURT (Gene Use Restricting Technology) are not forced upon them. Due to biotechnological interventions in the natural seeds they are made infertile. In Green Revolution the hybrid seeds posed the problem of lower productivity in long term but with the Biotechnological Revolution the farmers have become susceptible to the vagaries of international seed corporations. Jean Halloran asserts that, “Saving seeds is a fundamental human right”. But what is the value of right, if the seed is sterile?

Thus, the most controversial issue here relates to the debate about GM crops. The important aspect is the safety precautions around GM crops that are being demanded in the first world are unlikely to be implemented

⁴⁰ Gyorgy Scrinib (www.campaign.org)

⁴¹ Ahmad and Khan, (2001), op. cit., p. 292.

in the third world.⁴² It's not only the third world but the whole world seems to be divided about this issue of GM crops. People are optimistic about "Golden Rice", i.e., Vitamin A rich rice that has the potential to solve the problem of malnutrition in the third world but its critics like Scrinib⁴³ see it as an example of "ideology of genetic precision".

The Biotechnological Revolution in agriculture is hailed as an answer to world problem of food particularly, in the third world. But it presents a peculiar paradox. Though they need to enhance their production in future keeping in mind the altering of agro-climatic situation due to, rise of temperature owing to global warming and increase in salinity of soils. Yet, they cannot use the modern GM crop not because of a choiced decision (like there European counterparts) but as a compulsive policy matters. Their agriculture is export oriented and in light of growing political antagonism in Europe against GM crop, may invite trade barriers. Secondly even if, they resort to the system of labelling the GM crop, it is impossible for them to identify or trace the GM due to huge country side and lack of resources and technical expertise. Hence, labelling of GM crop is impractical. Further, only a few countries of the third world like Brazil, India and China can invest in the expensive research.

China has been the most vociferous user of GM technology in the third world. It was the first one to introduce Bt. Tobacco. It introduced Bt Corn way back in 1978. Today it has the 4th largest area under Bt crop production. China has the highest year on year growth with the 40% increase. This year for the first time the sown area for Bt cotton in China's exceeded more than half of the national cotton area⁴⁴. Of late, it had to withdraw Bt tobacco due to opposition from importers. China and Brazil

⁴² Robertson David and Anyrley Kellon, Globalization and the Environment: Risk Assessment and WTO, Massachetts, Edward and Elgar, 2001, p.151.

⁴³ Scrinib, op. cit.

⁴⁴ James Clive, Global Status of Commercialised Transgenic Crops, The International Service for the Acquisition of Agriculture – Biotech Applications, www.agribiotechnet.com, No. 27-2002, p. 3.

are looking forward to the Genetically Engineered crops. Recently the drought hit Zambia refused to receive GM crop as a 'tied aid'. It clearly represents the paradoxes faced by the third world and ascertains the need of tough decision making.

RED BIOTECHNOLOGY (THE HEALTH ISSUES)

Initially the applicability of biotechnology in health sector was seen with optimism. As it could help the poor of the South to fight death and disease with vaccine generating plants, which can reduce the cost of maintenance involved in traditional vaccination programmes and bring the health care system within the physical reach of people. There are two dimensions to this issue. a) The traditional medicinal system. b) Modern pharmaceutical sector.

a) Traditional medicinal system:

The issue of traditional system of medicines relates to the bioprospecting. With the 'greening of the market', the market for herbal products, extracted medicine and alternative therapy system is increasing. Sales of herbal medicine in U.S. exceeds U.S. \$ 30bn in 2000.⁴⁵ The folk knowledge, which is based upon oral transfer from generation to generation and the classical knowledge i.e. the documented knowledge both are susceptible to misappropriation. A Galaxo and W&Lcom's funded bioprospecting institution in Singapore, is alleged to have an agreement with India's Tropical, Botanical and Garden Research Institute. It offered commercial products developed from Kerala's Plant to 'third parties'.⁴⁶ Though the earlier organisation looking into the matter of IP i.e. WIPO has been sensitive to these concerns. In one of its meeting in October 1998 an agenda for 'future of IPR in field of traditional medicine was prepared.' It

⁴⁵ [www.grain.org/publications/the asia-2002-en.cfm](http://www.grain.org/publications/the%20asia-2002-en.cfm).

⁴⁶ www.grain.org/publications/tk-asia-2002.

prioritised activities in area of development of standards for the availability and scope and use of IPR in traditional medicines in Asian Countries. It is engaged in systematic documentation of traditional medicine for protection purposes, regional and inter-regional information exchange and compilation of requisite databases etc.⁴⁷ Many countries of third world are trying to bring out legislation for protection for the indigenous knowledge to ensure the consent and adequate compensation to the indigenous communities. In all these issues the core is the biotechnology industry as the indigenous knowledge is converted into patentable invention, through it.

(b) Modern Pharmaceutical Sector

The patent system in most of the third world countries is a colonial legacy. After Independence, attention was paid to their revision in accordance with the national priorities. The focus was not strong patent regime as it may lead to creation of monopolies. It included provisions like compulsory licensing in order to safeguard the interest of the people and fight the prevailing death and disease. But some analyst identify this very clause as a hindrance to R&D, which was the need of the hour. Amit Sengupta⁴⁸ says that compulsory licensing destroyed incentive for research. He quotes the example of tuberculosis, which is prevalent in the third world. For it, no new drug has been developed for the last 30 years, but he is hopeful that this situation may change now, as there is resurgence of the disease in developed countries.

The provision for compulsory licensing did not cause much problem in international arena directly as such provision existed in Paris convention. But with the incoming of the TRIPs regime it has become highly

⁴⁷ RA Mashelkar, "Intellectual Property Right and The Third World", FICCI Business Digest, December 2002, p. 17.

⁴⁸ Ranjit Dev Raj, "Anthrax Scare Highlights Drug Patent Problem", Inter Mess Services, October 2000, www.ipress.com.

contestable. It is held that the provision is non-exclusive and there are further stipulations that compulsory licensing should be refused if the patentee justify the inaction by legitimate reason. The developing countries see it as a measure to hinder R&D⁴⁹.

According to WHO more than one third of world population lacks access to essential drugs. The problem of the third world is compounded by the low investment in R&D. Though it provides a big market for big pharmaceutical giants but owing to the gross poverty and lack of adequate purchasing power, it does not provide them adequate incentive. Sengupta⁵⁰ also referred to the case of “orphan drugs” that were discovered to be effective against diseases in tropical and developing countries, but could not be manufactured because the multinational corporations envisage no profit in it. It is sent that the move to globalise the protection of IP is not politically sustainable, without at the same time making the delivery of to health technology more equitable.

Traditionally, the pharmaceutical industry of the north has been blaming the south of piracy through the process of reverse engineering. It was seen as an attempt to force the south to buy expensive medicine. Today there is rise of several pharmaceutical companies in third world, which are directly challenging their dominance through R&D, patent litigation and aggressive marketing particularly in the least developed countries and Aids hit African region by providing them with low cost health care systems. These third world firms considers that IP provides ‘technological protectionism’ to the north. But the Doha summit of 2001 witnessed softening of the north, particularly in the backdrop of the anthrax scare. Commentator say that “it took the anthrax scare in the United States and an offer of cheap drugs from India to highlight a problem familiar to people in developing

⁴⁹ Bibek Debroy, Beyond The Uruguay Round, University Press, Hyderabad, 1995.

⁵⁰ Ranjit Dev Raj, (2000), op. cit.

countries.” Due to tough patent laws, there is need of extending the poor’s access to affordable drugs”. A separate ‘Ministerial Declaration on TRIPs is seen as a major achievement by the third world countries. As Maran⁵¹, the Indian minister stated “The biggest gain was granted through “the right to break the monopoly over patented drugs in case of health emergencies like epidemics.” But Jayati Ghosh⁵² opines “the declaration won’t go far enough to provide legally binding commitments as it remains a political document. Infact, many pharmaceutical giants have declined to abide by it and see it as a mere political document rather than an economic one.” Few analysts points out that the post 2005 will give rise to “patient paradox” wherein the patient can neither afford highly effective high priced products neither will the cheaper and obsolete drugs to help them. Critics say that IPR enables. TNCs to hike prices and earn monopoly rents leading to collapse of social health care system. Infact, South Africa has recently passed the bill, inspite of restriction imposed by TRIPs for compulsory licensing.

GEOGRAPHICAL INDICATORS

This is the emerging area of discord not only on the lines of north and south but like the third world the first world too seems to be divided. TRIPs Article 28 defines, Geographical Indicators as “(the) indications which identify a good as originating in a territory, where a given quality, reputation or other characteristic of a good is essentially attributed to its geographical origin.” In the last round of preparatory talks for summit, Turkey, India, Switzerland, Pakistan, Mauritius, Sri Lanka, Egypt, Cuba supported the strong call made by CEFTA members, Latvia and Estonia. They made a strong call for negotiations for expanding the arena for same higher level of protection and currency given to wines and spirits-to other

⁵¹ Interview with Murasoli Maran, Chennai Frontline, December 7, 2001.

⁵² Jayati Ghosh, "How To Save Life Even Without Trying", Chennai, Frontline, Dec.7, 2002.

products. They said that if “benchmarks” (i.e.-flexible target dates for various stages of the negotiations) are to be set for the talks on agriculture and services, then there should be similar benchmarks for negotiations on geographical indications. On the other third world countries like Argentina, Mexico, Brazil, and Hong Kong, China argued that such negotiations should wait till the TRIPs council finishes its review of implementation of other agreements.

Experts suggests that premium products like Basmati rice, Darjeeling tea and Alphonso mangoes should be as “fiercely protected by India as Scotch whisky and champagne wines are protected in their countries of origin”. The forthcoming Column ministerial summit would be keenly watched for this among various issues.

