TRADE RELATED INTELLECTUAL PROPERTY RIGHTS
– IMPACT OF PHARMA INDUSTRY

REVIEW OF LITERATURE

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Creativity is about new ways of looking at issues. Therefore, a creative idea is a new way to handle people, places and situations. Creativity is considered the ultimate human activity, a highly complex process, difficult to formalize and to control. Although there is a general agreement regarding the distinctive nature of the creative product (idea, painting, poem, and so on), there is a controversy over the nature of the creative process. Some researchers hold that the creative thinking process is qualitatively different from “ordinary” day-to-day thinking, and involves a leap that cannot be formulated, analysed, or reconstructed – the creative spark. Others adopt a reductionist view that creative products are the outcome of ordinary thinking, only quantitatively different from everyday thinking. The WTO Agreement contains some 29 individual legal texts – covering everything from agriculture to textiles and clothing, and from services to government procurement, rules of origin additional Ministerial declarations, decisions and understandings which spell out further obligations and commitments for WTO members. However, a number of simple and fundamental principals run through all of these instruments which, together, make up the multilateral trading system. (K.R.Gupta)

The role of the patent system in making medicines available to needy consumers, particularly in poor countries, has been the subject of intense debate. In this respect, the linkages between intellectual property rights and public health are being addressed in several for a. the WTO Commission on Intellectual Property Rights, Innovation and Public Health, CIPIH, was set up in early 2004 to study a number of topics, including interfaces and linkages between intellectual property rights, innovation and public health, with emphasis on the importance and effectiveness of intellectual property rights regimes in stimulation of research and creation of new medicines against diseases which particularly affect developing countries. The CIPIH final report was published in April 2006. The issue of public health and access to medicines calls for a variety of policies, including those unrelated to intellectual property. The business community has an important perspective to contribute to the discussion, having participated in a number of public–private partnerships, and as well as in private sector initiatives for supplying needed drugs to developing countries. Business and industry is also providing free or affordable access
to biomedical and healthcare information for institutions in low-income countries through public-private initiatives. (M.M.S.KARKI)

As per Dr. A. Selvaraj (10) article, as Indian has signed WTO (World Trade organization) agreement, so it is now not only the process patent but also product patent is also permitted by the amended Patent act 2005. As India is more in generic products, to sustain in market and also from MNC, Indian pharmaceutical companies need to come up with product patent. At the same time, Government should aid Indian pharmaceutical companies to increase their research and development activity.

A volatile innovation scene, structural shifts in resource allocations to private and public sector R&D and the emergence of radically new science-based technologies continue to give rise to vigorous debate concerning IPRs. A constant tension between traditional structures, policies and goals of IPR protection and contemporary trends informs these debates. The core systemic question is to what extent established principles and policies of intellectual property law – if indeed they exist – should be relinquished in the new environment, or whether they are so robust and significant that they should be allowed to shape the contemporary innovation landscape in their own image. Some significant changes to intellectual property law have indeed resulted from changes in the innovation system, ie the manner in which innovation is organised and conducted across all sectors of the economy. But in other ways traditional principles have proved surprisingly resilient and influential. At the same time there have been significant changes in the mechanisms of policy formulation and ‘norm-setting’ in innovation-related IPRs. Whereas this was once a predominantly local and technical process dominated by the legal profession, now global debates linked to numerous other issues, such as trade and industrial development, conducted by diverse professional and NGOs in multifaceted organizations determine the shape of the international treaties that strongly influence municipal rule formulation. The ‘main game’ intellectual property policy formulation property policy formulation has shifted from Canberra to Geneva (where the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) are based. (William van Caenegem)

Globalization and Trips and their Implications on Access to Medicine As earlier noted, globalization is all about elimination and trade and other barriers that hitherto stood in the way of free trade, in order to encourage global competition. For any country, therefore, to be a part of this global trend, it must be one with manufacturing/industrial capabilities. It must be an exporter
of industrial goods. Industry is technology – driven and as such it is only one who has the technology that can be said to be industrialized. In other words, any country that does not possess manufacturing capabilities will be left out of the globalization trend.

In order to safeguard the interests of those who developed the technology and the knowledge of the manufacturing processes for export goods, the architects and drivers of globalization have designed a framework within the WTO to ensure that they maximally reap the gains of capitalism i.e. profit, irrespective of circumstances. The framework to achieve this objective is the TRIPS Agreement, which allows for patents on pharmaceutical products and processes. Indeed, the TRIPS Agreement can be said to be one of the offspring of globalization and it is through this mechanism that the developed countries control the global drug supply market. The mechanism through which this is done is the patent system on essential medicine. (Ayodele A. Adewole)

The most recent affronts on the rights of the developing countries like India to provide access to medicines at affordable prices to its citizens, has come through pressures brought by the US and the EU for the introduction of data exclusivity. This demand is linked to the implementation of Article 39.3 of the TRIPS Agreement, which requires WTO Members to protect undisclosed test or other data, developed with “considerable effort”, against “unfair commercial use” when such data are submitted for seeking marketing approval for products using “new chemical entities”. In addition, Members are required to protect such data against “disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.” While Article 39.3 is clearly intended to ensure that “undisclosed test data” was not misappropriated, the pharmaceutical industry associations in the United States and the European Union, representing the larger firms, have argued that Article 39.3 should be interpreted in a manner that provides statutory protection spanning a period of time to data submitted for obtaining marketing approval, among others. (Biswa Dhar KM Gopakumar)

