TRADE RELATED INTELLECTUAL PROPERTY RIGHTS
– IMPACT OF PHARMA INDUSTRY

IMPACT AND SUGGESTIONS

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IMPACT AND SUGGESTIONS

X. I. IMPACT OF INTELLECTUAL PROPERTY RIGHTS

EMPOWERMENT OF THE INDIVIDUAL

The knowledge-based economy has as its foundation the intellectual property capital of the individual. This provides it with creativity and innovation, which results in surging and dynamic development.

The digital revolution, the internet, and e-commerce, all global phenomena, serve to reinforce the role of individuals in creating a knowledge-based economy. They provide the mean globally link like-minded persons to establish the synergies necessary to create true forward movement, and to support and facilitate the sharing of common goals and the tool necessary to achieve the goals. E-commerce is also impressive in its exponential growth and its potential to facilitate distribution of a tremendous array of products and service.

In the era of the internet-commerce, and rapidly evolving digital technology, what is that empowers the individual? Creativity and innovation play a key role. Intellectual property provides clearly perceived intensives to foster and to actualize creativity and innovation. There is also measurable value in establishing a tangible connection between the products and service created, and demonstrable ability to derive compensation when these products or services are embraced by the public. These and other factors have been shown time and time again to motivate creators and innovators, business and enterprises, at all levels of society, to produce the tangible and intangible works and inventions which so enrich our economy, culture, and social lives.

There is an underside to this scenario, which is also well documented, and unfortunately much too familiar: How many countries or places are there with an inadequate intellectual property infrastructure, where the creators and innovators know with certainty that their creations and inventions will be stolen from them, and that they will receive no compensation, and no due credit? Such place will have little, if any, success in establishing or attracting new industries, R&D, technology transfers, manufacturing, and FDI into their economies.
INTELLECTUAL PROPERTY EMPOWERMENT

An efficient, energetic IP system creates and fosters national economic, social, and cultural growth. It can stimulate investment, R&D and related activities in the creation and dissemination of new products and services, and most importantly, there is a proliferation of newly created knowledge, which, in turn, further empowers the individual in society, as well as society in general. The result is a cycle of sharing and exploiting of new and useful knowledge, which ultimately benefits everyone in society. This is the promise of IP empowerment.

Through its program, budget allocation, activities, and its expressed objectives, WIPO supports the model of an IP system that empowers individual and societies. This is, quite simply, IP empowerment as an actualized model, and it is and will be the basis for the WIPO strategy over the next years.

One of the primary objectives of WIPO in the implementation of its IP empowerment strategy will be establish in a global community consisting individuals, government, business, and other relevant constituencies, all of whom will be making active use of intellectual property and the supporting IP system, as powerful tools facilitating the growth, development, and enhancement of knowledge-based economies. By spreading an IP culture and creating a global intellectual property-minded community the organization can contribute to the social, economic and culture well-being of nations.

THE COMPONENTS OF THE INTELLECTUAL PROPERTY - EMPOWERED SOCIETY.

Political will, a legislative framework, vital institutions, and an IP culture can be considered essential components of the IP-empowered society. In order to manifest and realize the full value which it has been demonstrated that intellectual property brings to society, there must be an environment in which these components are present and fully functional. The absence of any one of them gives rise to a stagnant and receding economy: a lack of creativity and innovation; and a business climate lacking in vitality, consistency, or reliability. Let us examine these components individually:

(1) Political Will.

Government leaders of WIPO member states recognize the value of intellectual property and the IP system; the need for legislation complaint with all
international obligations; the necessity for vital institutions such as IPOs, courts, cultural and research institutions; and the high value to be placed on an IP culture, in which all members of the public are fully aware of the positive impact which IPRs can bring to bear on economic, cultural, and social development, domestic and foreign trade, international investments, and technology transfer. It is the first component in the foundation of the IP-empowers society and it is essential that leaders show their commitments to the vision of IPO as a tool for improving the lives of their peoples.

(2) **Legislative Framework.**

While the necessity for political will cannot be underestimated, IPRs are based on a country’s national legislation. The legislation must be compliant with the obligations contained in the international IP treaties and conventions, particularly the Paris and Berne conventions, and the TRIPS agreement. Whenever the international IP community agrees by consensus that new international norms are required (such as through a diplomatic conference), the national legislative framework can be upgraded, so that newly adopted international norms such as in the PLT, and the WCT and WPPT, are woven into the legislative framework quickly and efficiently. It is also important that the legislative framework reflects a fair balance among all sectors, including the public, the private sector and industry, consumers, and government. The key role of this component, the legislative framework, underscore that the rule of law is one of the most important underpinnings of the IP-empowered society.

