INDIAN INDUSTRIES in the era of

INTELLECTUAL PROPERTY RIGHTS and WTO: Gearing for the Global competition

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Abstract

The term 'Intellectual Property" has come to be internationally recognized as covering patents, industrial designs, copyright, trade marks, know how and confidential information. Although the creation of trade mark has very little to do with intellectual creativity, it cannot be doubted that patents, designs and copyright are the product of intellectual effort and creative activity in the field of applied arts or technology and fine arts. In the information age, IPR protection takes on a pivotal role. Indeed, a healthy IPR framework is the sine qua non of the knowledge revolution. In a world linked by a digital framework, empowered by software, and where innovations of the mind, derived through massive expenditure of intellect and resources, are the key products, the strength of IPR regimes can mark the difference between a flourishing and an absent market. A global environment creates extraordinary new challenges in IP protection, which the international community is only just coming to terms with. Furthermore, Sound IPR policies will play a key role in developing some of India's most exciting growth areas, including software development, biotechnology, entertainment, and pharmaceutical development. This paper demonstrate the term `Intellectual Property Rights, examine how the WTO protect these rights and assess the likely impact of TRIPS Agreement on Indian Industries.

Keywords: IPR, TRIPS, WTO, Trademark, Patent, Copyrights

Introduction

Intellectual property right is in the nature of intangible property. In each case it consists of a bundle of rights in relation to certain material object created by the owner. In the case of Patents, property consists of the exclusive right to use the invention patented, to grant licenses to others to exercise the right or to sell that right to third person. The invention may be related to a new product or an improvement in an existing product or a new process of manufacturing an existing or a new product. For the acquisition of new monopoly, the conditions to be satisfied for acquisition, its duration, the licensing of these monopoly rights or their assignment to others are strictly governed by the

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Patents Act. After the expiry of the term of patent (WTO requirement of duration of patents is 20 years) it becomes a public property when anybody can use the patented invention.

In the case of Industrial designs, the property consists in the exclusive right to apply the design registered under the Designs Act 1911, in relation to the class of goods for which it is registered for a maximum period of 15 years subject to payment of renewal fees prescribed by the rules. This right can also be licensed for use by third parties or assigned to any person. On expiry of term of registration anybody can use the design. In case of Trademark, there are two types of rights; one conferred under the Trade and Merchandise Marks Act 1958 and other acquired in relation to a trade mark, trade name or a get-up by actual use in relation to some product or service. The rights conferred by registration are confined to the use of the mark in relation to the actual goods for which it is registered. The actual rights granted by registration enables the proprietor of registered mark to prevent others from not only using the mark as registered but also marks which are deceptively similar to the registered mark i.e. marks that nearly resemble the registered mark as to be likely to deceive or cause confusion among the consumers of the goods covered by registration. In case of an unregistered mark, a get-up and other badge of goodwill of business the protection is given to the goodwill of the business in relation to which such trademark or get-up is used. Such protection may also extend, in appropriate cases, to allied goods or businesses. Unlike patents, designs or copyrights the rights conferred by registration of a trade mark can be availed for a indefinite period by periodic renewal of registration and the proprietor being able to ward of rectification of the register on the ground of non-use or any other specified ground under the Act. In the case of an unregistered trade mark the right to protection of goodwill continues indefinitely provided the owner of the goodwill uses the mark lawfully and prevents other persons from infringing those rights by appropriate timely action (passing off) in courts of law against infringes.

Copyright like the patents and the industrial designs is purely a creation of the statute, the Copyrights Act 1957 as amended from time to time. But there is no formality required for the acquisition of the right. Copyright subsists in any original work specified in the act from the moment of its publication during the lifetime of the author plus sixty years. The works specified in the Act are (1) a literary, a dramatic and musical or artistic work, (2) a cinematography film and (3) a sound recording. Literary work includes computer programs, tables and compilations including computer databases. The licensing and assignment of copyright in any work is governed by the provisions of the Act.

Know-how and confidential information can be protected only so long as the owner is able to keep them secrets and takes action against unlawful use of such information by others by an action for breach of confidence or contract. The law of patents, designs and trademark are territorial in its operation. As regard copyright, by virtue of international conventions such as Berne convention and the Universal Copyright Convention copyright acquired in one country extends to other countries, which are members of these conventions. India is member of both conventions. Although the relevant statute defines the right conferred on a particular species of intellectual property as the exclusive right to use the patent, apply the design, use the trademarks or commercially exploit the work in certain forms (as in copyright), in practice what the

statute confers is the right to prevent competitors from commercially exploiting the respective right to the detriment of the owner of that property.