The World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS or “Agreement”), which sets out the mini-mum standards for the protection of intellectual property, including patents for pharmaceuticals, has come under fierce criticism because of the effects that increased levels of patent protection will have on drug prices. While TRIPS does offer safeguards to remedy negative effects of patent protection or patent
abuse, in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access. (Ellen F. M.’t Hoen)

Research and Development (R&D), which is linked to patenting system, is important to study, not only for the analysis of an individual industry, but also from an economy-wide viewpoint. For improvements in welfare, Solow (1957) emphasized an increase in the ratio of capital to labor, leading to technical progress. This progress takes the form of innovation in the industry and its diffusion across all the sectors of the economy. The innovation is of two forms namely product innovation and process innovation. One of the major problems, mentioned by Schumpeter (1943) in this regard, is that innovation has the status of a public good. Any innovation created by one firm provides usable information to the other firms at little and no cost. While all firms in the market stand to gain from the use such information, none is willing to incur the expenses necessary to produce it without compensation. In practice, such compensation often comes through the granting of patent that provides the innovating firm with temporary monopoly and, consequently, allows it to recoup its R&D costs. The dilemma of the patenting system is that, in encouraging R&D, it prevents the diffusion of innovation and consequently creates a noncompetitive situation (Tirole, 1995). As Penrose (1951) notes, “If national patent laws did not exist, it would be difficult to make a conclusive case for introducing them; but the fact that they do exist shifts the burden of proof and it is equally difficult to make a really conclusive case for abolishing them.” (Pradeep Gui, Ravinder Jha, Anita Kumari, Dibyendu Maiti, Mayur Trivedi)

Two important themes are advanced throughout this section. First, it is important that IPRs reforms be geared towards maximizing the benefits from intellectual protection rather than simply serving to avoid complaints under WTO’s dispute settlement system. Specifically, reforms should target local entrepreneurs and facilitate the dissemination of domestic and foreign knowledge. Second, in reforming their IPR’s systems, governments in developing countries should match their roles to their capabilities. Given a different structure of demand for IPRs protection and more limited government resources in developing countries, it would not be efficient to simply copy the institutions and procedures developed by industrial countries over several decades. (Keith E. Maskus)

Although the International Federation of Pharmaceutical Manufacturers (IFPMA) officially welcomed the declaration on TRIPS and public Health, individuals in the industry
expressed their concerns. For more than two years, IFPMA warned against the dangers of compulsory licensing, ever since NGOS started to propose compulsory licensing systems to overcome patent barriers. IFPMA’s position has not changed. It says that “Compulsory licensing is a threat to good public health by denying patients around the world the future benefits of R&D capabilities of the research-based industry from which new therapies come. The generic drug industry welcomed the Declaration, in particular the freedom of countries to decide the grounds for compulsory licensing. The generic drug industry did express concern about possible unilateral pressure to influence countries not to make full use of the declaration. The industry suggested that the developed WTO Members should commit to the Declaration in practice by refraining from exerting unilateral pressure. They also expressed disappointment that there was no resolution of the issue that arises when a country with limited production capacity that issues a compulsory license for a medicine cannot find an efficient, affordable, and reliable source of medicines, due to TRIPS restrictions on production and export of medicines. (Lakshmidevi Somanath).

Indian traditional medical system can be broadly classified into codified tradition and folk medicine. The codified tradition are Ayurveda, Unani, Siddha, and Gso-rig –pa (Tibetan system). This medical knowledge is documented and presented in thousands of medical manuscripts dealing with all branches of medicine and surgery. The literature also covers on medicine resources, products, and therapeutic application. About 25,000 natural products are documented in the traditional text along with their application. The medicinal manuscript is present in many libraries in India, Europe, United States of America and several Asian countries. Presently about 4 lakes registered physicians distributed across the entire country are the carriers of this codified system. The codified traditional are evidently in the public domain by virtue of their accessibility. The diverse expressions of medical knowledge in Indian society for purpose of classification can be fitted into two sets of traditions, viz., (a)codified traditions and (b)folk medicine. (Prof. T. Ramakrishan)

The IP Facts section analyses world trends in patent development since records began in 1883. The trend in patent grants is upward, particularly in the past two decades under the intensity of technological advancement and the moves towards international harmonization as coordinated by WIPO and the WTO. The study of the top 20 countries in terms of number of invention patents in two different periods shows that developed countries continue to be the
dominant holders of patent grants, although there has been a slight fragmentation over the past two decades. Developing countries increasingly pay attention to patent development, but they are still the ‘followers’ of developed countries, and only represent a fraction of patent ownerships. (Deli Yang)

The article by Dr. A. Selvaraj focuses on compatibility of Indian pharmaceutical company. Production wise, Indian manufactured drugs are at quite economic rate. The reasons are like infrastructure cost, labor cost, clinical trial cost, etc. but India is lacking in patented drug manufacturing. As compare to western countries, research and development activities of pharmaceutical industries are not up to the expectation. This can be because of process patent agreement. There are various steps government is taking to increase research and development activity as mention in the article. But what is the success rate of these steps to increase research and development activities in Indian not only by domestic pharmaceutical companies but also from multinational companies is need to study.

