TRADE RELATED INTELLECTUAL PROPERTY RIGHTS – IMPACT OF PHARMA INDUSTRY

INSTITUTIONS PROMOTING “INTELLECTUAL PROPERTY RIGHTS”

I. GOVERNMENT INSTITUTIONS

II. PRIVATE INSTITUTIONS

III. CIVIL SOCIETIES

IV. IPR TRAINING

CHAPTER - VII
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INSTITUTIONS PROMOTING “INTELLECTUAL PROPERTY RIGHTS”

Introduction:
Since the very dawn of civilization, intellectual property has been propagated and protected through many forms. Mythological stories and tales of how intellectuals and artisans preserved their skills have been part of folklore and history. With the advent of the industrial revolution, the pace of inventions and their usage gathered speed. It was at this time that the commercial potential of inventions was actually appreciated. In today’s context, time and resources being very valuable inputs in the knowledge economy, the management of Intellectual Property Rights (IPRs) has become a major issue to be addressed by the inventor, those who market an invention and the Government. As in many developing countries, an optimum exploitation of intellectual property is also a matter of concern and discussion in India. Being in a transitional phase, the Indian industry is still comprehending its IPR needs and experimenting with different approaches towards their management. Though the legal framework for the common intellectual properties has been in place since many years, the support systems have been established quite recently.

This research work attempts to bring out the recent initiatives and the various synergies that are operating to focus and develop IPR in India. The promotion of IPR is through the following channels. (Shahid Alikhan and Ragunah Mashelkar)

I. GOVERNMENT INSTITUTIONS
II. PRIVATE INSTITUTIONS
III. CIVIL SOCIETIES
IV. IPR TRAINING PROGRAMMES
VII. 1. GOVERNMENT INSTITUTIONS

Government plays a very dominant role in promoting IPR in India through various institutions, policies and programmes. Some of them are as follows:

National System of Innovations as a Policy Framework:

Innovation is the key of the production as well as processing of knowledge. Indeed, a nation’s ability to covert knowledge into wealth and social good through the process of innovation determines its future.

In the industrialized countries, and in a growing number of newly industrializing courtiers, policy markers have found that the concept of National System of Innovation (NSI), provides a useful framework for technology policy formulation. Such a policy helps define the necessary inputs, initiatives and incentives, which produces a competitive economy in today’s increasingly globalised markets. NSI can be thought of as a set of functioning institutions, organisations and policies, which interact constructively in the pursuit of a common set of social and economic goals and objectives, and which use innovation as the key promoter of change.

Different Types of Technology Innovations:

In a classical sense, we have three types of technology innovations. Firstly, there is a large system innovation (such as a man on the moon mission); secondly, incremental innovation (such as development of an improved fax machine); and finally radical breakthroughs (such as an accidental breakthrough leading to the antibiotic industry). These invariably take place through formal systems of innovation, namely universities, individual inventors, industrial R&D laboratories, etc., Governments play a critical role in launching and meaning large system innovations.

In incremental innovations, the government can play a facilitating role. Radical breakthroughs, are based on individual enterprise and the government dose not play a role in these. Large system innovations require large funding and complex management techniques. They also require a total commitment by the government. They are driven by visionary leaders, who have a faith in the ability of their people. Innovative blending of different technologies, huge systems engineering problems, etc., are part of such innovations. Many large scale space, defense and atomic energy programmes run by different countries represent such large system innovations.
National Innovation Policy: Nurturing the Innovation Base:

With increasing globalization, the question that is engaging attention with regard to the process of innovation, is as to where do the capabilities for innovation reside. Till recently, it was believed that they reside in nation states. Certain nation states were able to create the climate and provide the necessary infrastructure, which could spur innovative genius; certain other states have failed to do so. This is how nations began building up a National System of Innovation and evolving a National Innovation Policy, which went beyond the National Science Policy or National Science Policy or National Technology or National Technology Policy. While the idea of the innovation system is still valid, the national part of it is diminishing in its importance as R&D gets increasingly inter – nationalised, and the world becomes more and more integrated.