The contribution of intellectual property to economic and cultural development of a country in substantial. The granting of patent monopoly in consideration of disclosure of invention enables competitors in the field to manufacture new products or improved products or effect improvements in the process of manufacture. But for a patent system much of the technological information would have remained secret and lost to the world. As it is the patent specification that are available to the public contains practically all the information relating to any field of technology. What is not available in the patent literature is the confidential information, industrial and business secrets and what is called know-how which others have no free access but which could be obtained by negotiation with the owner of such information for a price.

Protection of trademarks enables consumer to obtain their products of the right quality, which they are accustomed to get identifying the product by the mark. If trademark cannot be protected from infringement the market will be flooded with shoddy and spurious goods by unscrupulous persons. Today copyright affects every industry conceivable. The printing, publishing and entertainment industry like the film and recording industry are almost completely dependent on copyright protection. The manufacture of any kind of machinery or machine is based on industrial drawings, which enjoy copyright protection.

INTERNATIONAL CHARACTER OF INTELLECTUAL PROPERTY

The enormous technological development of transport and communications has resulted in the globalization of trade and commerce. This has its impact on intellectual property, which is becoming international in character. Intellectual property can travel effortlessly from one country to another. Piracy of intellectual property has become international in character. This is particularly important in case of copyright. Piracy of copyright work has become extremely easy and inexpensive owing to gadgets like tape recorder, video cassette recorder, magnetic tape, photo copying machines and so on. No foolproof method of preventing piracy has so far been developed.

The international character of intellectual property is recognized in the various international conventions for the protection of such property. As technology in all the fields of human activities are developing exponentially the field of intellectual property is also expanding correspondingly. Protection of plant varieties, prevention of various forms of unfair competition or misappropriation of goodwill, reputation of trade values, unfair business practices, slavish copying of details of products, dilution of reputed trademarks and their commercial value by using them by competitors in field of activity different from the owners are becoming more and more difficult. Piracy of intellectual property has become international owing to globalization of trade and commerce. Intellectual property law is one of the fastest growing branch of law today practically all over the world. Broadcasting cable casting and telecasting rights are some of the new branches of intellectual property.

TRADE RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The agreement on the trade-related Aspects of the Intellectual Property Rights [TRIPS] of the WTO, which came into effect on January 1,1995, is to date the most comprehensive multilateral agreement on the intellectual property. WTO and TRIPS set the minimum level of protection of intellectual property protection and enforcement provision, every member country must provide to a right holder. TRIPS adds a substantial no. of additional obligations on matters where the pre-existing conventions are silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as a Paris-Plus Agreement. Significantly, Intellectual property rights have been recognized as vital to free trade. All countries that are a part of GATT / WTO have to amply with the TRIPS text. Under Article 65.2 of TRIPS, India as a developing country has fallen under the WTO commitments after January 1, 2000. The general goals of the TRIPS are contained in the Preamble of the Agreement, which reproduces the basic Uruguay Round negotiating objectives. These objectives include the distortions and impediments of international trade, promotion of effective and adequate protection of intellectual property rights, and ensuring that measures and procedures to enforce IPR, do not themselves become barriers to legitimate trade.

Intellectual property rights are enforced by an action for infringement of those rights before a District Court or High Court. Criminal prosecution is also possible in respect of trademark and copyright.

PATENTS

Patents are one of the oldest forms of intellectual property protection and the aim of a patent system is to encourage technological development by rewarding intellectual creativity. Patent under the act, is grant from the government to inventor for a limited period of time the exclusive right to make, use, exercise and vend invention. The patent protection provides a reward not only for the creation of an invention, but also for the development of an invention to the point at which it is technologically feasible and marketable, and this type of an incentive promotes additional creativity and encourages companies to continue their development of new technology to the point at which it is marketable, useful to the public and desirable for the public good. By international agreement, patents are available for inventions in all areas of technology. Process for developing or making things can be patented. Patents are intended for breakthroughs in technology, but they are also intended for small technological increments. There are few things, which cannot be patented for instance human genes cannot be patented. A perpetual motion machine, which goes against the laws of nature, cannot be patented unless someone can show it working.

The advantages of taking out a patent are very specifically and technically the fact that the owner of a patent can exclude all others in the territory covered by the patent from making, using, selling or importing the invention. The term of a patent is typically 20 years from the date on which the application is filed and what that does is give the developer of the technology the right to have it to himself for a certain number of years in exchange for full disclosure to the public of how to use it. When the patent rights expire, the technology becomes public property, and the public is free to use it for their own good.

