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FINDINGS AND CHALLENGES

IX. I. INTRODUCTION:

The findings, Problems/Challenges, Benefits, Impact and Suggestions are all drawn from various secondary sources, discussions with professionals and experts in the pharma sectors. The primary source of data was collected from selected pharma companies in Tamil Nadu. This sources formed the basis for analysis.

I (A) PRESENT PATENT SCENARIO IN INDIA

1. India will respect product patents. However, the patents so respected will only be those issued in India.

2. Product patents will be respected for a period of 20 years from the time of application and not from the time of grant of the patent. About ten thousand applications for patents were pending with the government in 2005; these date back to 1995 and are designated as mailbox applications. It will take several years to screen all the applications and award patents as appropriate. This will increase the breathing space for Indian pharmaceutical companies and Indian consumers.

3. New applications for patents will also be processed; again, the grant of patent will be for 20 years from the date of application. This is in accordance with the Patent Cooperation Treaty which India has signed, which will make it possible for a new invention to be simultaneously patented in a large number of countries.

4. Other agencies interested in the product will be provided an opportunity to oppose the grant of patent. Both pre-grant and post-grant opposition will be entertained. In the December 2004 ordinance, pre-grant opposition had been emasculated to a written application with no further representation allowed on the part of the opposer; in contrast, under the previous patent act, pre-grant opposition was a more powerful procedure with the opposer having a right of audience to the proceedings involved in the grant of patent. With the new Patents Act of 2005, pre-grant opposition has been strengthened: more time
has been allowed and the opposer has been given the right to be a party to the proceedings.

5. Even though the patent will be awarded with retrospective effect from the date of application, the implementation of the patent will only be with prospective effect. Thereby, generic versions of a drug will need to be withdrawn only after a patent is awarded and the company’s manufacturing and marketing the generic drugs will not be retrospectively liable for having manufactured and marketed the drug. Furthermore, companies manufacturing products patented between 1995 and 2005 will be allowed to continue to do so after paying a reasonable royalty to the patent holder.

6. Companies sometimes resort to ever greening to extend the duration of their hold of a patent. Ever greening refers to the making of minor modifications in a drug structure or formulation. The December 2004 ordinance passed by the Indian government did not address ever greening. However, in the Patents Act of 2005, the definition of patentability was modified to prevent ever greening. As an example, this could mean that once-weekly fluoxetine and escitalopram would likely not be granted fresh patents to extend the marketing rights of the patent holders of fluoxetine and citalopram, respectively. Fresh patents will not be granted for new indications for drug use; this was not explicitly prohibited in the December 2004 ordinance, but has been clarified in the Patents Act of 2005. (“The New Patent Regime implication of Patients in India”, www.ncbi.nlm.nih.gov/pmc/articles/PMC2900001, Indian J Psychiatry, 2007).

I (B) IMPACT OF POLICIES:

These policies so far have been very successful in keeping the prices down when compared to other countries. Another important achievement of the Indian drugs policy is its potential for exporting cheap drugs to developing countries. Therefore, since the implementation of the 1970 Patent Act, various health indicators have improved. In 1970 the child mortality rate was 137.2 deaths per thousand births, and in the year 2001 it had fallen to 67/1000. The average life expectancy in 1970 was 49.4 years and by the year 2001 it had increased to 63. This substantial improvement of health statistics cannot be attributed solely to the country’s pharmaceutical policy, and it is impossible to measure just how effective the policy has been in
providing cheap medicines, but there cannot be any doubt that wider access to drugs has been one of the factors that have allowed India to improve these figures

**Post – Trips (1995)** – After the TRIPS came into force lot of changes took place which affected India in several ways. Firstly, since 1995 the new drugs were stored in the mail box, as India got a window of 10 years. That is the provisions of TRIPS were applicable in India from the year 2005 but the drug patented from 1995 shall not be produced generically as the mail box has retrospective operation. Secondly, India had amended its patent law and had to grant patent for both process as well as product for a period of 20 years for all inventions including pharmaceutical products. Thirdly, consequent to second, today India is facing some terrible problem as far as access to medicine is concerned as the Indian companies like Cipla can no more produced the generic version of drugs in violation of TRIPS provisions. Recently, a number of cases have been filed by the foreign pharmaceutical companies against Indian companies for infringing the patent law. Moreover, the Indian manufactured drugs are also seized. Thus, it seems that if situations go on like these; then the developing countries like India and under developed countries will find it tough to meet the demand of their citizens even for the basic medicines as they lack the necessary infrastructure to invent drugs.