The article by R Saha talks about the innovation and need of innovation. India has signed TRIPS agreement in which the protection of intellectual property rights are obligatory in chemical, food and drug industry. Consequently to accept the changed scenario, not only Indian pharmaceutical companies but also government needs to adopt new strategies or policies to increase or motivate research and development activities in India. In amended patent act 2005, government has come up with different policies like tax exemption, funding, collaboration with academic, public and private sector etc to increase research and development activities. Indian pharmaceutical companies have adopted new strategies like collaboration, merger and acquisition, outsourcing etc to increase research and development activities.

The article by Gautam Arti and Kharia Anil focuses on government initiatives that are taken for rising research and development activities in Indian pharmaceutical company. Not only Indian pharmaceutical company but also government understood the significance of research and development activity, accordingly as to motivate research and development activity which needs huge investment, time, skilled people etc. government is giving special consideration by various ways like tax concession, export, import duty concessions, etc. so as Indian pharmaceutical companies will get encouraged for research and development activity. As per the editorials Ravi Kiran, Sunita Mistra (7) which focus on the changed scenario due to Amended Patent act 2005. India as a signatory member signed TRIPs for protecting product patent, preliminary India
refused for the change. This can be because of n number of reasons like if product patent becomes compulsory licensing may get affected, price of medicine may increase etc. patented product is like an asset to the company. It increases profitability of respective company and future competition or turnover won’t be on sale of product but it will be on the number of patent a company is holding. Indian domestic as well as international company understood the need of research activity to survive in market and nowadays most of them are changing from imitation to innovation by increasing R and D activity to sustain in market.

The article by Daara B Patel discusses about the opportunities of Indian pharmaceutical company from outsourcing point of view. Indian pharmaceutical company overview: Challenges and Opportunities, Daara B Patel, Product patents & drug price controls, 2nd June 2011, GoaCost of some of the Indian manufactured medicines is quite cheap as compared to the world. This may be because labor costs are cheaper than in the West. Infrastructure costs are lower and fixed cost is less that in the United States and Western Europe. Consequently, India can produce bulk drugs that cost 60% less that in the West and can open a production plant in India 40% cheaper than in developed countries. India has signed TRIPS agreement which secure product patent. As a result India has an opportunity or future in doing outsourcing work in research and development for many domestic as well as international companies which will increase its research and development ability.

As per the article by Anshu Shrivastava which focus on domestic and multinational company’s strategies before and after patent act. Before amended Patent act 2005, where only process patent was allowed, Indian companies had liberty to reproduces drugs manufactured by patent holding companies without paying any sort of fee and used to make profit. So innovation was missing. At the same time, multinational companies instead of bringing technology, innovation and finance in India brought import of bulk drugs which increased price of medicine to Indian customers. But now due to the Amended Patent Act 2005, scenario is changing.

The transition periods have meant that pharmaceuticals or medicines patented before developing countries implemented their TRIPS obligations will not receive patent protection, and thus generic competition is possible. Medicines patented after developing countries have implemented their TRIPS obligations are progressively coming onto the market and will constitute an increasing share of marketed medicines. Substantial change is expected after 2005,
when all developing countries will be required to provide patent protection for pharmaceutical products and the mailbox patents are processed. *(WHO Drug Information Vol 19, No. 3, 2005.)*

While the vast majority of tuberculosis and malaria drugs are off-patent and less than twenty percent of the drugs used to combat HIV/AIDS are patented in African countries, the developing world continues to suffer without adequate supply of the needed medicines. The fact of the matter is that the delivery and administration of vaccines and medicines often cost more than the drugs themselves, and it is the cost of transporting, storing, administering, and supervising the drugs that often impedes the delivery of medicines to the developing world. While some would like us to believe the problem lies simply with the price of the drugs themselves, such statements are illusory and deceitful. Though several activist organizations have blighted the issue to many around the world, the medical community itself was never convinced that strong patent laws have exacerbated the HIV/AIDS crisis or that patent laws have been an impediment to drug access. For instance, a highly respected 2001 study conducted by Amir Attaran and Lee Gillespie-White and published in the Journal of the American Medical Association states: [It appears that] patents and patent law are not a major barrier to treatment access in and of themselves. We conclude that a variety of de facto barriers are more responsible for impeding access to antiretroviral treatment, including but not limited to the poverty of African countries, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales taxes, and, above all, a lack of sufficient international financial aid to fund antiretroviral treatment.( Bryan c. Mercurio)

Foreign trade in pharmaceutical products The Indian pharmaceutical industry’s growth has been fuelled by exports. Its products are exported to a large number of countries with a sizeable share in the advanced regulated markets of the US and Western Europe. India currently exports drug intermediates, active pharmaceutical ingredients, finished dosage formulations, biopharmaceuticals and clinical services to various parts of the world. The top five export destinations of Indian pharmaceutical products are USA, Germany, Russia, UK and China. Indian exports of drugs and pharmaceuticals grew at a CAGR of 16.5% to ₹ 451.4 Bn during Feb 2012 to Dec.2012. Imports of drugs and pharmaceuticals into India recorded a CAGR of 17.6% during FY02-FY12 (up to Dec 2011). During FY12 (up to Dec 2011), pharmaceutical products worth 102.2 bn were imported into India. India is almost self sufficient in formulations; its imports mostly comprise bulk drugs and some intermediaries. These imports are free permitted,
except those that are restricted in the foreign trade policy. Import restrictions are mostly on drugs that contain narcotics and psychotropic components. (Dr. Tamma Koti Reddy)