THE WTO REQUIREMENTS	THE CURRENT LAW	STATUS
Both process and product patents must be available in all fields of technology	Indian patents Act, 1970, allows process patents only for food, medicine, drugs and chemicals	Product Patent has been made available from January 2005
Duration of patents must be 20 yrs.	Duration of process is 5 yrs from date of sealing or 7 yrs from date of filing. Duration of product patents is 14 yrs.	Patent laws have been amended in India to meet WTO requirements
There should be no discrimination between imported and domestic products.	Importation of a product is not equivalent to the working of a patent in India	Debatable Issue
Microbiological must be patented.	Patenting of life forms is not permitted	The biodiversity conservation bill, which will protect Indian germ plasm, is doing the rounds of the ministries.
Plant varieties must be protected through patents	No protection of plant varieties	A draft of the plant varieties bill has been approved for this purpose
Agricultural subsidies to be reduced if the aggregate measure of support (AMS) for agricultural sector exceeds 10%.	Due to price controls AMS is less than 10%	No compulsion to reduce agricultural subsidies in India
Export subsidies for exports account for more than 3.25 % of world trade in that product to be faced out after 2003	An export income exempts from tax export credit provided at concessional rates of interest.	Export subsidies have been phased out for gems and jewelry
TELECOM GOI monopoly over long distance and international services reviewed	Private parties are being permitted as operators	74% FDI has been permitted
INFOTECH Zero tariffs on computer, telecom products, semi-conductors and software by 2005.	30% duty on telecom equipment, 10% on computer components and zero duty on computer software.	Duty rates have been reduced to 5% and 0% on these items

COPYRIGHT

Copyright means the exclusive right to do or authorize others to do certain acts in relation to: Literary, dramatic, musical and artistic works, Cinematography films and Sound recordings. The nature of act varies according to the subject matter. Basically copyright is the right to copy or reproduce the work in which copyright subsists. The various acts for which copyright extends are listed in section 14 of the act. Copyright does not extend to any right beyond the scope of section 14. The exclusive right for doing the respective acts extends not only to the whole of the work but to any substantial part thereof or to any translation or adaptation thereof, where applicable. The term of the copyright is the life of the author of the work, plus sixty years with certain exceptions. Copyright is a kind of intellectual property the importance of which has increased enormously in recent times due to the rapid technological development in the field of printing, music, communication, entertainment and computer industries. Consequent upon India signing the GATT and entering the global market economy, a number of changes have been made in the Copyright Act of 1957 by the Amending Act of 1994.This has been done in order to give effect to the obligations arising from the signing of the GATT and to make Indian law more in line with the present law in many developed countries.

The object of the copyright law is to encourage authors, composers, artists, and designers to create original works by rewarding them with the exclusive right for a limited period to exploit the work for monitory gain. The economic exploitation is done by licensing such exclusive rights to entrepreneurs like publishers, film producers and record manufacturers for a monitory consideration. People who economically exploit the copyright are the greater beneficiaries of the copyright law than the creators of works of copyright. Hence, the object of copyright law is to protect the author of the copyright work from an unlawful reproduction or exploitation of his work by others. Copyright protection is essential to encourage exploitation of copyright work for the benefit of the public.

Today the law of copyright is of interest not only to those who deal with literary, dramatic or musical works but artists, dress designers, architects, publishers, persons concerned with cinematography films and entertainment industry. Apart from the above, copyright law affects the manufacturing industry as a whole. Copyright subsists in original industrial drawings used in the manufacture of machines and machine parts. The effect of this is that an unauthorized manufacture of a machine or a machine part based on such drawings (i.e. the three dimensional representation of the drawing) is an infringement of the copyright in the original drawing even if the person making the article has not seen the original drawing but has copied only a machine made in accordance with that drawing. This gives better protection than a patent for the article made accordance with that drawing. Patent expires after fourteen years, whereas copyright protection extends beyond sixty years. Besides, no formalities are required for copyright acquisition whereas obtaining a patent is a laborious and long drawn out process involving considerable expenditure.

Owing to the international character of copyright, various countries have joined to form conventions for the protection of copyright owned by its nationals in other countries.

The Berne Convention and Universal Copyright Convention are the result of such joint effort. Most of the countries of the world are members of atleast one of the three conventions. India is a member of two of these conventions. Accordingly Indian copyright owners can protect their copyright in almost any country in the world. The law of copyright in India is contained in the Copyright Act 1957 as amended subsequently from time to time. Taking appropriate actions can stop infringement of copyright. The remedies available are an injunction to damages on account of profits and in some cases conversion damages. Infringement of copyright is also an offence, punishable with imprisonment and fine.