Indian firms have been globally competitive in the generics business due to the following reasons:

- **The First mover advantage:** Indian companies have invested significant resources toward the development of a robust pipeline of generic drugs. Over the last three years, Indian companies have been responsible for one-third of the Abbreviated New Drug Application (ANDA) filings (new drug application made to the US FDA for launch of generic formulations).

- **Low-cost manufacturing base:** The cost of setting up a US FDA-approved plant in India is up to 50 per cent lower, compared to developed markets. As a result, outside the USA, India now has the highest number of US FDA-approved plants. Further, production costs in India are 40-70 per cent lower because of local equipment sourcing, tax incentives and general focus on process innovation.

- **Deep and low-cost talent pool:** Labour costs in India are 60-70 per cent lower due to the availability of a large pool of highly qualified personnel with strong chemistry skills. India produces about 100 thousand chemists and chemical engineers every year.
While these factors have contributed to the recent success of Indian firms, these advantages may not be sufficient as global innovator firms focus their attention on the generics business. Some of the global pharma companies have established partnerships with emerging markets-based manufacturers, in order to improve their cost competitiveness. In such an environment, the future winners in the generics sector are likely to have the following attributes:

- **Focus on complex and niche segments:** Long-term growth can be generated by focusing in specialized therapeutic areas and/or more complex molecules. Also, generic firms with an advanced drug development pipeline may end up being defensive acquisition targets, as innovator companies look to protect their patented drugs.

- **Strong competitive positioning:** New drug delivery systems can be used to compete with drugs whose formulation patents have not expired. These segments tend to be less competitive, but development of such applications requires significant capabilities in both research and marketing. Another leading indicator of strong competitive positioning and future profitability for a company can be its ANDA Para-IV pipeline, especially for companies who enjoy initial marketing exclusivity (a Para-IV filing involves challenging existing patents).

- **Backward integration:** Backward-integrated generic players with captive Active Pharmaceutical Ingredient (API) manufacturing capabilities are likely to enjoy higher margins. Backward integration can enable generic players to maintain quality standards and improve cost competitiveness.

The upcoming patent cliff provides strong growth opportunities for the Indian pharmaceutical companies. But Indian firms need to develop a stronger focus on value-added and differentiated products in order to capitalize on this opportunity.
IX. II. FINDINGS

A). FINDING ON THE ISSUES IN THE POST - TRIPS PERIOD

At general level, these policy reforms were driven by two related forces. First, the emergence of new technologies has demanded continuous adaptation of IPR instruments. Key examples of areas in which technological developments have raised new intellectual property questions include integrated circuits, computer software, and biotechnology inventions. The advent of the internet has posed special challenges to the printing and publishing and entertainment industries, because content in digital form can be perfectly reproduced at minimal cost. Secondly, the process of economic globalization has enabled intellectual property to cross international boundaries more easily. Indeed, for many rich countries, IPR-intensive goods and services constitute a rising share of the income they derive from their presence in foreign markets. It is not therefore surprising to see political economy forces at work in these countries, leading governments to raise IPR protection as a key negotiating issue in international trade agreements. India’s full-scale TRIPS compliance raises several critical issues from an access to medicines perspective. We can discuss these issues point by point