Venture Capital Financing:

In the developed countries, it is specifically defined as equity linked investment in privately held companies. The venture capitalists provide equity investments in companies that are not mature enough to get access to capital markets but has high growth of technology driven enterprises around the world. Indeed, Apple in computers or Genetech biomedical products, to take as examples, have benefited considerably because of the availability of such venture capital.

The financing contribute by the venture investor is often relatively modest compared to the total amount that the venture – backed firm finally raises. Some governments have played a crucial role in stimulating the venture capital. For instance in the USA, venture capital had crossed the US$ 100 billion by the year 2000. This has also spurred innovation in a number of other courtiers like India.

Global Innovation Chains:

The innovation chains cross transnational boundaries today. Companies realise that to gain a competitive advantage, they have to their technical assets and capabilities, across the world; it would be rather unwise to attempt self- sufficiency in technology development, particularly in an era where the R&D costs are increasing rapidly. With trade barriers among countries disappearing fast, companies have to provide the best technology globally to their customers. As a part of the global innovation strategy, several companies the world over are looking for new ideas and technologies, which the originator may have been unable to exploit for a variety of reasons.
**Incubators and Accelerators:**

It is generally recognized that the private sector is an effective medium for creating wealth, generating employment and promoting social well-being. In turn, entrepreneurial, knowledge-based, small and medium-sized enterprises are the backbone of the private sector as they help diversify the economy, and offer a wide range of goods and services both to national and international markets. Most countries have formulated strategies for promoting innovation and assisting small enterprises in acquiring modern technological resources.

Many countries have formulated strategies for promoting innovation and creating entrepreneurial ventures. In this context, business incubators and technology parks are now proving to be cost effective in nurturing start-up technology-based enterprises.

**Expenditure on S&T:**

Expenditure on S&T is a measure, however, incomplete, of a nation’s pursuit of innovation. As important are the uses of the funds, the productivity of research and the effectiveness of its utilisation. In most developing countries, this expenditure is still under one percent of the GDP. Table 8.1 (see next page) shows the R&D investment of different nations.

In scientifically advanced developing nations, for example India, a significant part of such investment is made by the government itself. Interestingly, the research budget of a large transnational corporation such as General Motors or IBM is much larger than that of the biggest developing country spenders, such as the Republic of Korea or China or India. Further, of the total world research expenditures, developing countries together still spend well under 5%.

**Institutional Issues:**

The institutional capacity of developing countries and countries in transition for policy coordination across government, and participatory processes for IP policy making vary widely and may, in some countries, be one of the IP system. In terms of participation in international rule making, there exists a duality, since some of these countries have no permanent representation. As a result, they are often little more than spectators at the meetings of the WTO and WIPO, whilst others are active and influential participants in the international rule making processes. Again, most countries face serious financial and human resource constraints in implanting new legislation and modernising IP office procedures.
And other important activities are: Role of Government in International Relations in IP, Competition Law, Role in Awareness Building and Effective Enforcement, Enforcement Provisions in the TRIPS Agreement, Primary of the Government Role, IPR Institutions

Some of the institutions promoting Intellectual Property Rights are: WIPO, CIPTC, IIPD, ITPTI, IPC, WHO, WTO, Designing Regimes, UGC, HRD, ITT, DSIR, DIT, DBT, MOEF, MSNE, Department of Agriculture & Cooperative, NIPIT, NIIPM, Controller General of Patents, Designs and Trademarks and etc.,
VII . II. ROLE OF THE PRIVATE SECTOR IN THE INTELLECTUAL PROPERTY RIGHTS

1) Inventions to innovations
2) Private societies /Associations as protector of IP
3) Patents as tools for encouraging private R & D
4) Responsibilities of the private sector

From inventions to innovation

In most countries, the sector proactively helps and advises in the legislative revision, in response to market needs of constantly emerging new technologies, administrative reforms and in the enforcement of intellectual property rights. The profit motive in the private sector helps to harness the creative expressions and inventions for bringing innovative new products to the market nationally and internationally, and in the creation of economic value and wealth which helps the overall economic growth and development.