TRADEMARK

Patents, registered designs and copyright are protected only for a limited period. The section on trademarks of the TRIPS Agreement gives a clear definition of what constitutes a trademark and lays down, in some detail, the dos and do-nots of such protection. Article 15.1 of TRIPS defines a trademark and the basic obligation of all members with regard to such protection. A trademark is 'any sign, or any combination of signs, capable of distinguishing the goods and services of one undertaking from those of the other undertakings…' A person who sells his goods under a particular trademark acquires a sort of limited exclusive right to the use of the mark in relation to those goods. Such a right acquired by use is recognized as a form of property in the trademark, and protected under common law. The law of trademarks is based mainly on two concepts: *distinctiveness and deceptive similarity.*

Under modern business conditions a trademark performs four functions: -

a) It identifies the product and its origin
b) It guarantees its unchanged quality
c) It advertises the product and
d) It creates an image for the product.

The concept of identifying the source of manufacture by a mark is an ancient one. But its importance in trade and commerce was recognised only after the industrial revolution, which enabled large-scale production and distribution of goods and publicity through the printing media. The growth of big companies dealing in various kinds of goods manufactured by itself or through other companies but marketed by it led to the use of its own trademark on goods manufactured by others but marketed by it or otherwise dealt by it. To cope up with this situation, the original concept of trademark indicating a source of manufacture was extended to include any connection in the course of trade. By virtue of extensive use and advertisement a trademark began to acquire goodwill and reputation among the customers. This tempted competitors to emulate the well known trademarks, thus arose the necessity for protecting the trademark.

Prior to the statutory registration of trademarks, the only way in which copying of a trademark could be prevented was by bringing an action for passing off, which required proof of use and reputation of the mark each time an action is launched against the infringer. This process was cumbersome, time consuming and the outcome uncertain. Hence a system of registration of trademark was evolved which gave statutory

recognition to ownership of trademarks, and defined the rights conferred by registration and defined remedies in respect of infringement of those rights. The statutory law relating to trademarks is codified in the Trade and Merchandise Marks Act 1958 and the Trade and Merchandise Marks Rules 1959.

According to Article 15.1 (TRIPS) for the first time in international law registration requirements were extended to service marks. Several developed countries had themselves allowed for registration of marks fairly recently, in the 1960's and 1970's, following the rising importance of service industries. Although the developing countries did oppose such an extension in the TRIPS negotiations they had no basic objections to protecting service marks at par with trademarks. Already, in the developing countries like India where the pre TRIPS law does not permit the registration of service marks, service industries do register their marks as trademarks on goods that they may use during the discharge of their services, including stationary articles. Several developing countries like Argentina, Brazil, Malaysia and Singapore had already allowed such registration of service marks as a part of TRIPS-implementing legislation in 1999. There is no provision for registration of service marks in India as present. Such marks or names used by business rendering various kinds of services can, therefore, be protected only by action for passing off.

Essentials to qualify as a Trademark

It was considered prudent in the TRIPS negotiations to draw up an illustrative list of signs, which are eligible for registration. This list in TRIPS includes personal names, letters, numerals, figurative elements and combination of colours as well as any combination of such signs. Some of the more ambitious demands on product shape or packaging or single colours originally proposed by the USA were not agreed for inclusion in the illustrative list. Earlier proposals for including sound and smell signs were rejected outright for not being practical and it was conceded that members could make registrability dependent on visual perceptibility. TRIPS now allows in Article 15.1 that registrability maybe made contingent on distinctiveness acquired through use. Thus, the shape of Coca-Cola bottle- HUB SKIRT- can be registered as a trademark, after it has been proven distinctive through use. Article 15.3 of TRIPS allows WTO members to make registrability dependent on use but use cannot be made a condition at the time of application. However, the applicant cannot be denied registration on the ground that he is not using the mark until three years have passed from the date of application

Common law countries like Australia and New Zealand have amended their trademark laws to provide for changes in registrability. German courts have also been restrictive in the grant of 3-dimensional trademarks on shape of goods and packaging. Rights may overlap with industrial design rights, which are limited in time, unlike trademarks. Article 20 lays down that 'the use of a trademark shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in special form or use in a manner detrimental to its capability to distinguish the goods and services of one undertaking from the other'. In past, India had attempted to impose special requirements on generic names of pharmaceutical products but required, as an executive directive in approving joint ventures, that foreign brand names be sued only

in conjunction with Indian names. Thus, 'hybrid' brands such as 'Maruti – Suzuki' for cars or 'Hero- Honda' for motorcycles were peculiar to the country.