U.S. and other industrialised countries have emphasized on the IPR clause as they claimed it would help in the technology transfer and increase as FDI. It is also alleged that MNCs shape Biotechnology for their own needs and propel motives in mind whose business plans are based in large measure on the best estimated return on investment⁵³ Third World is also particularly vulnerable to joint ventures as in the name of technology transfer. The transfer of indigenous knowledge also takes place. Through Biotechnological corporations, Biodiversity has becomes the private property. Their capital investment and IPR becomes the means for such privatisation. Zimmerman⁵⁴ points out that, there is little interest in developing vaccines and treatment for the spectrum of tropical disease. This is amply reflected in the 1996, WHO report, which states “that out of thus U.S. \$56 billion spent on health-related research and development worldwide, only 0.2% percent is spent on pneumonia, diarrhoeal diseases and tuberculosis – which together represent 18% of the global disease

⁵³ Zimmerman ‘Biotechnology and International Development’, The World Biotech Report, Proceedings of Biotech Conference, London, Vol. 1, May 1985.

⁵⁴ Ibid.

burden". It has a large market but lack of interest's due to the potential users lack the purchasing power of its potential users.

Today third world is just not being the passive consumer of biotechnology but is trying to carve a niche for itself. Singapore taking a clue of the possible opportunities targeted biotechnology as an area of priority treatment, for boosting its technological growth. The National Biotech Programme (WBP) was established in 1988 within the economic development Board (EDB) to co-ordinate and spearhead Singapore in the pre-eminent business hub⁵⁵. The need for joint endeavour was realised at various regional forums. South East Asian countries are trying to initiate regional collaborative projects. The latest action plan (for 2001-05) concentrates on 'ASEAN-help-ASEAN' for the development of science and technology. Knostadakopulos⁵⁶ through analysis show that the low level of patents registered by resident companies suggests that the growth of more advanced ASEAN economies has been based on the transfer and adoption of readymade technology from the industrialised world. Damardjati⁵⁷ provide the domestic reasons for low level of biotechnological research in developing countries he cites particular example of Indonesia and says "it is constrained by limited numbers of qualified scientist, discontinuities of fund sources, and/or sufficient supporting equipment." While others quote that for public institutions the focus of public institution is on research other than seeking patents. In Thailand National Centre for Genetic Engineer and Biotechnology was established under Ministry of Science and technology.

⁵⁵ Sachin Chaturvedi, Status of Biotechnology in Singapore, Delhi, RIS, Occasional Paper No. 52, p. 11.

⁵⁶ Konstada Kopulos, D., "The Challenge of Technological Development for ASEAN: Interregional and International Cooperation", ASEAN Economic Bulletin, Vol. 19, No. 1, April 2002, p. 102.

⁵⁷ Djohe S Damardjati, "Biotechnology In Agriculture In Asia", Tokyo, Asian Productivity Organisation, 1999, p.128.

Thus, development in Biotechnology is still in infancy in the third world. These have occurred mainly as a result of "Science Push" and are largely divorced from priorities out for National Agriculture Research. Kenya and Zimbabwe are making efforts to bring together the different stakeholders. Their earlier laws, which were not in conformity with TRIPS but were focused upon their national priorities, are set for amendment. In Kenya microorganism plant and animal are not regarded as an invention inviting patent protection. Zimbabwe holds the same position but has allowed PBRs for number of years. In Mexico, in 1991 most biotechnological inventions were protected.

As Carline⁵⁸ points out that there is a need of alternative technology transfer and diffusion mechanisms for public goods technology in developing countries. In practical application differences are visible in the approaches and policies decision but there is inherent commonality. This commonality of issues needs to be appreciated and worked towards. At biotechnological front the third world is witnessing a new world full of hopes. But with particular implications of IP the third world is faced with exceptional situation There is a need to evolve a coherent strategy which, must keep in mind both the short term and long term goals of sustainable development and should be in consonance with the political, social and economic needs of the people of the third world.

⁵⁸ Brenner Carline "Integrated Biotechnology in Intellectual Property Rights, OECD Development Centre, p. 96.

CHAPTER-IV

IPR: CRITICAL ASSESSMENT OF INDIAN POSITION

The transition from GATT to WTO in 1995 through the negotiating process of Uruguay Round, is perhaps the most important development for global economic system. It is believed to have given the new practical meaning to the term globalisation.¹ Chossudovsky² points out that the 1994 Marrakesh Agreement which initiated the WTO as a multilateral body, has bypassed the democratic process of each of the member country. It blatantly derogates national laws and constitution. It is pointed out that this process had two significant features in terms of developing countries. First, there was greater participation on their part. Secondly, the operations of the system fell short of the expectations of the developing countries.³

Few see this process as the intrusion into and occupation of the sovereign economic spaces of the third world countries, which has been formally sanctioned under these agreement. Deberoy⁴ counters the argument of severing of sovereignty of the third world by claiming that the sovereignty of US and Japan is equally at stake. Others insist on the unequal character of the participants. In this context, Amit Dasgupta⁵ argues that developing countries need a special consideration as comparing Nepal or Sierra Leone with US is non feasible. It is pertinent to reflect upon the view of different agencies regarding the impact on developing countries.

¹ Amit Dasgupta, "WTO and new issues", paper presentation in Kathmandu at Fifth Economic Co-operation Conference, 2001, p. 75.

² Michel Chossudovsky, "Seattle and Beyond" Mumbai, Economic and Political Weekly, 15 Jan 2000, p 101.

³ Trade and Development Review 2002, p 46.

⁴ Bibek Deberoy, Intellectual Property Rights, Delhi, BR Publishing Corporation, 1998, p. 3.

⁵ Amit Dasgupta, (2001), op. cit., p. 75.

The developing world apprehended that the very autonomy of their policy making in areas control to their economic development would be threatened. They also feared that the integration of their markets with that of the industrialized countries may not bring about much benefit to their economies but instead create further unequal interdependence between the two worlds.⁶

Due to controversies about expansion of GATT's, committee under Dunkel was established to provide new guidelines, its major recommendations were compiled under the title of Dunkel Draft Text.

Deepak Nayyar⁷ opines that this DDT was neither an intellectual construct nor received wisdom. It reflected the bargaining strength or weaknesses of groups of countries at different levels of development and the dynamics of the negotiations overtime.

The formulation of Dunkel Draft Text was seen as inimical to the interests of developing countries.⁸ Dhar & Rao⁹ point out that Dunkel Draft on TRIPs clearly show that interests of developing countries were completely disregarded. It was complete reversal of spirit of 70's, when the issue in international negotiations was about how to make technology transfer between north and south more equitable, while TRIPs focused on granting monopoly rights to the patentee from developed countries. They opine that in nutshell, message of Dunkel Draft Text on TRIPs was that developing countries have to content with an unequal world order.

⁶ SP Shukla,⁴ The Emerging International Trading Order: A Story of the Uruguay Round, New Delhi, National Working Group on Patent Laws, Sep. 1993, p. 3.

⁷ Deepak Nayyar, Dunkel Text: A Framework for Assessment in Uruguay Round and Dunkel proposals: An Overview, New Delhi, National Working Group on Patent Laws, July 1992, p. 10.

⁸ Gopinath, "IPR : Opting for the Lesser Evil" – The Economic Times, 13.5.92.

⁹ Biswajit Dhar and C. Niranjana Rao, "Dunkel Draft on TRIPs; Complete Denial of Developing Country's Interests", Mumbai, Economic and Political Weekly, Feb. 8, 1992.

These apprehensions are still reflected in their views at different forums. Regarding developing countries' apprehensions in Seattle meet in 1999 Rodrick¹⁰ observes that "many developing country governments noted the asymmetry in the multilateral trading regime, which they viewed as dominated by a narrow agenda of a few industrialized countries, thereby marginalizing the genuine development concerns of the vast majority of people".

In particular context to TRIPs, Kabiraj¹¹ says that inclusion of IPR in Uruguay Round of Multilateral Trade negotiation under GATT has created wide spread unease among the developing countries because it is feared that this would lead to absolute dominance of the developed countries on trade and technical matters, with far reaching implications on self-sufficiency and long term growth performance of developing countries.

Correa¹² visualizes TRIPs as measure of technological protectionism and say that stronger IPR will make "catching up" process more difficult.

Despite differences, the agreement to establish WTO came into force and various third world countries signed the agreement and became its members. Since it was a package deal, they had to accept all its clauses. The main reason cited by various Third World countries for the action is that they apprehended that they could not have an isolationist's attitude. This seems to be a pragmatic approach as through stimulation negotiation they can engage in bargaining process and can bring the contesting issue for further stimulation. The main concerns of the developing countries regarding the process of negotiations were –

¹⁰ Dani Rodrik, *The Global Governance of Trade as if Development Really Mattered*, UNDP, Oct. 2001, p. 2.

¹¹ Tarun Kabiraj, "Intellectual Property rights, TRIPs and technology transfer", in Mumbai, *Economic and Political Weekly*, 19th November, 1994, p. 2990.

¹² Correa, "TRIPs: An Asymmetrical Negotiation" Paper presented at International Conference on Patent Regime, New Delhi, *National Working Group on Patent Laws*, September 1993, p. 4.

1. The third world claimed that the agreement was not a negotiated agreement and its framework was based upon a joint paper submitted by IP Committee (US), Keidanaran (Japan) and UNICE (Europe).
2. It is claimed that, the negotiating process had by and large ignored the interests of the developing countries on the cost of the interest of the commercial enterprises.
3. Third world particularly objected to the non-transparent 'green room negotiations' as they felt that it was used as a coercive tactic by the developed countries.