- The TRIPS Agreement permits Members to enact special or limited exceptions to the exclusive rights granted to the right holder (Articles 13 and 30).
- Such exceptions should not conflict with a normal exploitation of the copyright work or patent and should not unreasonably prejudice the legitimate interest of the right holder (Articles 13 and 30).
- In the case of patent exceptions, the legitimate interests of third parties should be safeguarded (Article 30). (Alhaji Tejan)

The major sources of growth and competitiveness of the Indian pharmaceutical firms derive from the following: a) Cost competitiveness – the historical Indian patent law (process patent and not product patent), which enabled Indian companies to copy innovator molecules by manufacturing the product from a non-infringing process is the main source of cost advantage. This also led to product launches in India typically 6-10 years ahead of their launch in the US generics market. Since the Indian market is extremely price competitive, Indian companies develop capabilities in highly cost-efficient manufacturing processes. Indian pharmaceuticals also enjoy cost advantages in form of Indian tax rebates on R&D expenditure, and drugs developed using indigenous R&D are exempted from price controls in India.

Continued momentum in the US generics – approximately US $126bn worth of branded drugs are likely to go off-patent over the next ten years, leaving room for Indian companies to capitalize on this strong patent expiration cycle. Ranbaxy Laboratories, Dr. Reddy’s Laboratories, Cipla, Sun Pharmaceuticals, Wockhardt, and Biocon are some of the front-end pharmaceutical companies that have benefited from this changing regulatory environment and are poised to continue their international growth. (Business and Financial Networks, Internet Material)

Globally, the scientific foundation on which the Pharma industry rests has improved vastly over the years. Technologies for collecting and synthesizing biological data are improving and becoming much cheaper and more efficient. However, in the short term, the industry continues to face challenges like patent cliff, rising drug discovery cost, harsher regulations and price controls, coupled with spiraling healthcare cost. The worldwide sales of medicines reached 1.08 trillion USD in 2011 (an increase of 7.8% over the previous year) and are expected to reach 1.5
trillion USD by 2020. The emerging markets represent the fastest-growing segment of the
global pharma industry. Sales in the four BRIC countries (Brazil, China, India and Russia) were
up by 22.6% over the previous year, indicating that real surge in growth will come from the
emerging markets. Most of the projected increase in revenues will come from branded generics
rather than innovator products. The Indian Pharma industry is showing signs of healthy growth
and is likely to be in the top 10 global markets by value by 2020. In order to drive portable
growth in the future, companies will have to rethink the way they do business today. Recent
trends like mobile health along with innovations in health insurance and medical technology are
enabling the industry to deliver superior healthcare services. Further, the industry has seen many
regulatory interventions over the last one year, which will require careful consideration by
Pharma companies as they plan their future strategies. In this report, we look at the different
types of growth levers that have fuelled the growth of the Indian market, emerging new business
models, as well as the key success factors that need to be kept in mind to achieve sustainable
long-term growth. We hope this report presents an overview of some of the issues facing the
industry today and throws light on the road ahead for all stakeholders, to realize its full potential.  
(PwC Brand and Communications, India)

Congressional interest in methods to provide drugs at lower cost, particularly for the
elderly, has rekindled a discussion over the role the federal government plays in facilitating the
creation of new pharmaceuticals for the marketplace. Among the various federal laws that affect
technology development are those dealing with intellectual property rights, particularly patents.
Legislation concerning the ownership of inventions is intended to encourage additional private
sector investments often necessary to further develop marketable products. The current approach
attempts to balance the public sector’s interest in new and improved technologies with concerns
over providing companies valuable benefits without adequate accountability or compensation.
Questions have been raised as to whether or not this balance is appropriate, particularly with
respect to drug discovery. Critics maintain that the need for technology development incentives
in the pharmaceutical and/or biotechnology sectors is mitigated by industry access to
government-supported work at no cost, monopoly power through patent protection, and
additional regulatory and tax advantages such as those conveyed through the Drug Price
Competition and Patent Term Restoration Act and the Orphan Drug Act. Supporters of the
existing approach argue that these incentives are precisely what are required and have given rise to robust pharmaceutical and biotechnology industries. (John R. Thomas, Wendy H. Schacht)

Infectious diseases kill over 10 million people each year, more than 90% of whom are in the developing world. The leading causes of illness and death in Africa, Asia, and South America—regions that account for four-fifths of the world’s population—are HIV/AIDS, respiratory infections, malaria, and tuberculosis. In particular, the magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease or alleviate suffering. Each day, close to eight thousand people die of AIDS in the developing world. The reasons for the lack of access to essential medicines are manifold, but in many cases the high prices of drugs are a barrier to needed treatments. Prohibitive drug prices are often the result of strong intellectual property protection. Governments in developing countries that attempt to bring the price of medicines down have come under pressure from industrialized countries and the multinational pharmaceutical industry.