In envisioning the use of intellectual property tools for competitive strategies the 21st century, the inventive spirit of researchers and scientists should be combined with the innovative spirit of private sector enterprisers. In most countries around the globe, it is generally the private that are known to be distinguished innovators of products ranging from value added packaged cereals for children’s, to energy-efficient incandescent lamps to more effective and safer drugs and pharmaceuticals.

Private societies / Associations as protectors of IP

For creating new technologies and products, the private sector must constantly encourage research and development efforts and the commercialization of the resulting innovations. A well-remuneration inventor often finds his stake in the enterprises attractive enough to be an increasing part of it. While inventions and innovation are essential for active and successful participation in today’s competitive market place, the private sector in countries where inventive and creative capability is increasingly available should if one does not exist, help in setting up a national inventors association. Such as association preferably header by an eminent scientist could help advice and guide inventors commercializing their inventions. Such an association exists in over 80 countries most of whom are also members of the international federation of inventors association (IFIA). This helps each association’s interacting with other similar association in regards to their respective invention promotion activities. The growing role of the
private sector and some of its organizations in the protection and promotion of intellectual property worldwide may be cited here as examples. There is in respect of book publishing and the book publishing industry, the international publishers association (IPA) established in Paris in 1896. With its headquarters presently in Geneva, Switzerland it comprises national, regional and specialized levels. The IPA as a private sector non-government organization has consultative relations with a number of United Nations agencies and upholds the rights of publisher in the publication and distribution of works of the mind, subject to their respecting all legal attached to these works, nationally and internationally. Importantly, the IPA helps to promote and protect the principles of copyright and to encourage authorship and dissemination of creative works; also to defend copyrights against infringements, which would restrict the rights of author. The IPA also publishes inter alia, annual book title production in various countries, including new titles, new editions and reprints, as also final total of titles etc.

**Patents as tools for encouraging Private R & D**

While it is admitted that patents have an important role in stimulating innovation and investment, it is equally felt that the intellectual property and patent system should provide a balance between the necessity of suitable compensation for inventors and the public interest of enabling people to reap the benefits from new inventions. The balance is particularly important in order to prevent an adverse impact on health through any unreasonable Pharma and health care have become key sector in the growth of economy of any developing countries. Consequent to the TRIPS agreement a large number of countries, including the developed and developing as well as those in transition, were required to update and strengthen their patent legislation, and to revise their exclusion from patentability of pharmaceutical products. Although the transitional period for this was specified to be not later than the year 2005 for developing as those in transition, were required to update and strengthen their patent legislation and to revise their patent legislation and to revise their exclusion from patentability of pharmaceutical products.

**Importance of product patent for Private R & D**

Pharmaceutical companies understandably argued that to have an incentive to engage in research and development, as also to incur the large expenditure involved, product patents protection is a must. Interestingly of the world health organization list of 335 essential drugs produced by their expert committee at the end of 1999 hardly a few were covered by patent protection. Of these, five were designated as a complementary rather than essential. Thus since
most of the essential drugs are in the public domain and not protected by patents. And other drugs is neither likely to affect the supply of essential drugs to those in need, nor to have an impact on drug pricing. The anxiety of a high price rise on thus account does not appear to be fully justified.

However the provision in the TRIPS agreement allowing for compulsory licensing is important for developing countries since they provide the necessary flexibilities for addressing their public needs. Compulsory licensing provision allows governments to grant licenses to third parties to produce and distribute life saving drugs to ensure that these drugs are more readily available and more affordable for the general public. Although nothing in the TRIPS agreement limits government in issuing compulsory license, certain members states of the WTO interpret the concerned provision rather narrowly thus objecting to its broad based use.