(3) **Vital Institutions.**

IPRs intersect with society through the institutions that deal with them. Such institutions include government (IPOs and other relevant regulatory agencies such as those dealing with health and safety, taxation, consumer affairs, and foreign affairs); courts (including judges and lawyers); educational and research institutions and enforcement agencies./institutions must be sensitive to the value of IPRs, must not create barriers to growth to trade, and must encourage creativity and innovations literally through all of the action and decision which they take or implement. An exceptionally important dimension of these vital
institutions is human resources and their development and enhancement. No institution can function without good people doing their jobs well. A scenario in which human resources are not properly supported will not function optimally.

(4) **IP Culture.**

This component is last, not because it is the least important, but because it follows the other components in chronological and developmental evolution. In an IP culture governments and agencies seek to increase value and raise standard of living, by advocating an increased use of IP as a tool for economic growth. The private sector, from multinational corporate to SEMs and sole-proprietorship, recognizes the value of IP in knowledge-based industries. Research in science and technology and cultural institutions are value and funded. IT and communications technology are emphasized and employed effectively. The many and varied sectors of the IP culture communicate with each other, and act with both the intensives and benefits of the IP system in mind. The general public understands the benefits of purchasing legitimate goods and services and thereby boosts local industries and economies.

As was mentioned above, the absence of any one of these components can cripple the entire system and thereby seriously affect the economy. It is the web of these multi-level, essential components that serve to create the environment in which creativity and innovation are encouraged and stimulated; in which a steady stream of newly created and distributed products and service makes daily life more pleasant, efficient, and exciting; and in which business are focused on product creation and development, establishing brand equity and market share, solving problems, helping to eradicate disease and sickness, expanding educational possibilities, and in general, raising the standards of living for every person in society. That is the IP-empowered society. (Kamil Idris)
X. II. SUGGESTIONS & RECOMMENDATIONS

1. TRIPS to be reviewed to ensure that its provisions support access to essential medicines—the countries of the south should seek to retain the right to produce market and import affordable medicines. Particular attention should be paid to clarify, and if necessary, revise Article 28 (can be interpreted to limit parallel importing), Article 31 (can be interpreted to limit compulsory licensing), article 39.3 (requires that pharmaceutical R&D should be protected against disclosures); and article 41 (member countries must enforce Intellectual Property Rights)

2. Review of patent period of 20 years and consider shortening patent protection period for essential medicines.

3. Substantive review of Article 27.3 (b) to exempt a list of patented drug. Clarity by WTO as to whether parallel import is challengeable

4. Free use of public health safeguards such as compulsory license and parallel imports when there is a health crisis.

5. Compulsory license should be enforced and not be restrictive nor subject to threats.

6. Public health concerns should have priority over commercial and industrial concerns.

7. Measures to promote the genuine transfer of know-how and technology in the areas of pharmaceuticals to the developing countries.

8. TRIPS need to provide incentive to develop new drugs.

9. Reconciliation of TRIPS with the public health aspects of the International Covenant on Economic, Social and Cultural Rights (especially, article 12.1, 12.2c and the right to health). Civil society’s and some governments’ recommendations, actions and possible measures to offset the negative impact of TRIPS on access to medicines include:

10. Medicine on the Essential Drugs List produced by the WHO should be exempted from the TRIPS provision. WHO list should be amended to include all essential medicines not just cheap ones.

11. Global public fund to support the rational use of medicines and the research and development of medicine, which address public health needs.

Differential pricing (companies charge different prices in different market such as lower prices for drugs in poor countries) should be widely promoted and encouraged[28].
However, differential pricing is not a panacea since it is based on certain conditions such as the idea that companies must recover R&D costs, so consumers in richer countries might face even higher prices. Many observers note that differential pricing is already practised by firms who segment markets to maximise profit. In this case it might only increase prices to consumers in rich countries and will have a negative impact on poor consumers in those countries. Furthermore, as pointed out by TAC and other NGOs, differential pricing in small African markets may only work to dampen the demand for generic drugs from countries such as India and Brazil who can manufacture these drugs. This will further reinforce the monopoly power of the pharmaceuticals.

12. Greater resort to non-public use measures by developing countries. This is an alternative to compulsory licensing which does not require negotiation with patent holder. Additionally, as noted by Love (2001), “there is no right to injunctive relief; but companies may seek compensation as an eminent domain taking.”

13. Developing countries must be more aggressive about issuing licenses.

14. Developing countries should adopt article 30 patent exceptions for product that are produced for humanitarian use (this will overcome the problem of exporting under compulsory license.)

**Need of Public Awareness of IP: The key Elements**

Precepts of intellectual property (IP) have become powerful drivers of economic growth. When linked to the development of human capital these become a dynamic combination in terms of stimulating creativity and innovation, generating revenue, promoting investment, enhancing culture, preventing ‘brain drain,’ and nurturing overall economic well-being. Yet, the evolution of the intellectual property system has largely remained isolated, till almost the last quarter of the previous century, to the realm of legal and technical jargons, lending it an aura of complexity bordering on chaos for some and mystifying for others.