The study confirms that even though the R&D expenditure of the firm is less effective than the advertisement and marketing expenditure, expenditure of the firm on this head in the long run can be more productive in the form of more commercial patent patents and higher revenue. Furthermore, marketing and advertisement expenditure on the part of the firms to create a ‘niche market’ for their product with ‘brand loyalty’ among the consumers. The broad consensus on the economic debate on IPRs is that the economic interests involved are significant. At some level nearly all legitimately traded goods and services operate under, patent, copyright, or trademark protection (Maskus, 1994). There are indicators that strong patent regime may lead to increased global trade, attract more Foreign Direct Investment (FDI) for host countries, lead to increased licensing of technologies and possibly contribute to more local production through FDI in developing countries. Strong IPRs may lead to pharmaceutical research and development (R&D) which could be more appropriate to the needs of developing countries and at the same time contribute to higher growth rates in these countries. Arguments put forward in favour of strong intellectual property rights are mainly to encourage inventors to invent new products and processes, which are an improvement over older technologies. By improving and maintaining high rates of inventiveness, intellectual property rights contribute to
faster rates of technological change and thereby the rate of development of industries and countries. (Internet Extract)

Technology Transfer in Pharmaceutical Industry has been viewed from the perspective of Innovation and Research & Development. Since research is carried out in Laboratories on small scale before it could be produced on commercial scale. Thus, Technology Transfer is important for such research to materialize on a larger scale for commercialization especially in case of developing and under developing countries. Technology Transfer is defined as “the process of taking an invention from its inception in a laboratory to product development phase and then to a commercial scale”. Technology Transfer is an integral part of New Drug Discovery and development of new medicinal products. Thus if Technology Transfer process to production site is carried out at an affordable cost, the cost of product development would not raise during pilot scale up. For successful Technology Transfer of a product, the Departments responsible in a pharmaceutical industry are: Research & Development; Production; Engineering; Quality Control and Quality Assurance. Technology Transfer may be said to be successful if the receiving unit and the transferee can effectively utilize the technology for business gain. (Kaur Amneet, Sharma o.p., Dhari jatinder)

If the proprietor of the confidential information asserts that the information has been communicated in violation of its confidential nature, he or she may file suit to obtain all the remedies that are available in any other civil action, including an injunction, monetary damages, an accounting of profits and the delivery-up of all infringement copies. A preliminary injunction would be important to protect the disclosure of trade secrets and other confidential information. The plaintiff may also request an Anton Piller order, which permits the court to issue an ex parte order analogous to a search warrant that permits the plaintiff to search the defendant’s premises in order to remove evidence so that such items can be taken into protective custody pending the trial of the matter. The Anton Piller order is used both as an injunction to prevent the destruction of property critical to a trial, but also a discovery device. A related mechanism, the so-called Mareva injunction, allows the court to grant an injunction to prevent the defendant from removing is assets from the jurisdiction or destroying or disabling them. There are no specific criminal penalties under Indian law for the unauthorized communication of trade secrets, or for the breach of trust that usually accompanies such claim. (Alan Guterman & Bentley f. Anderson)
The author provides an overview of the functions, value, and impact that a patent system has in the age of rapid technological innovation. The patent system needs to be constantly adjusted and implemented so that the best balance between the right holders, new entrants to the market; the public at large and civil society is achieved. The potential of the patent system has been widely recognized in the context of knowledge creation and dynamic innovation.

He has described how patent information and its diffusion stimulate economic development. It has also explored how new technologies have had an enormous impact on the patent system and why some countries swiftly and strategically responded to the challenges from those new technologies by successfully adjusting their patent policies and systems. Two significant fields of new technology – computer and communication technology (including the internet), and biotechnology – have been examined in detail to show that patent policy decisions will continue to be crucial to the success of the knowledge and technology driven economy in the twenty-first century. Exclusively strong patent protection for new technologies may adversely affect economies. Therefore policy-makers will have to consider and implement policies which provide a balance by offering incentives to stimulate R&D, while ensuring a competitive environment for pioneers. Finally, patents are a power tool for economic development. The tool can be developing and developed nations alike, by multinational corporations as well as SMEs. (Kamil Idris)

Misunderstandings 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 concepts of ‘ownership’ of these resources and products derived from them. In fact, as a result of inadequate understanding of the basics IP, vested interests, politicians and general public make misleading statements, which are not based on the laws and practices of IP. The other elements 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., Pharma and fear of genetically modified crops. (Shahid Alikhan & Raghunath Mashelkar)
The logic of IPR as individual private right needs to be balanced with health as a public good. This requires a dynamic response from the government in framing the public policy choices which has to balance the innovator and the consumer. It is also essential for the innovator interest groups to understand the dynamics of different environment and composition of economic and social space in applying the yardsticks of IP jurisprudence. The road ahead for Indian pharma industry and Indian health care system will depend upon the public policy choices and policies framed on the ground realities and innovative protection measures embarked by the government with the private players. Most importantly there is an urgent need to embark on capacity building exercise of the human resources needed in the field of Patents. We need to train and update the skills of scientists, lawyers, judiciary and patent offices to cope with the regime and interface with patent regimes of the other parts of the world. (V.C. Vivekanandan,)