INDUSTRIAL DESIGN

The object of design registration is to see that others applying it to their goods without permission do not deprive the originator of a profitable design of his reward.Design means only the features of shape configuration, pattern or ornament applied to any article by any industrial process, which in the finished article appeal to and are judged solely by the eye and which is not a mere mechanical device. A design in order to be registrable must be new or original not previously published in India. A design may be incorporated in the article itself as in the case of a shape or configuration which is three dimensional in nature or it may be represented two dimensionally on apiece of paper in such a way that the article to which it is applied could be visualized. Shape and configuration are three dimensional, e.g. the shape of bottle, vase and so on; while patterns or ornaments are two dimensional as in the case of patterns for textiles, wallpaper, etc which serves the purpose of decoration. A design must have individuality of appearance, which makes it not merely visible but also noticed. Industrial design is different from a trademark. If after the expiry of the monopoly period, the other traders do not use the design then in due course of time it becomes distinctive of the goods of the original proprietor and acquires significance as a trademark.

The registered proprietor of a design has exclusive rights to apply a design to any article in any class in which it is registered. This right is called a Copyright in the design. Copyright in the design can last for a maximum of 15 years. Thereafter it becomes public property and anybody can use it. But there is a flip side to registration. Registration does not give any exclusive right to the registered proprietor.

INDIAN INDUSTRIES AND INTELLECTUAL PROPERTY RIGHTS

i. Traditional Industries

India has vast traditional and skilled manpower. The prosperity of many parts of India can be attributed to this manpower. Besides this the knowledge in our country exists in the following forms: Documented in local languages, non-documented but existing in traditional practices, oral practices and in folklore. Traditional knowledge is the product of the continuity of creative skills and craftsmanship in a variety of cultures, traditions and beliefs since ancient period. The traditional societies have generated a vast reservoir of information and experiences that have helped in sustaining their social and economic life. To prevent piracy and to protect our knowledge system, there is an urgent need of its documentation.

Today in the globalised world where more and more people are looking to India be it for Mehendi tattoos, Bhandani dupattas, lac bangles etc it is very vital that we take pro-active steps to protect our ancient arts and crafts. The real purpose of such protection is the inherent economic potential of traditional knowledge.

For instance it has been observed that a large number of people world over are shifting to "Ayurvedic" medicines. Developed countries have varied perspectives ranging from conservation to economic exploitation of the "traditional knowledge base" in obtaining new products processes in a large number of applications of commercial importance. There is also urgent need to spread awareness about patents, trademarks, copyrights etc among these skilled artisans so as to make them aware of the procedure to protect their heritage as well as earn a rightful amount from its commercial exploitation in the global markets. To prevent piracy and to protect our knowledge system, there is an urgent need of its documentation. This documentation would contribute, to the promotion and dissemination of innovations and also be significant for researchers and scientists.

The Government of India has taken an important initiative to establish National Traditional Knowledge Digital Library (TKDL), so that in the current phase all the documented information about medicinal plants in Indian traditional system become accessible to the patent examiners globally with the objective to prevent the grant of patents for non-original inventions. It is time that the government takes responsible steps to rectify the situation and formulates legislation's to protect indigenous intellectual property rights. If the government does not take immediate steps to create trademarks and patents for the traditional industry Indian artisans and local craftsmen will have to be prepared to undergo litigation in order to be able to earn a fair profit for their "own creations".

India possesses a great wealth of biological diversity in its forests, its wetlands and in its marine areas. India is one of the 12-mega biodiversity countries with a wealth of more than 7500 species of medicinal plants being used by its ethnic communities .The medical texts of Ayurveda enumerate more than 1700 species of plants. Such bio-diversity can be used as repellents, insecticides, healing and protecting skin in chewing gum, denitrifies, cosmetics, therapeutics, pharmaceuticals and ophthalmic. India, with approximately 8% of world's biodiversity and as one of the greatest storehouses of traditional knowledge, has the potential of becoming a major player in the global trade in herbs-based formulations, medicines and products.