More recently, the web-based file-sharing of ‘peer to peer’ applications, like Napster, have caused the disturbing phenomenon of illegal consumer behavior, by the tens of millions in ‘peer to peer’ sharing and downloading on the Internet of music, video games and films. Therefore, the need for demystification of intellectual property precepts and practices for wider public understanding and awareness in necessary. It should be done in a simple language so that IP literacy can be encouraged at all levels. Similarly, much of the politicization of IP starts from
incorrect or understanding of the basic of the IP system. Therefore, depoliticisation of IP – a concept related to demystification – at various levels of the society, is equally important.

In appreciating the of IP, and the potential positive impact that it can have on society if it is used as a proper tool of development, awareness of its relevance, importance and usefulness, should be spread among all the sections of the society and all persons involved in the process. In a culture, where IP is known to help in development, government official and agencies act to increase the value and raise the standards of living by advocating an increased use of IP rights. The private sector, from multinational corporations down to SMEs, recognise the value IP rights in knowledge – based industries and economics. The public understands the benefits of purchasing legitimate goods and services, thereby boosting local industries and economies, as also increasing the tax base. The absence of IP culture can conceivably result in a stagnant, receding economy, a lack of creativity and inventiveness, and a business climate bereft of foreign direct investment (FDI), consisinventiveness, and a reliability. It is thus essential that the creators and inventors be helped and supported in the protection of their work.

- A structured approach to public awareness programmes based on an interactive and continuous evaluation of user requirements;
- Development of specific, target – oriented awareness programmes; young people should also be involved in taking a participatory, inclusive approach, for example through invention clubs in schools, etc.,
- Wide dissemination of the usefulness of intellectual property system through optimal use of various means of communication;
- Promotion of a culture of respect for intellectual property rights through appropriate educational policies.

**International Efforts in Demystification:**

Keeping in view the importance of intellectual property rights, almost all countries are beginning to recognize the importance of systematically informing the public about the role of intellectual property in their daily lives as well as in achieving economic goals and developmental aspirations. Furthermore, such public awareness is considered key to effective enforcement of intellectual property rights, activities designed to demystify intellectual property and create a better understanding of its relevance to society, are being undertaken through an array of programmes including National Focus Action Plans (NFAPs).
Demystification of Biopiracy Based Perceptions:

Some of the conflict have arisen from the perception that rich companies and researchers from the developed world have been attracted to the wealth that the lesser developed countries have in their biodiversity, and in their traditional knowledge systems. The rich nations will argue that access to such biodiversity and community knowledge by the industrially developed nations is necessary for the larger welfare of mankind, as this advanced knowledge and leads to new products, which in turn contribute to the well-being of global consumers. The other hand those who supposedly guard the interests of the benefit them in any way, while their natural resource and intellectual property continues to be appropriated and exploited.

The conflicts further deepen, when it is claimed that many researchers from the developed world have obtained knowledge about biodiversity and its uses from local innovators, communities and institutions, but they have not even acknowledged their contributions, let alone sharing of the benefits resulting from such knowledge.

Conclusion:

Misunderstanding over the use of intellectual property rights in connection with culturally and socially sensitive material previously assumed to be in the public domain can cause particularly severe difficulties. Companies, especially in the pharmaceutical and agro-food industries, are increasingly turning to new sources – such as genetic material, traditional remedies, little known plants and animal species – in their search for new products. This has provoked emotional debates over the concept of ‘ownership’ of these resources and of products derived from them.

This increasing politicization of intellectual property issues means that business has to focus on developing an effective communications strategy concerning intellectual property issues, and on encouraging education about the importance of intellectual property for society. This is essential if it is to garner the support of the public, and ensure that gains made to strengthen protection are not whittled away due to political opposition. Public support for intellectual property rights would also greatly alleviate enforcement problems made more acute by new technologies and globalization.
In fact, as a result of inadequate understanding of the basics of IP, vested interests, politicians and the general public make misleading statements, which are not based on the laws and practices of IP. The other element that influences the IP system is the lack of balance when it comes to interests of different stakeholders, most often in relation to health safety and agricultural security, i.e., pharmas and fear of genetically modified crops.

- Giving India the IPR edge: Problems faced by Indian pharmaceutical companies while registering IPR commonly are documentation work, financial support, technology, unavailability of Research and development centre while registering IPR. Following are the suggestions as,
- There is a need to expedite for the process of examining the patent application to stimulate innovation.
- A time limit for filing and disposing of pre–grant oppositions should be provided at the earliest.
- Pharmaceutical must improve its R&D productivity and its legal framework must be altered to promote innovation and discourage imitation and prove that its products really work and provide value for money.
- Provide financial incentives to encourage innovations & research.
- Different institutions should be funded for undergoing research. The Indian education system and the industry need to come together to plug the shortage, which will require significant investment. (Shahid Alikhan, Intellectual Property and Competitive Strategies in the 21st Century).