Generics manufacturers primarily produce medicines based on formulae in the public domain or patented by other companies. They may do some additional research to produce their own versions. Generics are based both in the Industrial and the developing world. The primary goal of both pharmaceutical and generic companies is to make profit. For pharmaceuticals, profit mostly comes from the sales of patented drugs, which only they have the right to manufacture and sell. For generics, profit generally comes from selling unpatented-no longer patented or patented elsewhere—drugs at prices lower than those of their competitors. The pharmaceutical sector is overwhelmingly Northern-based and dominated by a few large multinational companies. Most of their profits are also made in the industrialized countries. Although developing countries comprise over 80 per cent of the world’s population, only represent 21 per cent of global medicine sales. (Prof.SyedAshfaq Hussain)

The origin and development of patent system shows that each country has enacted patent laws which subserve its national and public interests best. And the patent laws of the country have varied from time depending on their economic development. However a general desire was felt for the harmonization of the laws of industrial property on worldwide basis. When many foreign visitors was not willing to exhibit their inventions in an international exhibition of inventions held in 1870 as Austria in view of the inadequate legal protection offered to the exhibited inventions, led to certain International developments. Firstly a special Austrian law secured special temporary protection to all foreigners participating in the exhibition for their
inventions. Secondly, the congress of Vienna for patent reform was convened during the same year. (B.Sandhya)

A mere patentability policy is meaningless unless such policy is implemented consistently, in a way linked to positive efforts of researcher and industry to raise their scientific and technological skill. Such investment and efforts constitute an important part of the absorption capacity of a country for technology transfer. Simply manipulating the scope and level of IP protection as a policy tool, without a solid linkage with other policies to increase creative research activities and investment in human resources, may result in a waste of resources. (Hiroko Yamane.)

Most countries are net ‘importers’ of IP however one measures the flow of IP- in almost economies, whether developed or developing, IP is predominantly owned by foreign firms, and most report a net outflow of royalties and deployment of IP laws and policy as central to their economic strategies. The national treatment principle rules out the possibility of offering stronger IP protection only to domestic interest. And a strong IP system is seen as a means of attracting investment and the inflow of investment TRIPS compliance can be used as a signal to this end. A country may seek to pursue interests both as consumer and as producers of IP, by accepting the systemic benefits of IP protection as essential infrastructure for knowledge economy, regardless of whoever may own or excise individual IP rights. (Antony Taubman.)

Export markets increasingly drive IPI: in a turnover of US $ 5 billion, exports constitute $3.2 billion and the industry is poised to grow to $ 25 billion by 2012. The share of IPI in world pharmaceutical market I 1.0% (ranks 13th) in value and 8% (ranks 4th) in volume terms. The global market for generic drug is estimated at $ 27 billion (2001) and the expiry of patents on dtgs will be worth $ 80 million (2005) offers a huge opportunity to IPI. India today has the largest number of US food and Drug administration (FDA) approved drug manufacturing facilities outside the US. Government of India (GOI) encouraged the R and D in Pharmaceutical companies by extending 10 year tax holiday to this sector. Besides, planning commission has earmarked $ 34 million towards drug industry R and D promotion fund for the tenth plan. (State industrial products)

Law and regulations and final judicial decisions and administrative rulings of general application, made effective by a member pertaining to the subject matter of this agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property
rights. Shall be published or where such publication is not practicable, made publicly available, in a national language -, in such a manner as to enable government and right holders to become acquainting with them. Agreement which are in force between the government or a governmental agency of a member and the government or a governmental agency of another membr shall also be published. (Richard Gilbert)

The DOJ /FTC Report concludes that a patent pool is unlikely to raise antitrust concern if: The pool is limited to patents that are essential to implement that standard, The pool grants non-exclusive license that do not prevent licensee from developing alternative technologies, Patentees grant non–exclusive license to the pool and retain the right to license their patents separately outside the pool and Licensees are required to grant back non exclusively license to use patents they hold that are essential to comply with the technology. (Nair, 2010)

Being a late starter, it is unrealistic to expect the Indian companies to bank on indigenous discovery, development and marketing of new drugs as the main growth strategy. A part from the uncertainties inherent in this activity, India even today does not have the full capability to develop a drug from concept to the market place. The strategy, therefore will be to discover candidate drugs, patent them and license them out (after reaching defined milestone of development) to large global pharma companies, very much like the pattern adopted by the Japanese and start up biotechnology companies. This approach has already been used by major Indian companies such as Ranbaxy, Dr. Reddy’s, and Nicholas Piramal, Glenmark, Suven Pharma and Others.

In 2001, Mckinseys did a study on the Indian pharma industry which predicted the Indian industry to reach a total production value of US $ 25 billion by 2010 and US $ 100 billion by 2020. Current estimates for 2010-2011 are around US $ 23 billion with the domestic and export markets almost equal. The growth of the export markets at a higher than that of the domestic market is not an indication of the domestic market; rather it is a strategy of the larger Indian companies to look for larger market shares for the generic APIs and formulations in the global market. This is indeed remarkable considering the uncertainties plaguing this segment and the global economic recession of the last three years. (Kim, 2012)

This paper examines how the role of patent and utility models in innovations and economic growth varies by level of economic development. Using a panel dataset of over 70 countries, it was found that patent protection is an important determinant of innovation and that
patentable innovations contribute to economic growth in developed countries, but not in developing. Instead, in developing economies a minor form of intellectual property rights (IPRs)- namely utility models- is conducive to innovation and growth, controlling for other factor. Using Korean firm level data as a case study, the authors found that utility model innovations contribute to firm performance when firms are technologically legging and those minor innovations can be a learning device and thus a stepping stone for developing more patentable innovations later on. Upon reaching higher levels of technological capabilities, firms become more reliant upon patents and less on utility models. Thus, the lesson here is that patent protection enhances the innovations and economic growth in countries where the capacity to conduct innovative research exists. Where this capacity is weaker a system that provides intensives to conduct to growth. The significant of this paper is to emphasize the importance not just of the strength of IPRs but of the appropriate type of IPRs for economic development. (Protection through the biological diversity act 2002)