**Responsibilities of the private sector**

The private sector in this field will also have to comply with the TRIPs provisions. It should not be overlooked that the techno-economic as well as the social purpose and objective of the patent system to provide an incentives for research and development and in the contest of healthcare, to ensure easier and availability of life saving drugs especially for treating tropical and other diseases as well as AIDS particularly in certain developing countries. This latter task is important because between 22 and 23 million people are living with AIDS in sub Saharan Africa alone.

While protection of inventive and creative research through use of the intellectual property system is imperative in Research and development promotion has also be an important aspect of private sector activities. At the same time private enterprises producing easily pirated products in the pharmaceutical sector activities. In the process of activating socio-economic growth with equity, knowledge will not remain the prerogative of the few in this 21st century. Members of each society need to be provided with access to knowledge and be helped to become a knowledge worker. In the knowledge-based society of the current century the private sector should devote increasing attention to achieving gains from stronger intellectual property rights and ensure that the intellectual property rights system is used advantageously.
VII. III. CIVIL SOCIETY AND INTELLECTUAL PROPERTY

THE NATURE OF CIVIL SOCIETY

The current concept of civil society has grown during the last two and a half centuries. After the American and French revolution, like-minded sections of the population in the liberal world, with the gradually increasing competition in the marketplace, started associations or organizations of their respective common interests.

Civil society consists of many institutions, trade unions, charity organizations, neighbourhood groups, self-help organizations, etc. It includes a cross-section of voluntary organizations, social interest groups and cooperatives. It includes importantly, non-governmental organizations, as also groups engaged in public interest areas like checking and controlling of crime, human rights, environmental improvements, etc. during the last decade or so, such groups have emerged in the field of intellectual property rights also.

These networks evidently help and assist both the society and the economy. While they contribute the necessary checks and balances to the power of the state in their respective countries, they also encourage cooperative mutual support in societies; enhance social cohesion and economic development.

Civil society organizations, whether they are national or international, contribute their knowledge and expertise in monitoring of activities concerned with sustainable development. They do have a kind of overlap with, or dependence on the state or government sector, as well as the private sector. The overlap could be on questions of public heath, or in respect of human rights of creators and inventors of intellectual works.

In particular, national non-governmental organizations in the intellectual property sector, such as the local music industry, the software industry, the publishing sector, the collective management administrations, as well as the national inventors associations, where they exist, not only contribute substantially towards an increasingly quality conscious approach to economic management, but also help generate resources for different social programmes.

ROLE OF NGOs

For dialogue and transparency at every level, national, regional and international, these non-governmental organizations (NGOs) are represented in most United Nations’ agencies, and participate actively in those agencies in giving their views for determining policy making. Many of them have done original research and brought out position papers; they hole conferences on
the subject of intellectual property rights and their protection, and these activities are conveyed through the press as also over the websites. Internet has also given them an opportunity to reach out. For example, 27 international non-governmental organizations took part in the third session of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held in June 2002 at Geneva.

Important among these organizations were the: International Literary and Artistic Association (ALAI); Centre for International Industrial Property Studies (CEIPI), which teaches international intellectual property; International Chamber of Commerce (ICC); International Confederation of Music Publishers (ICMP); Crop Life International, a global federation representing the plant science industry; International Federation of Pharmaceutical Manufacturers Associations (IFPMA), which represents the worldwide research-based pharmaceutical industry; International Federation of Industrial Property Attorneys (FICPI), an organization working for the interests of patent and trademark professionals worldwide; International Federation of Musicians (FIM); International Federation of Reproduction Rights Organizations (IFRRO), which links together all reproduction rights organizations and international associations of right holders; Genetic Resources Action International (GRAIN), which promotes the sustainable management and use of agriculture biodiversity based on people’s control over genetic resources and local and maintaining an international environment, intended to improve opportunities for people to manage their own health through effective self-medication products; Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, a research institution devoted to the field of national, European and international intellectual property law; Institute for Agriculture and Trade Policy (IATP), which promotes resilient family farms, rural communities and ecosystem around the world through research and education, science and technology, and advocacy; International Environmental Law Research Centre (IELRC), an independent research organization focusing on International and comparative environmental law issues, with particular emphasis on India and East Africa; International Plant Genetic Resources Institute (IPGRI), which is devoted solely to the study and promotion of agricultural biodiversity; International Seed Federation (ISF), a non-governmental, non-profit organization representing the seed industry; International Publishers Association (IPA), which represents the publishing industry worldwide and is an accredited non-governmental organization enjoying consultative status in the United Nations; and World
Conservation Union (IUCN), the mission of which is to influence, encourage and assist societies throughout the world to conserve the integrity and diversity of nature and to ensure that any use of natural resources is equitable and ecologically sustainable.