South presumes that the agreement and institution are tilted in favour of north as it is covertly used by north to legally maintain its technical dominance over the south. This is particularly apt in case of formulation of TRIPs. As it will adversely affect the third world's attempt to have access to ever increasing treasure house of expanding world stock of technology. In this regard Shukla points out the rationale to incorporate IPR into GATT agenda, he says that issue of IPR was important for the industrialized countries and they have a near monopoly of knowledge and technology. They would like to strengthen their hold by perpetuating the monopolistic position through raising the patent and copyright protection all over the world.¹³ Apart from these broader issues regarding the nature of negotiations, in particular context to intellectual property, they were concerned about the following issues:

1. They were apprehensive about the intentions of the industrialized nations as they perceived that the controversy regarding the issue of IPR vis-a-vis biotechnology could be traced back to the issue of ownership of germplasm.

¹³ SP Shukla (1993), op. cit., p. 3.

2. It is argued that it will lead to international division of work, between those countries where innovation was produced and where the products that contained them are exported and consumed.¹⁴
3. The issue was intrinsically linked to their development, as IPR also relates to the arena of transfer of technology. It was seen as an instrument, which will further enhance technical dominance of north.
4. They point out that though developed countries insist on harmonization of IPR system, they refused to grant patent, in their process of industrialization. Patent system was gradually enforced as they shifted from being net users to net producers of the technology.
5. They were particularly concerned about the issues regarding bio piracy and bio prospecting.
6. They demanded that it involve the issues of misappropriation of traditional knowledge and rights of indigenous communities.
7. Third World argued that process the of globalisation lead to the appropriation of elements of collective knowledge of societies into proprietary knowledge which in turn is used for commercial purposes.

These apprehensions are materializing to some extent as the Trade and Development Report¹⁵ quotes the recent World Bank estimate which states that, "only a handful of developed countries could expect benefit from implementation of the agreement on TRIPs and said that developing

¹⁴ Correa, "TRIPs: An Asymmetric Negotiation in Patent Regime in TRIPs" Paper Presented at International Conference on Patent Regime Proposed in Uruguay Round, Sep. 23, Vol.93, NWGPL, p. 4.

¹⁵ Trade and Development Report 2002, p. 35.

countries ... would incur considerable costs in administering IPR, in addition to significant costs in terms of patent right”.

The IPR Commission in its Report on IPR and Development Policy¹⁶ explains the situation in the light of lack of institutional framework and expertise in the developing countries. Trade and Development Report suggests, that a real side adjustment is required about the adequacy of technical assistance. Many developing countries believe that at minimum, longer transaction periods are required. Though in the recent Doha Summit 2001, the transition period for accepting the terms of TRIPs has been extended for the Least Developing Countries upto 2016.

TRIPs has far reaching political implications, as the IP issue vis-à-vis biotechnology poses a competitive challenge for the developing countries. As Juma and Mugabe¹⁷ points out that Biotechnology is still within the general framework of National Science and Technology Policy. Science and Technology can no longer be narrowly focused as a scientist working in isolation. But today, it has become a commercial enterprise. Singurdson says that the emerging technological landscape has global characteristics, which have led to corporate mergers and emergence, corporate strategic alliances. He opines that the latter has become the focus of national concern in many countries as, they are perceived to erode national sovereignty both from military and economic point of view. In nutshell, they observes, that MNC's are becoming strong advocates of technoglobalism while national and supra national bureaucracy still appears to be strong for techno nationalism.¹⁸ While others opine that the Governments of technology exporting countries have also become active in

¹⁶ Integrating Intellectual Property Rights and Development Policy, IPR Commission, London, 2002 (www.iprcommission.org).

¹⁷ Juma & Mugabe, “Public Policy and New Generic Technologies: A Case of Biotechnology in Sub-Saharan Africa” in Raghavan (ed.), *New Generic Technologies in Developing Countries*, Great Britain, Mac Millan Press Limited, 1997, p. 120.

¹⁸ *Ibid.*, p. 277.

the promotion and regulation of technical trade. In the context of third world, it is also pointed out that “technology is being brought and sold like a commodity. The late comers (developing countries) are like spectators arriving at the last moment at a cup’s final and having to buy tickets from vendors at expensive prices.”¹⁹ Omvedt provides a varied perception regarding the issue of access of technology to third world due to increasing cost. He opines “... if patents will make expensive and unsustainable biotechnologies less accessible all the better. Easily accessible enslaving technologies are more dangerous.” Such an argument can be explicitly regarded as an attempt to hinder the path of technological progress of third world.

In the context of IP protection in biotechnology, Gopinath²⁰ questions the long duration of protection for patents. He says that in areas of biotechnology, the developments are taking place at lightning speed and extent of patent duration for years and decades seems obsolete. Developed countries have justified it on the basis of increasing costs of R&D. Yet, the issue needs to be analysed in terms of the impact that long period generates on the production process in the third world, as these technologies may be obsolete in their place of origin. Yet, due to time lag in its dissemination and diffusion across the border, the protection may economically benefit industrialised firms in keeping their technological control intact.

Nachane²¹ argues that the long term, stricter regime of patent is beneficial for the third world but in short term major adjustment are needed. On the

¹⁹ Ruth Guna, “Prospects for Developing Countries under the TRIPS Agreement”, Vanderbilt Journal of Transnational Law, Vol. 29:735, 1996, p. 264.

²⁰ K. Gopinath, “IPR: Opting For The Lesser Evil”, Economic Times 13.5.92.

²¹ Nachane, “Intellectual Property Rights in the Uruguay Round”, An Indian Perspective, Mumbai, Economic and Political Weekly, Feb. 1995, p. 165.

contrary, Kuleessa and Bruehl²² opine that patent protection can well result in impulse of growth in the developing countries in medium and long term, as it forces local firms to innovate rather than to imitate. But they argue that such requirements could only be met by wealthier developing countries and the emerging new economies. Juma and Mugabe²³ argues that diffusion of new technology to poorer nations will be slower, as it will be more costly than imitation based technology. In this regard Kuleessa and Bruehl²⁴ opine that in less developed countries, social cost are first of all harder to take and secondly, time taken for possible future profit is also uncertain. The argument is also substantiated by the analysis of IPR Commission. It claims that since, the developing countries are net importers of technology, the globalisation of IP will result in very substantial additional net transfers from developing to developed countries.²⁵

In this context Gupta²⁶ says that no technological change is without cost. Today the focus is to shift the process from the mechanics to biology as a mode of production. While critics opine that the substitution will have major social repercussions and create dislocation such as unemployment etc. Dealing positively with these technology induced changes will require major social restructuring and full examination of issues.²⁷ Substantiating the argument, Moser²⁸ emphasizes the importance and need for vigil over biotechnology. He says that “scientific inquiry has been understood, to demand freedom and absence of control. Science is supposed to bless, as

²² Margata E. Kuleessa and Tajja Bruehl, “International Protection Intellectual Property and its North- South Implications: The General Discussion And The Case Of Biotechnology”, in Tussie (ed.), TRIPs, Uruguay Round and Third World Interests, Boulder, Lynner Rienner Publishers, pp. 620-621.

²³ Juma and Mugabe, (1997), *op. cit.*, p. 205.

²⁴ Margata E. Kuleessa and Tajja Bruehl, *op. cit.*, pp. 620-621.

²⁵ Integrating Intellectual Property Rights and Development Policy (2002), *op.cit.*

²⁶ Anil K. Gupta, Making Indian Agriculture more intensive and competitive: The Case of IPR, Indian Journal of Agriculture Economy, Vol. 54, No. 3, 1999, p.347.

²⁷ Susantha Coonatilake, Towards Global Science: Mining Civilizational Knowledge, New Delhi, Vistaar Publications, p. 183.

²⁸ Moser, “Introduction” in Shiva and Moser (ed.) Biopolitics, Madras, Orient Longman, 1996, p.14.

when, it is left alone....” But today, biotechnology cannot be left alone to scientist and businessman, as it is woven into the developmental issues of the third world. It is increasingly affecting our lives today and more people are facing its problematic consequences, so both local and global politics must address the issue.

As evident, in terms of linkages between biotechnology and biodiversity vis-à-vis patent, Kulesa and Bruch²⁹ point out that almost 90% of biodiversity is located in Asian and Latin American developing countries. While biotechnology is an almost exclusive domain of developed countries. They suggest that this distribution has temporarily been seen as a chance for inducing change in developing countries wherein ‘they receive modern technology in return of biodiversity.’ Critics doubt such a proposition and argue that transnational biotechnological companies will not be willing to export capital-intensive technologies, if no profit is involved. This attempt to control the biodiversity of South should be seen in light of crucial issues of national production process. Drawing the parallel from history Fowler³⁰ states that colonial power attempted to control biological material through the control of production, as exploiters also seek plants, which later on form the basis of European dye, chemical & pharmaceutical industry. In the context of modern biotechnology, patents have played a seminal role, particularly after the onset of the TRIPs regime.

The paramount marker of the TRIPs agreement was its overarching influence in various spheres of activity. While WIPO mainly dealt with the issue of industrial property, the focus of TRIPs is on intellectual property. In order to comply with the stipulations of the TRIPs agreement, most third world states are expected to initiate domestic legal reforms vis-à-vis

²⁹ Margata E. Kulesa and Tajja Bruchl, op. cit., pp. 620-621.

³⁰ Fowler, “Biotechnology, patents and the Third World”, in Shiva And Moser (ed.) *Biopolitics*, Madras, Orient Longman, 1996, p. 215

IPR. Before analyzing the changes, it is pertinent to look at the context of origin of post-colonial patent laws.