Most patenting activity needs to be observed in the inventions pertaining to the medicinal plants, spices, fruits, vegetables, wood, dyes, and fiber. There is also a need to institute mechanisms for sharing of benefits arising out of the commercial exploitation of biological resources using such traditional knowledge. In India this is proposed to be done through the bio-diversity legislation, which is before the Parliament now. The government of India has also initiated action for preparation of a digital database on traditional knowledge relating to medicinal plants. The main objective of creating such a database is to avoid grant of patent on the knowledge, which is in public domain. The great task has to be completed at the earliest in order to avoid future litigation is clear evidence of the commercial value which the pharmaceutical industry places on indigenous peoples intellectual property.

ii. Agriculture

In India today, there is large scale Subsistence farming being carried out and very little commercial farming. Inspite of all the fertile soil and optimum growing conditions India has not been able to fully harness its potential in the commercial trading arena. There are various reasons for this but now in the LPG 21st century world it is imperative that we do some thinking on our agricultural sector and try to leverage our "Competitive Advantage" in it. In today's patenting regime where large-scale commercial farming is the order of the day it is very crucial to be fastest in registering one's patents or else face the consequences of some large MNC else reaping the benefit from its patent. The argument goes that Patenting of Agricultural commodities enables the patent holder to gain a "Premium Price" on it which would act as an incentive to produce more of it in an cost-effective, efficient manner. The plants and animals were kept out of the purview of patents when the concept was developed initially. However, in fifties, discussion started on finding out ways in which more plant varieties could be developed and breeders could be given incentives to innovate and disclose the improvements.

The TRIPS agreement provides for patents for goods which can be identified as originating in a territory, or a region in that territory, where a given quality, reputation or other characteristic is essentially attributable to its geographical origin.

In Texas, a company called RiceTec took out the patents on Basmati rice (which is grown in the Indian and Pakistani regions).However, towards the middle of August 2001, three patents were awarded to RiceTec-Texmati, Jasmati and Kasmati, all cross breeds of Basmati. IPR's are thus going to be the guiding force in protecting various agricultural commodities so as to enable the rightful owners (i.e. farmers and agriculturists reap the monetary benefits from its commercial exploitation).

iii. PHARMACEUTICAL INDUSTRY

Currently the Indian pharmaceutical industry is a vibrant, high technology based and high growth oriented industry-attracting attention the world over for its immense potential to produce high quality drugs and pharmaceutical formulations. The Pharmaceutical industry is among the most highly R&D intensive industry. The new millennium brings both new opportunities and new prospects on the one hand and on the other hand emergence of a radically altered Pharmaceutical Order, post2005. The industry is characterized by:

- Very intense competition with about 24,000companies – large, big, medium and small fighting for their own place under the sun in more than Rs. 17,000 crore market.
- Continuous drug discovery and rapid introduction of new products.
- The seemingly ever-increasing and almost never-ending governmental regulations and policy changes.

- Stifling price controls, eroding profits and consequently a vanishing bottom line.
- Rigorous controls on formulations and an absence of international patent protection resulting in me-too maze of products with little or no product differentiation.
- Increasing health awareness among the people and importance given to mediclaim.
- Increasing dominance of trade associations and their constant demand for increase in trade margins.

In India, there is one big paradox. The Indian drug industry has been protected from foreign competition for two decades. And yet it is one of the most competitive in the world. Indian drug exports grew by 35% annually over the past decade to reach $71m in 1994. It has been said that India was violating its obligations on pharmaceutical and agricultural chemical patents.

PATENT PROTECTION FOR PHARMACEUTICALS RAISES THE FOLLOWING DISTINCT ISSUES:

1. What is the impact on public health? Some say patenting drugs raises costs, puts them out of the reach of the poor (in this case most of the country), and therefore damages public health. Others counter that it encourages the introduction of new drugs, either by directly encouraging invention in the country (in India) or through newly invented imports that are protected, or through foreign investment in production (and possibly research) in India. (India's size might make this a more attractive prospect than investing in a smaller country.)

2. What is the impact on Indian manufacturing and the Indian economy? The small players, who have been making copies, fear that they will not have sufficient capital or technology to invent new drugs that can be patented. As a result, they feel the market will be polarized in favour of foreign multinationals. The larger firms on the other hand, are in full support of patents, which they hope will attract foreign investment, and thereby stimulate joint ventures and research. The Governments Point of view while the government — along with foreign multinationals — is keen to implement the agreement, it has faced resistance from local drug manufacturers and consumers. According to the government once the crutches of weak patent law are removed, it can successfully negotiate with research-based international companies, to boost export earnings, create more employment and benefit from the transfer of technology.