A few more similar organizations are:
- Aboriginal and Torres Strait Islander Commission (ATSIC)
- Australia’s National Policy making and advocacy organization for indigenous people
- Union of Industrial and Employers’ Confederations of Europe (UNICE)
- World Federation for Culture Collections (WFCC)
- A network of specialist microbiologists
- Biotechnology Industry Organisation (BIO)
- International Centre for Trade and Sustainable Development (ICTSD)
- European Chemical Industry Council (CEFIC)
- International Association of Plant Breeders for the Cooperation for Development and Solidarity (CIDSE)
- Indigenous Peoples Biodiversity Information Network (IBIN)
- An international coalition of 14 catholic development organizations
- Centre for Documentation, Research and Information of Indigenous Peoples (doCip)
- A Swiss NGO linking indigenous people and the United Nations
- International Association for the Protection of Industrial Property (AIPPI)
- World’s leading non-governmental organization for research into and formulation of policy for the law relating to the protection of industrial property.

The point of concern of those in favour of strong intellectual property rights protection, and those who are not in favour of such a protection, can best be seen in two statements in connection with public health concerns as quoted in the recent Commission on Intellectual Property Rights (CIPR) Report entitled “Integrating Intellectual Property Rights and Development Policy”.

Firstly, that made by Sir Richard Sykes, former Chairman of GSK at the Royal Institute of International Affairs in London on 14 March, 2002, in which it is stated that “few would argue with the need for IP protection in the developed world, but some question whether it is appropriate to extend its coverage to the developing world, which the TRIPS Agreement is gradually doing… IP protection is not the cause of the present lack of access to medicines in
developing countries. At Doha last November (2001), WTO members agreed to defer TRIPS implementation for the least developed countries until 2016…. TRIPS will not prevent other developing countries like Brazil and India from obtaining access to the medicines they need.

Secondly, Oxfam, on behalf of the non-governmental organisatins (NGOs) has argued the opposite, in its statement to the effect that, “Why do developing countries object so strongly to TRIPS? Its essential flaw is to oblige all countries rich and poor, to grant at least 20 years patent protection for new medicines, thereby delaying production of the inexpensive generic substitutes upon which developing country health services and poor people depend. And there is no upside; the increased profits harvested by international drug firms from developing world markets will not be ploughed back into extra research into poor people’s diseases – a fact some companies will in private admit”.

**Flexibility in the TRIPS Agreement**

Some civil society groups have argued for an outright abolition of the TRIPS Agreement. This does not seem feasible. A much better alternative is to consider certain ‘flexibilities’, over nearly two dozen of these, that exist in the TRIPS Agreement. It is important for civil society organizations, the private sector and the governments, to use these flexibilities to the fullest advantage in the process of implementing the Agreement provisions as well as national legislations. In fact, an awareness building campaign in regard to existence of these flexibilities in the TRIPS Agreement should be undertaken by the concerned civil society organizations with positive collaboration and assistance from governments. It should be stepped up as it would greatly help, inter alia, in supporting access to medicines as well.

The Commission’s programmes, it was stated, included working with the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) to consider the link between the TRIPS Agreement and health issues, as well as working constructively with the concerned non-governmental organizations and the civil society, in arriving at a global solution to the problem.

The CBD provides in its Article 16 that access to and transfer of technology, in particular to developing countries, should be provided for and facilitated under favourable terms, including concessional and preferential terms, where mutually agreed. In the case of technology that is protected by patents and other intellectual property rights, such access and transfer shall be on
terms that recognize and are consistent with adequate and effective protection of intellectual property rights.