The rationale and role of existing patent laws in various third world countries:

After securing political independence, the aim of the post-colonial state was to secure social and economic freedom for its people. For this, legislative reforms were initiated. The paramount concern was how to reorient the national production process so as to fulfill the immediate needs and long-term national goals. There was an urgent need to reorient the colonial economy, which served the needs of the mother economy. There was general recognition of the need of planned economy that can focus on redistributive aspects. One of the instruments of reorienting colonial economy was through the tool of patent. Requirement of capital and technological base was a major challenge before the ex-colonies in their nascent stage of development. Situated in the larger framework of cold war, the ideological underpinnings provided them the opportunity for engaging in the process of international bargaining.

The pre-colonial laws were framed to serve the interest of the investor and entrepreneur. The first task before the new government was to balance the patent law in favour of people and economy in general. So, that it could provide impetus to the production process. Though the state played an important role in the production, and Research & Development activities, one of its intention was to develop indigenous science and technology and gain self-reliance. It also aimed at enthusing local entrepreneurs. In this context, most countries provided for liberal patent regimes. They adopted 'process patent' rather than 'product patent', as it could boost the industry and keep prices of essential commodities under check. Mechanisms like compulsory licensing etc. were evolved, to handle emergency situations, which legalized state's claim over the patent.

Most of the third world countries, kept essentials like medicines and chemicals out of the purview of the patent. As most of them had agricultural base and mass poverty was a regular feature, ample amount of caution was exercised to ensure that food was kept out of the realm of the patents. Thus, IPR was used as a policy tool.

Unlike the West, there was virtual absence of debates regarding the patent on life forms. Due to ethical consideration and moreover, due to the lack of technological advancement on the front of life science. So, the issue largely remained out of context. In fact, in the third world, knowledge is seen as a constituent of public domain. The idea of proprietary knowledge was seen as a foreign importation, particularly, the issue of ownership of living entities for the purpose of changing their inherent genetic map was perceived as an ethical issue rather than a purely scientific discourse.

In their developmental endeavor, the third world countries were also assisted by various multilateral agencies, mainly through the fora of United Nations. This helped in transfer of technology, which was essential for their developmental needs. Along with the issues of equity one of the main problems was the nature of technology. In advanced countries the focus of technology was on saving labour and primary material from the developing countries³¹. While the needs of the third world were entirely different.

Gradually, many third world countries taking full benefit of their patent regimes and the international transfer of technology arrangements advanced towards their goal. Minimal standards were achieved in short duration. This provided base for the later developments.

In the international domain, the decade of 80's posed economic challenges to the industrialized countries in form of shrinking markets and profits.

³¹ Report of Second Development Decade, New York, United Nations, 1971, p.18.

One of the factor pointed out was the increasing trade in counterfeit products. They claimed that the third world had inadequate IP protection laws, which infact, legalized such malpractices. Another factor was the emergence of few developing countries on the front of technology. Particularly, their initial success in fields of pharmaceutical and agricultural biotechnology, was perceived as an attempt to hinder future profits. There was sudden increase in the intensity of their demand for higher protection and strict enforcement of IPR's.

In particular context to biotechnology, Rao³² says that the main reason for the proposal of developed countries to extend patent protection to biotechnology was that it was easily imitable. When the technology was not imitable, the existing patent system functioned well to prevent easy diffusion of technologies in the developing countries. But when new technologies which were easily imitable emerged, easy diffusion were possible. Therefore, the developed countries were keen on insisting change in patent system. Through the long negotiated process, WTO was established. One of its main instrument, TRIPs is bound to have fundamental impact upon the third world economy. The particular impact on the agriculture and pharmaceutical sector needs to beconsidered.

India: A Case in Point

To illustrate the paradoxes and challenges faced by the third world countries, as an elucidation the case of India is presented. By tracing the trajectory of the Indian patent law and through analysis of the debates regarding India's position on the issue of IPR and biotechnology. The main reasons for citing India are :

³² N. Rao, "Trade Related Intellectual Property Rights – Question of Patents", Mumbai, Economic and Political Weekly, 13 May 1989, p. 1057.

1. Due to the historical factor as S.J. Patel³³ points out; in 1859, India was amongst the first colonies where Patent Act was introduced and it served as a 'grandfather Act' to all other colonial patent laws.
2. In its post-colonial era laws were reformed keeping in mind the national priorities with the aim of self-reliance and development and to quite an extent, India was successful in establishing strong scientific base that helped in achieving these aims.
3. India is cited due to the leading position taken by India on various foras on the issue of IP. India and Brazil in 1961 proposed for reconsideration of IP laws. As K.S. Ramchandran³⁴ opines India has for long resisted moves for bringing IP on the formal agenda of GATT.
4. A strong public opinion was generated in the country owing to India's positions in GATT and TRIPs. The issue was also used for political mobilization.
5. India has been used as the point of focus because in the long history of over a century it has witnessed changes in perception on the issue, are clearly evident.

The Introduction of Patent Law in India

In 1859, the Patent Act XV was passed to grant exclusive privileges to the inventors, so as to enable English patent holders to acquire control over Indian markets. It is pointed out that these enactments were extensively used to honour the inventors creativity, in effect they sought to protect the

³³ Surendra J. Patel, "Intellectual Property Rights in Uruguay Round", Mumbai, Economic and Political Weekly, p. 24.

³⁴ K.S. Ramchandran, "Give or Take – Not Bickering", New Delhi, Financial Express, 20 May 1989.

industrialist, manufacturers and importers.³⁵ It was followed by Patents and Design Act 1911 through a separate order.

Recognizing the importance of the issue involved, immediately after independence, efforts were made to fit patent regulation in accordance with the national goals of technological self-reliance.³⁶ In 1948, the Government of India set up a committee under Bakshi Tek Chand. It reported that “the Indian Patent System failed in its main purpose, namely to stimulate invention among Indians and to encourage the development and exploration of new inventions so as to secure benefits for largest section of public”.³⁷ It recommended provisions for compulsory licensing and secondly, for evolution of efficient machinery to tackle the issues of abuses.³⁸

The second committee was set up under Justice Rajagopala Ayyangar. It stated that foreign patentees, who accounted for 80% to 90% of the total patentees were acquiring patents with the object of protecting export market from competition from rival manufacturers and that they were working to achieve monopolistic control over the market.³⁹ This committee identified essential pre-requisite for assimilating the benefits of patent system with technological advancement and for encouraging inventors. It revealed that the system should be modified to suit Indian environment.⁴⁰ Significantly, this report became the basis of Indian Patent Law 1970.

³⁵ G.B. Reddy, Intellectual Property Rights and the Law, Hyderabad, Gogia Law Agency, 2nd ed. 2001, p. 135.

³⁶ P. Bhattacharya and Chaudhari, Globalization and India: A Multi-Dimensional Perspective, New Delhi, Lancers book, 2000, pp. 91-92.

³⁷ Nitya Anand, “Patent Laws : The Indian Experience”, Sage Publications, Science and Society, p.273

³⁸ Dunkel, “Dunkel Draft Text: Threat to Economic Sovereignty”, New Delhi, National Working Groups on Patent, p. 135.

³⁹ Anita Ramanna, “Policy Implications of India’s Patent Reforms”, Mumbai, Economic and Political Weekly, 25 May 2002, p. 2065.

⁴⁰ Dunkel, op. cit., p. 135.

Radical departures were witnessed in the field of food, chemical and pharmaceuticals, which were exempted from patent requirement. Secondly, the period of protection was greatly reduced. Thirdly, importation provisions were made, to ensure that patented products are made in country.⁴¹ It is claimed that it was essentially designed to enable Indian industry to acquire cheap technology, at a time when technological self-reliance was an important national goal. The bill proposed by this committee was kept before the Lok Sabha in 1966. Since, the House dissolved, the bill collapsed. In 1967 the bill was presented to a new Lok Sabha and after deliberations by Joint Parliamentary Committee and on the basis of national consensus, the bill was passed in 1972 and was called Indian Patent Act, 1970.⁴²

The main concern of the bill amply reflects the need of the developing countries. The bill soon became a model for other developing countries. Argentina, Brazil, Chili, Mexico, Egypt and several other developing countries.⁴³ Mehrotra⁴⁴ argues that the act had made a balance between the rights of patentee (inventor) and welfare of people (public interest). The main objectives of the bill were :

1. It changed the very objective of the patent systems, as it became an instrument for attaining the objectives of national development.
2. It aimed at promotion and enhancement of national production system and not merely generate monopolies.
3. System of compulsory licensing was introduced and promoted.

⁴¹ P. Bhattacharya and Chaudhari, (2001), op. cit., pp. 92-93.

⁴² Dunkel, op. cit., p. 136.

⁴³ Dunkel, op. cit., p. 82.

⁴⁴ Tarun Kabiraj, op. cit., p. 2995.

4. Under Article 87 novel system of 'license of right' was introduced, to overcome weakness and delays in obtaining license from the patentees. Article 89 also provided for revocation of patent grants.⁴⁵

One of its seminal feature was that along with the 'product patent,' it provided for the 'process patent' wherein exact process patent was provided for. It made reverse engineering possible. This provision was significantly responsible for the rise of Indian pharmaceutical industry.