Often valuable information is shared with people outside the company due to the non – awareness of the intellectual property rights and the crucial significance of IPR in the corporate existence. It is not uncommon to overhear interesting information which appears to be confidential in nature to a pair of trained ears (or those seeking such information) to overhear animated discussions at the seminar, on the golf course, during a flight, etc. While conducting an IP exercise, it becomes evident that the incumbent engaged in such airing of views had no idea that the central topic of his discussions was the subject matter of the organisation’s intellectual asset. The issue of education is essential if the organisation’s core business involves the creation or use of IP. Intellectual property education ensures that all the members of theorganisation are able to help identify intellectual assets, assist in obtaining appropriate protection, management and commercialization of the IP. Another advantage of creating IP awareness is to get trained ears from within the organization who are aware enough to spot an infringement of the organisation’s products/services and bring it to the knowledge of the organisation’s legal term for appropriate action. Often during an IP audit procedure, there are a number of IP assets unearthed that the company did not even know that it possessed. Trade secrets such as evolution of the internal pricing strategies, old customer database photographs and log entries of records of historical value are unearthed that are priceless in terms of intellectual assets. (Sunitha, K.Sreedharan)
IPR are recognized as enjoying human rights status, the first human right’s inspired justification of IPR dates back to the French Revolution. The Declaration of the Rights of Man and Citizen (1789) included “property” among the “natural and imprescriptible rights of man”. During the elaboration of the Law of 1791 providing a rights of representation to authors, it was stated that “the property of the work which is born of the writer’s thought is the most sacred, the most legitimate, the most unassailable, and the most personal of all properties”. The human rights status of IPR is also confirmed in the UDHR and the ICESCR. Art. 27 of the UDHR of 1948 states that “Everyone has the rights to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author” as part of the list of fundamental liberties. (Ayyangar 1959)

In the world today, intellectual property laws are far from uniform. This inconsistency reflects the fundamental schism that exists between developed and developing countries regarding the benefits and perceived dangers of property rights in technology and related items. An inventor in a developed country will seek strong intellectual property protection to prevent those located in developing countries from “free – riding” on his work and to establish additional markets through which to recover the costs of development. On the other hand, governments in many poor and developing countries are reluctant to provide any strong degree of protection to foreign inventors and firms, since protection of this sort may work as a disincentive to local innovators to build their own research and marketing capabilities and, perhaps more importantly, allow foreign firms to exercise undue control over the availability and affordability of the protected items. (Alan S. Gullerman, Robert Brown)

The study focuses on the fundamental understanding of IP. IP as a concept is advanced and distinguished from some similar concepts, such as intellectual capital and industrial property. It explains the scope of IP and how IPP is expanding, as well as discussing common features among types of IP. It discusses the controversial views on IPP and the difficulties of striking a balance between the interests of originators and of the general public. The author has examined the expanding interdisciplinary field. (Deli Yang)

Two cases demonstrate the importance and complexity of IPP. The Harry Potter case illustrates the importance of copyrights for writers, and shows how IP has played a significant role in the creation of wealth from the dissemination of original creativity into related licensed products. The Arsenal trademark dispute between the club and a street vendor shows how IP can
be controversial subject, with different interpretations as to the rights and wrongs of an issue. The vast economic literature on product quality focuses primarily on issues like quality optimization by producers and consumers, quality signalling and their economic implications. However, the definition of product quality has remained abstract and the issue of the construction of quality, at a conceptual and operational level, has not been adequately addressed in this literature. Our paper shows that even the conceptual construction of quality may have important political economy dimensions. Of course, these political economy forces will vary from sector to sector, and broad generalizations may be difficult to arrive at. This paper makes an attempt to present a new insight into the construction of quality in the context of pharmaceuticals. We have examined how the various political economy forces, driven by the diversity of objective functions of the different sets of economic agents involved in the process of production, distribution and consumption of drugs, have shaped the increasingly complex construction of drug quality, both globally and in India. We have come up with a comprehensive multi-dimensional definition of drug quality in this paper incorporating a whole range of parameters. Based on these distinct parametric, we have identified in this paper the structural changes that the drug industry is undergoing as a result of the newly emerging construction of drug quality. The economic consequences of these structural changes are evident. We have shown that quality-driven automation will lead to a compositional shift in employment from unskilled to skilled labor, although the size of both is likely to shrink. Moreover, it may lead to the Marxian alienation of labor eroding labor’s relative bargaining power vis-à-vis the entrepreneur. We have also argued that quality-driven exports in this industry, even within a free-trade framework, will initiate an anti-H/O/S process and will lead to a fall in the real wage of labor. Finally, we have shown that the market structure for the Indian drug industry may be characterized by two non-overlapping: an oligopolistic one for high-quality drugs and a perfectly competitive one for low quality. (Amit S Ray, Aaradindu Bhaduri)