Both Article 16.5 and Article 22 provide countries with some maneuverability with regard to IPRs. These articles specify that while recognizing that patents and other intellectual property rights may have an influence on the implementation of the CBD, the States party to the Convention shall cooperate, subject to national legislation and international law to ensure that such rights do not run counter to its objectives.

CIVIL SOCIETY AND BIODIVERSITY

The Environmental Forum of the Peoples Summit of the Americas for the Hemispheric Integration Process, held at Santiago, Chile, in April 1998, reiterated that the protection of biodiversity was a priority for the hemisphere, and indicated that the civil society’s recommendations were that it was necessary to recognize the need for:

- Affirming the collective rights of local communities to biodiversity resources and knowledge,
- Food security as a right,
- Protection of agriculture, biodiversity and intellectual property over genetic resources,
- Establishing bio-security standards which prevent the release of genetically manipulated organisms.

The Intergovernmental Committee (IGC) in its first meeting held in April 2001 at Geneva, had identified certain major issues of concern. These were in respect of:

i. Genetic Resources:
   a. Contractual agreement for access to these resources and benefit-sharing; legislative, administrative and policy measures to regulate access to such resources and benefit-sharing
   b. Multilateral systems for facilitating access to genetic resources and benefit-sharing
   c. Protection of biotechnological inventions

ii. Traditional Knowledge:
   a. Terminological and conceptual issues
   b. Standards concerning the availability, scope and use of intellectual property rights in traditional knowledge
c. Legal criteria of the definition of prior art
d. Enforcement of rights in traditional knowledge.

VII. IV. IPR TRAINING PROGRAMMES

Introduction:

Patents have emerged as a major area of business competence. It has become as important as understanding innovation, technology, marketing, finance, corporate governance, industrial economics and strategy. Importance of Intellectual Properties (IPR's), especially Patents, needs no emphasis and is largely well understood at the Corporates. At the same time, in the changing paradigm of global business, one central force that supports this change and shall regulate more closely in time to come is Intellectual Property Laws and Practices. It is therefore important for all Innovation Companies to have focused R&D efforts to ensure that the amount of resources spent on research is well justified and in the right direction allowing efficient 'Patent Portfolio Creation Management'. To achieve this, it is inevitable for each Corporate to have an IP trained team of R&D Professionals, Technocrats, and Scientists. The various institutions promoting IPR are organizing training programmes on IPR and related issues.

Objectives of the IPR Training Course:

The training course would focus on the following themes:

- Management strategies and priorities in harnessing benefits from IPR
- Aspects of IPR which influence decision making in science policy, planning of R&D, exploiting results of R&D and international collaboration
- Contemporary and recent global developments on IPR
- Exchange of country specific information on IPR and management practices
- Promotion of scientist-to-scientist contact and interactions
A Sample Model of IPR Training Module of NIIPM is as follows

**PUBLIC TRAINING PROGRAMME: AT A GLANCE NIIPM**

Table No.47 - Training Course on “IPR Management”

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<tr>
<th>Sl. No.</th>
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<th>Scheduled to be held on Dates with registration date shown in bracket</th>
<th>Fees (in Rs.)</th>
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<td>An Introduction to the IPR (for beginners)</td>
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<td>Processing of Indian/Foreign Patent Application</td>
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<td>Drafting, Interpretation of Patent specification and Claims</td>
<td>11(^{th})-12(^{th}) June 2013&lt;br&gt;(04/06/2013)&lt;br&gt;28(^{th})-29(^{th}) Oct 2013&lt;br&gt;(21/10/2013)&lt;br&gt;27(^{th})-28(^{th}) Nov 2013&lt;br&gt;(20/11/2013)&lt;br&gt;10(^{th})-11(^{th}) Mar 2014&lt;br&gt;(03/03/2014)</td>
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National Institution of Intellectual Property Management (NIIPM), Nagpur