The provision for process patent and seven year duration of protection proved to be a boom for Indian pharmaceutical industry, Indian firms developed cheaper processors for successful pharmaceutical products, developed and patented abroad. This was mainly attributed to the Patent Act 1970. The success of Indian pharmaceutical sector should be seen in the light of comment of a committee of the US (Kefauer Committee) which stated that prices of drugs in India were amongst the highest in the world, early sixties"⁴⁶. Therefore it helped to reduce the price and approach the market abroad. Yet, the R&D intensity of Indian Pharmaceutical is fairly low, it is merely 2% of turnover whereas double digit investment is done by its foreign counter parts.⁴⁷ The process of reverse engineering was identified by US corporate as the legitimization of piracy which aimed at promoting trade in counterfeit products. Due to which India was brought under 'priority list' under US 'Special 301' USTR provision. This is applicable to the states which fail to provide IP protection to US commodities. Yet, it is also a known fact, that these provisions were invoked in the backdrop of the Uruguay round negotiations wherein the third world was coerced to accept certain provisions in the package deal of WTO.

⁴⁵ Dunkel, op. cit., p. 82.

⁴⁶ Parvinder Singh, "Intellectual Property Rights and the Pharmaceutical Industry", New Delhi, Proceedings of the Seminar Conducted by National Working Group on Patent Laws, p. 3.

⁴⁷ Nachane, op. cit., p. 263.

At this juncture, it is pertinent to examine the opinion of various organisations and political parties on the issue of accessing to GATT and analyse the gradual changes that were witnessed in their approaches. The issue of IP was highlighted in late 80s on the question of joining Paris Convention. In this regard Prime Minister Science Advisory Council had constituted a study group on patent in 1986. It recommended that nothing should be done to undermine the supremacy of patent Act. Industry also supported this view. Indo-American Chamber of Commerce in December 1988 suggested Government of India, against joining Paris Union and urged it to maintain status-quo.⁴⁸ In case of change, they demanded national debate.

Later, the debate assumed wide proportions, particularly in wake of Dunkel Proposal. There was wide spread concern about Dunkel Draft and there was demand for extensive national debate. In the wake of vociferous urging by industry and trade organisation on issue of DDT package, Government of India asked for more time for deliberations. The contradictory views within the Cabinet, led to setting up of a Cabinet Committee as there was major apprehension, particularly in the backdrop of 1991 financial crisis. It was feared that international financial institutions would try taking advantage of the political and economic vulnerability of India and track support by promising large scale financial flows, technology transfer and modernization.

The Cabinet Committee was constituted under Human Resource Development Minister Arjun Singh⁴⁹. The rationale behind constituting was committee on GATT under the Human Resource Development Ministry is a very controversial proposition. This Parliamentary Act, precisely conveys the casual approach that the third world countries have

⁴⁸ Parvinder Singh, op. cit., pp. 5-6.

⁴⁹ Anita Ramanna, "Policy Implications of India's Patent Reforms", Mumbai, Economic and Political Weekly, 25 May, 2002, p. 2064.

adopted towards crucial international issues. This clearly brings out the lack of experience and expertise and the unpreparedness of the government of the day. It invited leaders of various constituencies viz. industry, trade organisation etc. for consultation.

Another committee was constituted under Gujral. Opinion was particularly apprehensive about the TRIPs agreement as Gujral Committee, opined that TRIPs agreement was an attempt by the industrialized countries to strengthen their monopoly over technology. The committee saw it as a protectionist, anti competitive and anti liberalization approach.⁵⁰ Gujral Committee expressed concern over the fact that the agreement would have a 'grave impact' on drug prices and would pose a threat to the indigenous drug industry which could be gobbled up by the foreign multinationals.⁵¹ In spite of the differences, the Commerce Ministry accepted and claimed the DDT proposals it 'as the only option'.⁵² Nayar says that it was a defeatist approach and did not adequately saw the option that was still available for the country.

In this context, later the Arjun Singh Panel Report accused the Commerce Ministry of first eliciting data and views from the Indian Industry in the implication of adherence to DDT and then allegedly "fiddling with the figures" to play down the adverse impact of adherence to DDT in India.⁵³ In this connection Iyar sites the privately circulated paper which stated that changes in Patent Act are in the offing. Yet the Union Minister assured the parliament that it had no intention of changing patent law.⁵⁴

⁵⁰ People's Commission on GATT: On Constitutional Implications of the Final Act, New Delhi, Centre for Study of Global Trade and Sustainable Development, 1986, p. 42.

⁵¹ Ibid.

⁵² B.M. "Encroaching Political Support for Structural Adjustment", Mumbai, Economic and Political Weekly, January 25, 1992.

⁵³ Economic Times, May 1, 1992.

⁵⁴ People's Commission on GATT (1986), op. cit., p. 42.

Rajiv Kumar⁵⁵ suggests that there was a shift in India's stand from confrontationist stance to lower profile and constructive role. The deviation from its original stand is mainly attributed to the severe balance of payment crisis experienced by India in 1991. The situation forced India to seek immediate aid from International Monetary Fund (IMF) and the role played by US in it, is particularly cited. Rajiv Kumar sees the change of stance as a parallel process to the receipt of structural adjustment loan from World Bank.⁵⁶

Correa⁵⁷ too maintains that TRIPs has left little margin for domestic legislation. Nayyar claims that the new structure hampered the sanctity of the national legal structure. Correa here in this context, Nayyar particularly cites Article 27 of TRIPs relating to the scope of patentability and Article 31, as these provisions delimit the notion of sovereignty of state. It is suggested that it was better for developing countries like India to opt out and get concessions bilaterally. While Anandi Shahu⁵⁸ states that "Article 31 gives lots of scope and leverage, to the Government of the country concerned so that their people in the country are not put in any difficulty".

National Working Group on Patents, cautioned that Dunkel Draft package will lead to 'Latin Americanisation' of The East and South. The Dispute Settlement Mechanism was also a particular concern as it was argued that the disputes between sovereign rights of a country will be decided by a body over whose constitution, the developed countries have complete control.

⁵⁵ Rajiv Kumar, "The Walk away from Leadership: India" in Daina Tussie and David Glover (ed.), The Developing Countries in World Trade, Boulder, Lynce Rienner Publishers, 1993, p. 158.

⁵⁶ Ibid., p. 157.

⁵⁷ Correa, op. cit., p. 94.

⁵⁸ Proceedings of Parliamentary Debate (Lok Sabha) on the Patents (Amendment) Bill, 2002.

Yet, the Commerce Minister is believed to have advised the Cabinet to accept the Dunkel proposals on grounds that an international accord on the basis of Dunkel Package may help us to “buy peace” in relation with developed countries.⁵⁹ This statement must be seen in the light of various provisions of super 301 which were imposed on developing countries in the negotiating process.

It would now be relevant to analyse the views of different political parties. Though there were discerning voices within the Congress, but since it was in the power, the dominant view prevailed.

The main opposition party BJP⁶⁰ which strongly believed in strengthening of international economic cooperation. It supported the idea of new world economic order so that, the developing countries will not have to play subordinate role. Yet, it too opposed the Dunkel Draft Text as it would result in imbalances in economic progress of member country. It indicated that DDT recognizes three categories viz. developed, developing, least developed countries. BJP argued that DDT proposes to eliminate the second and bring developing countries into unequal competition with highly developed economies. It also questioned the rationale of any new formal setup and said that there was no need of new ‘MTO’(Multilateral Trade Organisation) as WIPO and GATT already existed. It wanted no extension of patent in areas of drugs, pharmaceuticals, chemicals and agriculture. It further supported the continuation of provision for compulsory licensing. It insisted that DDT ‘as a total package’ should not be accepted. Infact Ramanna⁶¹ claims that the controversy about patent was fueled by nationalist oriented BJP, as the patent issue was used in bolstering its agenda of Hindu nation.

⁵⁹ BM (1992), op. cit.

⁶⁰ Anil Kumar and Sunil K. Garg, Dunkel Report – Text and Implications, New Delhi, Anupam Publishers, 1993, pp. 46-47.

⁶¹ Anitha Ramanna, paper present on US and TRIPs/CBD Relationship.

The position of CPI(M)⁶² is evident from its views presented before the Cabinet Sub-committee, wherein it argued that :

1. DDT has implications for economic sovereignty of the country.
2. It saw this as nothing but an attempt of globalisation of the US, provision of Super 301, giving all the powerful countries the legal instrument to force their priorities on economic – technical developments of the developing countries. Which is legalised through the institution of GATT.
3. Trans-nationalisation of global economy will lead to conversion of Indian capitalist into sub contractors in search of short term profits.
4. They claim that DDT rejected special needs and differential treatment in IPR in view of the special national economic and technological conditions of the development countries.

But the Commerce Ministry has rejected bulk of criticism voiced at various fora including deliberations by group of Ministers. It maintained apart from 'improvements and clarification' in few areas including TRIPs, as a whole was more or less acceptable. The Commerce Ministry's background paper on DDT suggested that :

1. It agreed that some prices will increase as until then only 10-15% of drugs were patented. They argued that in case of adverse impact, compulsory licensing provisions can be evoked.
2. It claimed that due to adverse impact of process patenting regime, the foreign firms hesitated in allocating more funds. However, with

⁶² "The GATT Dunkel Proposal - Retrograde Step Towards Recolonisation", People Democracy, February 2, 1992.

the introduction of product patent now such funds, will be available for tropical diseases research.

4. Rejecting the criticisms, it claimed that reversal of burden, to some extent, already existed in Indian Evidence Act.⁶³

Gradually, there was shift in opinion of various constituencies of the corporate world too. This was amply reflected, once, Indian government signed the Marakesh agreement. In particular context to TRIPs, the pro-reform element within the political parties and rise of more modern and professionally managed segment of industry were advocating changes in existing structures. In this context, Lanjouw⁶⁴ too indicates the shift in the nature of debate on patents in Indian industry. She notes, that “No one any longer expressed doubts that India could, in fact, be in compliance with WTO’S IP requirement when deadlines were reached...” In the back drop of P(A) Bill she observes that a new debate was underway in the country on whether India should voluntarily skip to the end of period under EMR and go straight to product patent. This seems like an exaggerated statement as the debate was particularly focused on pharma sector and changes of such magnitude pose a threat to the existence of the pharma industry.