The value of IP to a company depends on the extent of business advantage it can provide. The manner of protection plays an important role in defining IP value. Intellectual Property that is strategically well protected always has high business value than unplanned IP. The strength of protection depends on various factors ranging from the nature of IP to the quality of attorney. For example, a fanciful trade mark such as Kodak has more value than a descriptive mark such as House of Coffee and therefore, a company that protects a fanciful mark will have higher business
advantage than the one using a descriptive mark. In addition to the manner of protection, strength of protection depends on number of patents in the field, if the field is crowded and has many patents relating to tables, the value of the patent will be much lower as opposed to there being very few patents or inventions in the field. Most companies perform patent mapping and technology landscaping exercises to understand the layout of patent domain before initiating their research efforts. These activities enable companies to identify white spaces in a domain and thereby, help companies orient their research towards gaps that can result in strong and valuable IP. Competitor activities are consistently monitored by companies to understand their IP direction and frame invention/creation development approach. Intentions, that fall into the white space, where the field is not crowded and which are devoid of competitor activity are considered to provide greater business value. (Kalyan C Kankanala)

The strategic role of patent is not limited to its protective ownership. Due to a patent’s multiple signaling, a multi dimensional role exists for a patent and hence PQ should be measured through a coordinated multi model synergistic approach. This requires identification of as many non redundant measures that cover these strategic roles as possible. A firm which has decided to play the patent game has to become conscious of the fact that technology is its fulcrum. By emphasizing on technical quality derived from the basic patent characteristics, a firm can reduce market uncertainties in the use of its patents – from creation, to application and finally licensing and its dependence on patent grant quality to justify and leverage its patenting strategies. The firm thus becomes proactive in identifying, managing and licensing patents of and for its portfolio. (Mukundan R and Karuna)

Whereas the length of the patent protection characterizes the duration of the monopoly power, the scope of a patent bears on the intensity of the induced monopoly power (Merges and Nelson 1990). The breadth of a patent defines the range of products that are encompassed by the claims of the patent and therefore protects the patent are, the broader the patent. The height of a patent, on the other hand, confers protection against improvements or applications that are easy or trivial. The value of a patent to a firm depends on how effective its protection is in these two dimensions (breadth and height), in addition to being related monotonically to the patent length. (Corinne Langinier and GianCarlo Moschinin)

The conclusion is based on separate estimates of the benefits and costs of patents to innovative firms. We use two different techniques to estimate the value of patents to their
owners. The first technique examines the decision to pay patent maintenance fees. The size of the fee sets a lower bound on the expected value of the patent at each payment date. A large fraction of patents lapse each time maintenance fees are due. Using well–known econometric tools, we use payment information on a large set of patents to calculate patent value.

The second technique relies on the stock market valuation of publicly traded firms. Firm share value is determined by investor expectations about future firm profits. Expected future profits depend on the assets owned by a firm; both physical assets and intangible assets including patents. We use standard econometric tools to apportion share value to the different assets owned by a firm. Thus, we can calculate the value of a firm’s patent portfolio, and from that, the value of the average patent.

These two rather different techniques produce estimates that roughly correspond. The mean is calculated worldwide patent value of $370,000 for publicly traded American firms. Like other researchers, we find that patent values vary tremendously depending on the industry. The average value of patents held by large firms is easily an order of magnitude larger than the average value of patent held by firms in other industries. Also, the distribution of patent value is skewed so that the median patent value is nearly an order of magnitude smaller than the mean.

(James Bessen and Michael Meurer1)

Instances where a TK–Derived intention has been granted a patent are:

(a) The Jeewani drug, where, a group of scientists belonging to Tropical Botanical Gardens Research Institute observed Kani tribals residing in the Western Ghats eating some fruits and leaves to avoid fatigue. In the process they discovered the energy and immunity enhancing properties of those plants and thereafter obtained patents in relation to these discoveries, obtained patents in relation to these discoveries which was granted by the Patent Office.

(b) The Hoodia drug, based in South Africa, where the plant supplements was used to manufacture dietary supplements. In this instance, the San people of South Africa used the plant as appetite suppressants.

In addition to the above instance, the Chinese patent office has granted many patents pertaining to the medicinal field, which ultimately result from TK.
TK promotes community interests, while patent law promotes personal monopoly. When both worlds overlap with each other in the case of TK – derived inventions, there emerges a need to find a mean path that strikes a balance between the two.

This has best been brought out in India through the Biodiversity Act, 2002. The important provision of the Act is Section 2 (a) read with Section 6(2) (ref. 14) which introduces the concept of ‘benefit – sharing’ in relation to commercialization of products obtained / derived from knowledge/ resource that is conserved/ protected by ‘benefit claimers’. (Shravan Kalluri)

**The report on ‘Indian Pharmaceutical Industry’** gives valuable insight on basics of the industry, domestic demand and growth drivers, exports market, imports statistics, regulatory landscape, a brief note on biopharma & crams and performance analysis of key industry players. The report also provides CARE Research’s Outlook on the domestic and exports market for the next 5 years.

The report is indispensable for any company in the pharmaceutical industry, banks/ Financial Institutions (FIs), policy makers, research & academic institutions, other international and national agencies etc. Additionally, the twelve monthly updates from the date of subscription of the said report would form a potent tool for the subscribers to keep abreast with the recent developments in the industry.

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