Under the WTO led product patent regime, the mandate to the Pharma industry is to focus on innovation and research. Protection of intellectual property is vital for encouraging and sustaining such innovation and research. The catch lies in understanding the so-called protection and using it to one's advantage.

This aspect needs to be rectified with urgency, more so for our Pharmaceutical Industry, as India is uniquely positioned amongst emerging markets of the world to play a significant role in the international health care scenario.

Deregulation and Patent protection are considered necessary encouragement for research and development because they allow companies to recover the costs. But their immediate impact could be social upheaval, resulting from an increase in the price of essential drugs; and it is the lifting of price controls that could have a more serious impact on drug consumers. According to a recent study by the Indian Drug Manufacturers Association, within the next 10 years, patents of most of the world's top 10 drugs will expire. The market for generic drugs will correspondingly increase.

"With well-established capabilities in the manufacture of bulk drugs, India can meet the challenge from the 'hard' patent regime, by invading Western markets with generic drugs". Indian firms have established an international niche. Ranbaxy is already the world's second largest manufacturer of Cefaclor (the world's largest selling antibiotic at US$1bn a year). Therefore, strengthened "patent protection" is expected to encourage foreign direct investment in India. The study stresses that an environment hospitable to foreign innovative technology sets in motion a range of other dynamics such as licensing, co-marketing and joint ventures, generating multiplier effects that benefit local drug manufacturers. Patent protection could improve the quality of medical care in India, as the country progresses from a copying culture, to one that induces local innovation.

However, the extent that a new intellectual property regime will have a direct impact in stimulating research and development in India remains open to debate. The indigenous capability will be hit hard. The Indian pharmaceutical companies know very well that the transition from the era of process patents to one of product patents will lead to severe shake out during the next few years and the number of companies will dwindle drastically. The infrastructure created by local industry will remain unutilized. Local production will be confined to making age-old drugs, denying the benefits of new drugs and innovation. Today while India is under increasing pressure to provide market access to foreign companies, India can't export its drugs to Western markets due to non-tariff barriers in the form of social and environmental regulations. This is undermining India's comparative advantage by way of lower prices. Recently, the EU threatened to impose countervailing duties on Indian drug exports because they were cheaper than locally produced drugs. Thus while our generic drugs are subjected to non-tariff barriers, our consumers will be hit by higher prices for new drugs

The global pharmaceutical industry is a knowledge industry and the emerging Indian Pharma industry will have to be no exception. It has survived so far without developing new molecules. But with the advent of the new patent regime, the strategies will have to change. Indian Pharma industry apart from pursuing novel synthetic routes to known molecules must pursue basic research for patent-worthy inventions comprising new molecules. However, the impact of product patenting will apply only to new molecules, which have applied for patents after 1995. For these few new molecules, patents will lead to monopoly, as no other company will launch the same molecule.

The patents for almost all the drugs have already been filed, therefore for all practical purposes nothing is going to change. For most of the diseases there are already known cures, therefore product patenting won't drastically change things. It will probably change drastically only for those companies which come out with breakthrough blockbuster molecules, which happens only once in twenty years or so. Taking the case

of Viagra, this drug was introduced a year or two ago. It is a new drug but it is not protected from the sword of process patenting. Viagra came to market few years ago but before this, it took almost 10 to 12 years of laboratory trials, clinical trials before the molecule was launched. Therefore the patent for the molecule has been filed 12 to 13 years before and thus has not been protected. Moreover in 5 to 7 years it will be off patent, since the lifetime of a patent is only 20 years.

INDUSTRY TRENDS:

- Increased focus on R&D: Major domestic players such as Ranbaxy, Dr Reddy's Labs, Cipla, Nicholas Piramal and Wockhardt are aggressively investing in R&D. Dr Reddy's Labs and Ranbaxy have already discovered one new chemical entity (NCE) and are in Phase II and Phase I of the clinical trials respectively.
- Marketing tie-ups: Domestic players and MNCs have entered into marketing arrangements to increase market penetration and further strengthen their position in respective therapeutic segments. For example, Ranbaxy has tied up with Cipla, Glaxo and Hoechst Marion Roussell (HMR) for products in specific therapeutic segments and HMR has tied up with Nicholas Piramal.
- Product rationalization/ brand acquisition/ company acquisition: Most of the top pharmaceutical companies are consolidating their position in the domestic market either through product rationalization (e.g. Glaxo) or brand or company acquisitions (e.g. Nicholas Piramal and Cadila Pharmaceuticals are actively acquiring companies). HMR, Glaxo, Wockhardt and Ranbaxy have cut down their product portfolio in order to be more focused. Similarly companies such as Sun Pharmaceuticals, Nicholas Piramal and Dr Reddy's Labs have opted for brand/company acquisitions to increase market penetration.
- Increasing the market penetration through enhanced distribution channels: This would both increase the geographical reach in the domestic market and facilitate the licensing of products from MNCs in the forthcoming product patent regime.
- Upgrading manufacturing facilities: Most of these companies have already upgraded their manufacturing facilities and have approval or are in the process of getting approval from the US FDA, UK MCA authorities and other international agencies. This is the basic requirement for access to the high margin but highly regulated developed markets of Europe and the US.