Before the Gujral Committee (constituted by Parliament, to look into the impact of WTO) had stated that India failed to get required technology due to absence of product patent, the technology was not transferred as its cheap imitation was the major concern for industrialized countries and firms.⁶⁵

In 1997, FICCI (Federation of Indian Chambers of Industry and Commerce) established International Institute of Intellectual Property

⁶³ R. Ravikant and M. Mishra, *The Economic Times*, March 29, 1992.

⁶⁴ Anita Ramanna (2002), *op. cit.*, p. 2065.

⁶⁵ *Ibid.*

Development which aims at promoting the patenting culture amongst the scientific and technical committee and promote use of IPR as a strategic tool for forwarding business interest. TRIPs agreement is also analysed in wider context of the constitutional issues. Due to its constitutional implications, the Patent Amendment Bill was challenged in Delhi High Court.

It was pointed out that according to the new provision, the persons who have valid grounds for objection to the grant of EMR's, would be unable to do so and hence they will be deprived of their means of livelihood. This is a violation of fundamental right under Article 19(1)(g) and Article 21.⁶⁶

In context of Article 27 of TRIPs, which provides for patent / sui generis system of plant protection. Nachane⁶⁷ opines that reaction of farmers is likely to be a function of their holdings. It is realized that Indian farmer could access benefit of biotechnology, only if India is a party to IPR protection, relatively large farmer support and is opposed by small farmers. Infact, farmers lobby was one of the prime actors in opposing DDT. While on the contrary Usha Menon⁶⁸ says that since modern technology is controlled by private interest, such technology would not be available to farmers. She opines this impediment to the absorptions of technology would be made difficult as government too is shifting its research base from development of finished varieties to concentrate on basic research. But it also involves deeper issues.

Analyst state that providing proprietary rights over basic tools of farmers i.e. seed will amount to encroachment of their rights to occupation under Article 19 of Indian constitution. It is also related to the fundamental question of food security, as it make threaten citizen's right to life under

⁶⁶ Writ Petition Filed by Vandana Shiva in Delhi High Court.

⁶⁷ Nachane, op. cit., p. 216.

⁶⁸ Menon, "Intellectual Property Rights and Agricultural Development". Economic and Political Weekly, 6-13 July, p. 1666.

Article 21. Infact, in this context Zaveri refers to the judgment of Supreme Court, which stated that, “the right of a citizen to live under Article 21 costs obligation on the state. This obligation is reinforced under Article 37, it is the duty of state to secure health to its citizens wherein the court said that it ‘is a primary duty’.⁶⁹” (Ref. (1988) 4 SCC 117.

Many commentators also claim it to be against the spirit of the universal declaration of Human Rights. As Article 25 lays that, “everyone has the right to a standard of living adequate for the health and well being of himself and his family including medical care and necessary social services.....” In this context Keayla⁷⁰ quotes the resolution of the sub committee of UN Commission on Human Rights which noted that IPR in TRIPs agreement constituted contravention of International Human Right Laws.

In particular context to India, it is opine that it will impinch upon the duty of provided under Article 47 of Directive Principles of State Policy, which directs the state “raise the level of nutrition and the standard of living and to improve public health”. It is pointed out that patents second amendment bill provides stronger protection to patent holders and implies that the balance of inventor and general public is being shifted in favour of former.

Inspite of all the debates within the government and at the level of civil society. all the countries are bound with the provision of TRIPs.

They are obliged to amend their domestic laws in accordance to the TRIPs agreement. It would imply major modification in the existing structures.

⁶⁹ N.B. Zaveri, Patents for Future, Mumbai, Vakils, Feffer and Simons Limited, 2001, p. 154.

⁷⁰ Keayla, TRIPs, Patent System: Issues for Patent (Second Amendment), 1999, in Kaul and Ahuja (ed.), Law of IPR: In Prospect and Retrospect, Delhi, DU Faculty of Law, 2001.

The major modifications required vis-a-vis the existing Indian Patent Law 1970 are⁷¹:

1970 Act	Modification
<ul style="list-style-type: none"> ▪ No product patent allowed for pharmaceuticals, food products and agrochemicals; only process patents. 	<ul style="list-style-type: none"> ▪ Product patents to be allowed in all fields of technology without exception.
<ul style="list-style-type: none"> ▪ Duration : 14 years for all except for patents in pharmaceuticals, food products and agrochemicals, where it is seven years. 	<ul style="list-style-type: none"> ▪ Uniform duration of 20 years.
<ul style="list-style-type: none"> ▪ Government has powers to grant compulsory licenses. 	<ul style="list-style-type: none"> ▪ Compulsory licenses to be given only on merits of each case.
<ul style="list-style-type: none"> ▪ Importation does not amount to working of patent. 	<ul style="list-style-type: none"> ▪ No discrimination between imported and domestic products.
<ul style="list-style-type: none"> ▪ For process patents, in case of infringement, burden of proof on plaintiff. 	<ul style="list-style-type: none"> ▪ The burden of proof will rest on the infringer (reversal of burden of proof).

The table amply reflects the direction of Patents Law reform in India. The shift in the laws are evident. It is also important to know the trajectory of IPR laws in India, with particular reference to patent laws.⁷²

⁷¹ P. Ganguli, Gearing up for Patents, The Indian Scenario, Hyderabad, University Press, 1998, p. 32.

⁷² www.patentindia.com

1856	The Act VI of 1856 on Protection of inventions based on the British Patent Law of 1852. Certain Exclusive Privileges granted to inventors of New Manufacturers for a period of 14 years.
1859	The Act modified as act XV, patent monopolies called exclusive privileges (making, selling and using inventions in India and authorizing others to do so for 14 years.
1911	The Indian Patents of Designs Acts.
1972	The Patents Act (Act 39 of 1970) came into force on 20 ^h April 1972.
1999	On March 29, 1999 Patents (Amendments) Act, (1999) came into force from 01-01-1995.
2002	The Patents (Amendment) Act 2002 came into force from 20 th May 2003.

The last two were the result of India's international commitment. In India the patent reform process began with the passing of ordinance in 1994 to amend Patent Act 1970. In 1995, it was passed by Lok Sabha but could not be put forth before the Rajya Sabha. It provided provision for mail box mechanism for accepting product patent application to examine the grant of EMR. Since it was not passed, EU and US filed complaint against India due to its failure to comply with article 70.8 of the TRIPs Act.⁷³ In 1999 it was passed mainly to accommodate the provision of EMR. Section 5 was amended by adding sub-section (2) for granting of patent for pharmaceutical products which facilitate the applicant to file their application for grant of EMR.

⁷³ Business Standard, August 30, 1998.

The time lap between various enactment dealing with the patent laws amply reflect the changing pace. Infact as India approaches 2005, wherein transitory phase ends, India will have to bring new laws in effect. As India approaches its next stage of patent reform, the terms of debates are already fixed. The opinion regarding patenting of life forms have again come to the centrestage it is of particular importance in the light of recent supreme court judgement in Damminaco case, wherein the court has granted patent rights over a microorganism. Parallels are drawn with Diamond vs. Chakraborty Case (US).

Secondly, it should be noted that due to lack of any institutional arrangements like depositories etc. India's genetic resources are finding their way towards foreign depositories. It represents dilemma as the opinion is not very favourable regarding patenting of life forms. Yet, in order to safeguard its genetic resources, it is imperative to install legal and institutional infrastructure.

The debate in India amply reflects the paradoxes and challenges faced by its Third World counter parts one of the prime concern is regarding the provision in Article 27 wherein they will have to grant IPR over living forms. This is not just an issue of law, but involves greater dimensions. It would be apt to quote Guna⁷⁴ wherein he traces the cultural reason behind the opposition of IPR regime in the third world. He opines that "the idea of intellectual goods as property meet 'unprecedented resistance' in many Asian countries". Though these countries may abide by the law but it would not easily translate into culture.

It is imperative for third world to consider its long term security while negotiating in international forums.

⁷⁴ Ruth Guna, op. cit., p. 263.

CHAPTER - V

CONCLUSION

In the light of forthcoming Cancun, WTO Ministerial Meet, it is an opportune moment for the third world to review and reflect, so as to determine future strategy. Intermingling of the issues of IPR, with the advancement of biotechnology has produced immense challenges and opportunities for the third world.

This analytical work has focused on the implications of the interplay of IPR & biotechnology vis-à-vis the third world. In retrospect, the work reflected upon the international regime and by tracing the trajectory of the IPR, it attempted to fit the latter in the broader framework of the former.

An attempt was made to trace the process of evolution of biotechnology as an industry. It tried to understand its linkage with IPR regime particularly through the mode of patents. Effort was made to decipher the complex relationship between biotechnology and biodiversity particularly in the light of recent controversies.

It also inquired as to how the combination of the two factors viz. IPR and biotechnology have implications for the third world. By tracing the historical trajectory an attempt was made to trace bonds of commonality for the future. It analyses various contentious issues between the third world and the world at large.

International opinion about the position of Third World regarding the issues of IPR and biotechnology was reviewed. The Third World countries are trying to accommodate and amend their domestic legislation according

to the provisions of TRIPs. The case of India had been presented as an elucidation of the debates presents in the third world.

In this objective assessment, it is amply clear that the linkages generated due to the interaction of the issues of IP and biotechnology have crossed over the domain of law and science respectively to enter into every sphere of public discourse, be it politics or ethics. This has particular implications for the third world, as the intermingling of these two disciplines have long term impact upon the security of millions. It poses a threat to the claim of an individual's human rights and citizen's fundamental rights to life, food and health in third world. In this instance, the law is following science to accommodate new issues generated by technological advancements.

However as is evident from the analyses of the trajectory of issues of IPR and biotechnology, rather than being based upon principle of jurisprudence these issues influenced by the behaviour of individual actors. In the international arena, it was amply reflected in the negotiation process, during the Uruguay Round. Despite being apprehensive initially, the third world accepted, the package deal of WTO. The change in the attitude of the third world towards the issue of IPR is also reflective of the changes in their perspective, particularly in the post cold war scenario.

Today, Third World is at the receiving end of the negotiations. It is mainly attributed to their lack of expertise and experience and also due to the increase in technicalities involved in the issue. The gravity of the situation is supplemented by their lack of adequate legal and administrative infrastructure. Actually, these are secondary issues as the Third World countries are primarily engaged in struggles of daily survival, which seek immediate attention. In the emerging international order the third world needs to adopt a precautionary approach, as these vital issues cannot be ignored. Since, it also involves the issues of transfer of technology and

proprietary knowledge, it has implications on the long-term strategic and developmental needs of third world.

The Third World is particularly apprehensive about the partnership of biotechnology and intellectual property rights regime. Though concern regarding inequities involved in technology and the proprietary knowledge existed for long, but the issue gained popular currency only after the negotiations and enactment of TRIPs agreement. The nature of technological developments demanded new measures for protection. Particularly, biotechnology industry urged for stricter IP protection norms due to highly imitative nature of this knowledge based industry. This move was perceived as an attempt to keep the technology in the exclusive domain of the developed countries, leading to enhancement of technological dependency of the third world.

In the postcolonial era, most of the third world countries used legislative measures as tools of public policy. In particular, patent laws were reframed, so as to play instrumental role in realising national priorities. In most countries, patent laws provided for exemption in food, chemical and pharmaceutical from the list of patentable products and followed the mode of 'process patent'. The new regime, as analyzed before, is diametrically opposite to the existing framework, wherein the term of patent is extended to twenty years and moves are made towards adoption of 'product' patent regime. In new framework, the exemption clause is workable only in case of emergency. Such conditionalities do not go too well with the defined national objectives of the third world. It also adversely affects their production process, which may have adverse socio-political and economic implications. Thus, patent regime is apprehended to produce adverse impact on food and health security.

Another overriding concern is regarding reform and amendment in the domestic laws, in compliance with the provisions of TRIPs agreement, to

bring domestic intellectual property reforms on the lines of the provision of TRIPs. The new measures are more stringent and are perceived to be inimical to the national priorities of the countries of third world.

Regarding the proprietary rights over the plant variety, the TRIPs agreement provides for provides the option of either adopting patent system or 'sui generis' system. It is apprehended that such measures may lead to immense increase in the prices of seeds and will greatly hamper the rights of farmers to save seed. Since, seeds are intrinsically linked to the farmer, it may have adverse impact upon the rural social fabric. Biotechnological advances coupled with IP protection are deemed as suicidal for the farmers. Particularly, with the introduction of GURT technology, rights and livelihood of the farmer and the food security of the state would be threatened. This may also lead to collapse of public distribution system.

In biotechnology, biodiversity is the raw material. The third world is blessed with enormous biodiversity, but the industrailised countries uses and amends the germplasm of the south to suit their needs on basis of their technological superiority. These modifications are later claimed as an invention in form of GM products and proprietary rights are secured over it through the instrument of IP. The third world is debarred of its germplasm without any compensation, but in turn has to pay huge amount as royalty for the use of the commercially useful genetically modified products.

In particular context to biotechnology, the current IPR regime focuses on the identification of the particular trails or characteristic of gene with the application of biotechnology, the traditional knowledge has been converted into proprietary knowledge through the instruments of IPR's. It is important for third world to create scientific and technical infrastructure and capacities so that they can prove the scientificity of the claims of

traditional knowledge system. Many visualize this arrangement as drainage of resources of the third world and suggest that they should engage in tie ups with foreign collaborators. However in this arrangement due to the increasing costs of technical advancement and the tightening of patent regime, the third world debt will thereby enhancing their longterm dependency on industrialized countries. It would also adversely affect the national production system. To discern these designs, it is imperative for the third world to actively engage in the process of negotiations, as it is their future that is at stake.

Another overriding concern is that TRIPs only recognizes one domain of knowledge i.e. 'formal' western system and neglects the public domain of collective knowledge system.

Due to the non-acknowledgement of its traditional knowledge, third world has become vulnerable to the quest of TNC's. In this process not only the germplasm but also the traditional knowledge is at stake. It adversely affects the very existence of the indigenous communities. The researchers through the mode of biotechnology, appropriate the traditional knowledge to produce proprietary knowledge. This process is legitimized through the tool of intellectual property. Though CBD has recognized the sovereign right of state over its natural resources, but through the flourishing business mechanism of bioprospecting, both the traditional knowledge and germplasm are at stake. Third World is confronted with a new situation, where in the guise of Eco Tourism, bioprospecting prospers. WIPO has taken the note of the issue of traditional knowledge system but it is pertinent to bring it on WTO agenda.

In this context, equally important is to fight the nuances on the domestic front. Few African countries have enacted domestic legislations to protect their traditional knowledge systems and rights of indigenous community. Law has to be supported by the societal measures Wide dissemination of

information amongst the masses is required so as to generate awareness regarding their knowledge and generate zeal to protect it. It is important as many individuals from within the community are engaged in patenting their traditional knowledge, in the foreign lands as is evident in the turmeric case.

Third world countries allege that the present patent system legalise bio piracy. Particularly the domestic Legislations of few countries are identified as providing incentive to such process. Third world must take the issue of Article 108 of US Patent Act to WTO's Dispute Settlement Mechanism because by not recognizing foreign 'prior art', it in effect legitimizes bio piracy.

To avoid biopiracy many alternative models have been suggested and applied at community level like maintenance of registers, codification of folk and tribal knowledge, digital codification of classical knowledge, establishment of Traditional Knowledge Digital Libraries etc. The mere codification and enactment of laws are not enough as they seem to be mere defense mechanisms. It is suggested that these knowledge resources should be used rationally and optimally. Its commercial exploitations should be encouraged. It would serve the interest of the community in two ways. Firstly, it will bring monetary benefits to the stake holders and secondly, it will work as incentive for conservation of natural resources. This rationale since to be a more pragmatic steps in the era of the commercialisation.

In the absence of legal and administrative structures like depositaries or membership to any international treaty, the micro organisms of the third world find their way in the depositaries of the north, whereby through research they are converted into patentable objects. Thus, the cutting edge of the industrialized countries lies in its biotechnological advances while that of third world in its biodiversity. Suggestions are made to engaged

actively in exchange programmes wherein third world should bargain for technology transfer while transferring their germplasm. Such arrangements will make technology accessible to them. However this is not adequate compensation for the transfer of natural wealth.

The process of acquiring germplasm is old but the current situation of appropriations of traditional knowledge has taken serious dimensions. As now the biotech companies also use the traditional knowledge for extracting commercially valuable information. Rather than going for benefit sharing arrangement, the contribution of these indigenous communities is not even acknowledged.

To confront this inequitable situation, alternative mechanism of 'Collective Intellectual Property Rights' is suggested. As the general perception in the third world is that traditional knowledge system is part of public domain that cannot be privately appropriated. This alternative may pose problems as conflicts may arise regarding the issue of who should be given priority; the rights of the state or short of the community, as the issues of ownership of biodiversity and the traditional knowledge are implicit. It can also lead to private appropriation by few individuals, which is deemed as more harmful for it would produce inequity within the system. Vigilance at the level of community is paramount. In this context the role of regional groupings is essential as they share geographical intimacy, they can provide a viable monitoring option

At international level to deal with the menace there is a need to establish some kind of international monitoring mechanism. With the coordinated efforts of the states, and the involvement of agencies like WIPO; the system for international monitoring of the patents application involving traditional and indigenous knowledge of foreign lands should be initiated. Though, it may appear to be a tedious and enduring process, yet it seems viable in the long-term interest.

The second concern deals with the experimental branch of biotechnology i.e. genetic engineering. Initially, it was hailed as an 'eco-friendly' answer to the world problems of hunger, death and disease. But its extension in the arena of food crops and lifeforms has generated debate across ideological spectrum. It's potential to forge new international alliances is evident. On the issue of GM crop old partners EU and US are engaged in legal and political battles. While two of its most ardent supporters of GM crop i.e. China and US were once situated in dramatically opposite ideological camps.

GM crop has presented dilemmas before the Third World it restricts ability to take an independent stand by readily accepting or rejectioning the use of GM crop. Their decision-making process is influenced by the opinion of other international actors. Thus, it greatly reduces the element of rational choice before the third world. It is forced to reject the technological advances due to export orientation of their economy. It also includes implicit issues of ownership of germplasm, relation with biodiversity and concerns regarding biosafety.

With the extension of Genetic Engineering technique to modify living organism, the ethical issue has taken legal overtones. Due to considerations of bio-safety, this debate has become highly politicised, as the third world countries are the 'center of origin' of most species. The interaction of the induced GMO with its wild variety may have catastrophic implications on the ecology. Before introducing patent on life forms, Third World must ensure that its infrastructure is adequately planned. This issue needs to be debated in the context of wider socio-economic issues.

In this objective assessment about the process, which was initiated during the Uruguay Round and continues to be a dominant paradigm still, it is amply clear that this system of international politics and economy, has

posed several challenges before the apparatus of the state. This international regime is perceived as a threat not only to political or economic sovereignty of state by affecting its domestic legislation and international economic integration. It has generated predicament in the relationship of executive and legislature. It has particular implications for the federal structures. The international regime has attempted to redefine the role and structure of state. Though regulative powers of the state have increased but in effect, its power to make rational choices is greatly curtailed particularly, in terms of the third world.