The companies are setting up subsidiaries abroad or strategic alliances to exploit the tremendous opportunities in the generics market expected in the next 5 to 10 years. They have started applying for drug master file / product registration / abbreviated new drug application (ANDAs) worldwide. Moreover, as the TRIPS Agreement does not allow for backdating, drugs already in the market will be exempt from patenting.

SOFTWARE

The software industry has maintained an impressive growth rate and we have the dream of becoming an IT superpower, raising India's software exports from $2 billion to $50 billion in the next 10 years. If this has to happen then, the country has to reduce the content of body shopping and move on to innovative IT products, which will need IP protection .The Indian IT industry has not so far cared for this, but it will have to pay an increasing attention to this aspect. The lack of sufficient IPR protection will discourage content providers to invest in innovative services and their delivery. Data protection and privacy in legal treatment of electronic transactions will be crucial in generating public confidence about using new services.

The issue of Intellectual Property Rights (IPR) is one of the most important aspects of the software industry's business model. The problem of software theft and "piracy" (illegal duplication of software) is affecting both large and small software publishers. In India too, with the proliferation of the PC, software piracy is rampant, drastically affecting software companies. Software piracy hurts the industry in two ways. First, it creates a bad impression in the minds of prospective clients who want to outsource from India. In an environment of piracy, a client would be very reluctant to part with the source code of his applications software, even for maintenance work. Being a sensitive issue, it is rarely raised by the client upfront, but his discomfort could be dangerous to the deal. Secondly, it is in the interest of the software industry of India that piracy is checked. Obviously, we too wouldn't want our own software being pirated, thus losing revenue on it. The software products industry cannot develop and flourish if piracy is rampant. Today the Indian software industry, including new entrants, is keen on developing products based on the latest technologies, and commerce. These software publishers of products will not be able to survive if they cannot safeguard and reap the benefits of their creative products. The government has further strengthened the Copyright Act with inputs from industry association NASSCOM which regularly initiates action against software pirates. But, what is more important is education of the enforcement authorities and implementation of the law. Most countries including India do not recognize patents on software with the exception of the USA, which incidentally also has the most advanced software industry, from where developments have led to licensing revenues for a number of companies.

BIO-TECHNOLOGY

Under a suitable framework and active cooperation between the private and public sectors, biotechnology could provide India better healthcare, improved agricultural productivity, more foods and better affordability to the increasing population. India needs to change in managing its traditional and highly resourceful biological and intellectual capital resources. The country has a rich biodiversity and a strong system of indigenous knowledge and technology in areas such as healthcare and agricultural practice. A revision of the international legislation on protection of IPR to include protection of indigenous knowledge has been developed. The changing Indian patent law will attract foreign investment in biotech by private sector. India is due for comprehensive amendments in patent laws in compliance with the WTO agreement by 2005. Indian patent law, particularly for biotechnology, at the same time must create a harmony between the global laws and national laws.

Efforts to develop an international system of intellectual property rights are moving slowly as a result of disagreements between the three groups - the technology marketers, the technology buyers with a strong indigenous infrastructure and adaptive capacity, and the technology buyers with little research capacity. Patent protection laws are important to technology sellers. There are advantages in providing patent rights in biotechnology. They encourage the development of local research capability and higher private sector investments, particularly by MNCs interested in developing specific products for domestic markets. IPR may also be used in bargaining for improved access to overseas markets for a nation's export. The main disadvantage is that IPR gives proprietary protection to living organisms that some consider being a part of the biodiversity and natural heritage of society. Taking the case of the much-publicized neem or turmeric-based patented technologies, in which India had the traditional medicinal knowledge but not the sense to first file the patents to retain intellectual property and exploit it commercially. What is lacking is the innovative and entrepreneurial environment. There are few hundred botanical plant crude preparations though in use as traditional medicines, have not been characterized at the molecular level, patented or exploited commercially through proper technology transfer.

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