In spite of the differences in the perception and needs of the third world countries, it is imperative for them to present a united front on the negotiating table. The partnership should not be only on account of their past shared experiences but should also be based upon considerations for future. There is a need to evolve a strategically planned approach on crucial issues.

Third world needs to adopt a more pragmatic approach, which can fulfill their strategic needs. It should endeavor to rejuvenate international institutions like WIPO and UNCTAD. So, that these institutions can serve as fora for third world engagement and influence the decision-making procedures on crucial issues including TRIPs and all other international agreements of WTO. On the particular issues of IPRs, the third world needs to chalk out a well-planned coordinated strategy. It is suggested that G-77 as a forum of developing countries should also consider such matters and provide a common ground for strategic negotiations.

The need to forge alliance is not only essential for the state but the alliances within the civil society across the third world is of paramount importance. The process of negotiation regarding Doha Ministerial Declaration on Health amply reflects that, accordance if united attempts are made by states, and non state actors are mobilized, they can succeed

in changing the international agenda in accordance with their needs. Non-Governmental Organisations and citizen's alliances can provide a platform for sharing and learning from each other's experience and policy imperatives.

Another crucial factor that began with Uruguay Round was the rise of various non-state actors like corporate, lobbies and the civil society. From mere pressure group, they have emerged to play decisive role. The former were particularly active in bringing the IPR agenda in WTO while the latter are fore, runners in the protest against such attempts.

While amending their domestic policy they should keep their long term national interest in mind. But the commonality of national interest has to be found in the third world, so that they could move towards more equitable standards of IPR rather than bearing the brunt of biotechnological revolution, they can now become its beneficiaries. Thus it is pertinent on part of the Third World to adopt a pragmatic approach and engage actively and strategically in the bargaining process.

The whole controversy regarding the linkages of intellectual property and biotechnology vis-à-vis the third world can be summarized in one single word "seed". Seed, which are abundantly found in the Third World is interpreted in two capacities. First, as a 'germplasm' and secondly, as a 'grain'. As a 'germplasm' it is the ingredient for biotechnology while as a grain it is the manifestation of cumulative knowledge of generations, which is vulnerable to contesting claims of Intellectual Property Right. For India, it is imperative to work towards harmonization of the two.

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APPENDIX - I

Relevant Provisions of Agreement on Trade-Related Aspects Of Intellectual Property Rights

Agreement on trade-related aspects of intellectual property rights including trade in counterfeit goods.

Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective adequate protection of intellectual property rights and to ensure that measures and procedures to enforce intellectual property rights do not themselves outcome barriers to legitimate trade;

Recognising, to this end, the need for new rules and disciplines concerning:

- a) the applicability of the basic principles of the GATT 1994 and of relevant international intellectual property agreements or conventions;
- b) the provisions of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;
- c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal system;
- d) the provisions of effective and expeditious procedures for the multilateral prevention and settlement of disputes between government; and
- e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognising that intellectual property rights are private rights;

Recognising the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognising the underlying the public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognising also the special needs of the least-developed country Members in respect of maximum. Flexibility in the domestic implementation of laws and

regulations in order to enable them to create a sound and viable technological base;

Emphasising the importance of reducing tensions by reaching strengthened commitments to resolve dispute on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property organization (WIPO) as well as other relevant intellectual organisations;

Hereby agree as follows:

Part I
General Provisions and Basic Principles
Article 1
Nature and scope of obligations

1. Members shall give effect to the provisions of this agreement. Members may, but shall not be obliged to implement in their domestic law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of the Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.
2. For the purpose of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 to 7 part II.
3. Members shall accord the treatment provided for in the Agreement to the nationals of other Members. In respect of the relevant intellectual property right, the nationals of these Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the MTO members of those conventions. Any member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights.

Section 3: Geographical Indications
Article 22
Protection of geographical indications

1. Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

2. In respect of geographical indication, Members shall provide the legal means for interested parties to prevent:
 - (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;
 - (b) any use which constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Conventions (1967).
3. A Member shall, ex officio of its legislation so permits or at the request of an interested party, refuse or invalidate the registration of a trade mark which contains or consists of geographical indication with respect to goods not originating in the territory indicated, if use of the indication in the trade mark for such goods in that Member is of such a nature as to mislead the public as to the true place of origin.
4. The provisions of the preceding paragraphs of this Article shall apply to a geographical indication which although literally true as to the territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory.

Section 5: Patents

Article 27

Patentable subject matter

1. Subject to the provisions of paragraphs 2 and below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality; including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.
3. Members may also exclude from patentability:
 - a. diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

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

Article 28

Rights conferred.

1. A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of the patent is a product, to prevent third parties not having his consent from the acts of making, using, offering for sale, selling, or importing for these purposes that product;
 - (b) Where the subject matter of a patent is a process, to prevent third parties not having his consent from the act of using the process, and from the acts of : using, offering for sale, selling or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29

Conditions on patent applicants

1. Members shall require that an application for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning his corresponding foreign applications and grants.

Article 30

Exceptions to rights conferred

Members may provided limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other use without Authorisation of the right holder

Where the law of Member allows for other use of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorized by the Government, the following provisions shall be respected.

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. this requirement may be waived by a member in the case of a national emergency or other circumstances of extreme urgency or in case of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search knows or has demonstrable grounds to know that a valid patent is or will be used by the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorised, and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
 - (k) Members are not obliged to apply conditions set forth in sub-paragraphs (b) and (f) above where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur
1. where such use is authorized to permit the exploitation of a patent (the second patent) which cannot be exploited without infringing another patent (the first patent) . The following additional conditions shall apply.
 - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (ii) the owner of the first patent shall be entitled to a cross licence on reasonable terms to use the invention claimed in the second patent; and
 - (iii) the use authorized in respect of the first patent shall be non-assignable except assignment of the second patent.

**Article 32
Revocation/forfeiture**

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

**Article 33
Term of protection**

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

**Article 34
Process patents: Burden of proof**

1. for the purpose of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 285 above, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, members shall provide, in at least one of the following circumstances, that any identical product when produced without the

consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

- (a) if the product obtained by the patented process is new;
 - (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.
2. Any Member shall be free to provide that the burden of proof indicated in paragraph I shall be on the alleged infringer only if the condition referred to in sub-paragraph (b) is fulfilled.
 3. In the addition of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business Secrets shall be taken into account.

APPENDIX – II

Relevant Provisions of Convention on Biological Diversity

Preamble

The contracting parties,

Conscious of the intrinsic value of biological diversity and of the ecological, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components,

Conscious also of the importance of biological diversity for evolution and for maintaining life sustaining systems of the biosphere,

Affirming that the conservation of biological diversity is a common concern of human kind,

Reaffirming that States have sovereign rights over their own biological diversity and for using their biological resources in a sustainable manner,

Concerned that biological diversity is being significantly reduced by certain human activities,

Aware of the general lack of information and knowledge regarding biological diversity and of the urgent need to develop scientific technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures,

Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,

Nothing that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat,

Noting further that the fundamental requirement for the conservation of biological diversity is the in situ conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings,

Noting further that ex. Situ measures, preferably in the country or origin, also have an important role to play,

Recognizing the close and traditional dependence of many indigenous local communities embodying traditional lifestyles on biological resources, and the

desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components.

Recognizing also the vital role that women play in the conservation and sustainable use of biological diversity and affirming the need for the full participation of women at all levels of policy-making and implementation for biological diversity conservation,

Stressing the importance of, and the need to promote international, regional and global cooperation among States and intergovernmental organizations and the non-governmental sector for the conservation of biological diversity and the sustainable use of its components,

Acknowledging that the provision of new and additional financial resources and appropriate access to relevant technologies can be expected to make a substantial difference in the world's ability to address the loss of biological diversity,

Acknowledging further that special provision is required to meet the needs of the developing countries, including the provision of new and additional financial resources and appropriate access to relevant technologies,

Noting in this regard the special conditions of the least developed countries and small island States,

Acknowledging the substantial investments are required to conserve biological diversity and that there is the expectation of a broad range of environmental, economic and social benefits, economic and social benefits from those investment,

Recognizing that economic and social development and poverty eradicating are the first and overriding priorities of developing countries,

Aware that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential,

Noting that, ultimately, the conservation and sustainable use of biological diversity will strengthen friendly relations among states and contribute to peace for humankind, conservation of biological diversity and sustainable use of its components, and

Determined to conserve and sustainably use biological diversity for the benefit of present and future generations,

Have agreed as follows:

Article 1. Objectives

The objectives of this convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 10. Sustainable Use of Components of Biological Diversity

Each Contracting Party shall, as far as possible and as appropriate:

- (a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;
- (b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;
- (c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;
- (d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and
- (e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.

Article 15. Access to Genetic Resources.

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that party.
6. Each Contracting Party shall endeavor to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Article 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Articles to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.
2. Access to and transfer to technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Article 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be a provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.
3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to an transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1,2 and above.
5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 18. Technical and Scientific Cooperation

1. The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.
2. Each Contracting Parties, in particular developing countries, in implementing this Convention, inter alia, through the development and implementation of national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building.
3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.
4. The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies in pursuance of the objectives of this Convention. For this purpose, the Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.
5. The Contracting parties shall, subject to mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.

Article 19 Handling of Biotechnology and Distribution of its Benefits.

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on fair and equitable basis by contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.
3. The parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.
4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information above the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting party into which those organisms are to be introduced.