1. The issue of price increases: The Indian public is concerned that massive price increases of the pharmaceutical products following patent reform to comply with TRIPs will preempt widespread access to valuable pharmaceuticals. In a clearly unequal world, it is important to ensure that economic interdependence does not lead to the codification of intergovernmental agreements that are biased against developing countries in general, and the poor within these countries in particular. The process patent system greatly facilitated domestic manufacturers to specialize and often excel in producing inexpensive, generic versions of on-patent drugs. The product patent regime would disallow such production and trade. It is apprehended that the prices of newly patented drugs would increase substantially, thereby imposing tremendous social and economic costs on the poor on these countries. The argument the higher prices would induce greater innovative activity by the patent protected developed nations is highly flawed. Even if a large part of the expenditure by multinational firms on R&D is geared towards the many so-called „poor” country diseases, (viz., tuberculosis, malaria, cholera, HIV/AIDS, etc.), the developing country consumers would still find the cost of medicines prohibitive; consequently, through low sales, R&D investment would be reduced. In fact, a recent UNDP report
estimates that once TRIPs comes into force, it could induce a price hike ranging between 12% and 68%. To except developing countries to accept such price spirals without adequately addressing their concerns of access to cheaper medicines to fight life threatening diseases, particularly in a public health emergency, seems unfair.24 some analysts and experts suggest otherwise. The off-patent market is still huge and can be explored further. Indian companies will gain strength in the coming years as partners in marketing and research-based outsourcing, ensuring. As far as the anti-AIDS drug prices go, the cheap availability of drugs. Government will always have the power to intervene and come up with a desirable pricing policy, if prices move up. The Indian government has gone on record to say that the fears of spiraling of drug prices is unfounded as 97 per cent of the drugs sold in India are off-patent. There are alternatives available to the government to ensure availability of. The important fact is that drugs patented products at affordable prices, which are already being manufactured as generics will not be eligible for patents. Hence fears that in the future all drug prices will be higher appear unfounded. The new drugs are supposed to be introduced in the Indian market unfounded. making the share of patented drugs to rise. But it should be remembered that after some time the patent expiries which contributes to the generics market. Because India is one of the world's biggest producers of generic drugs25, this loan will have a severe knock-on effect on many developing countries which depend on imported generic drugs from India. In most cases, generic products are available once the patent protections afforded to the original developer have expired. When generic products become available, the market competition often leads to substantially lower prices for both the original brand name product and the generic forms. The time it takes a generic drug to appear on the market varies.

The government under the new regime can declare an emergency and canel its patent, if a drug is desperately needed. New regime of product patent will attract more and more FDI in India: Till now there has been low level of presence of pharmaceutical multinationals in Indian market because of the rigid price controls and absence of product patents. There has not been significant foreign direct investment (FDI) in the Pharmaceutical industry in India. The position is expected to change with the introduction of product patents. The main concern about TRIPs provisions of WTO agreement is in respect of Patents. There is a feeling that the Multi National Companies
(MNCs) will have upper hand in maximizing the benefits of IP in developing countries like India. This is because of the fact that MNCs have not only financial powers but also adequate expertise in managing efficiently the portfolio of IP.

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5. Another area which is causing concern is the fear of appropriation of community knowledge available in such countries. Such an appropriation results in huge commercial profit to the MNCs without any adequate benefits to the community who provided the knowledge. There is therefore an urgent need to safeguard such “community knowledge” by appropriate legislations and policies. In this direction new IP legislations such as a sui generics system would not only to protect the community knowledge but also help appropriate sharing of the revenue earned through such IPRs. Therefore such a system should be formulated and brought into force on a priority basis. Further time bound actions are to be initiated and completed to establish appropriate infrastructure (like patent office with modern facilities and officials, patent information systems) creation of knowledgeable IP professionals and efficient legal systems to quickly provide justice in the case of IP disputes.

A change in the market dynamics: Over the past decade, several drugs (with features similar to patent protected drugs overseas) have been launched in the Indian markets but very few path breaking new molecules have been developed. In India most patients pay for medicines through their own funding and is not backed by medical insurance schemes.
6. **Amendment to Section 3(d):** The new addition to section 3(d), says: The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of a new property or new use for a known substance or of the mere use of a known process, machine or apparatus-unless such process results in a new product or employs at least on new reactant. The Act further clarifies that „salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of the known of substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”. Evidently, this clause will restrict the usual practice of developing portfolio of patents around drug molecules and ever greening (process by which the length of patent validity period is extended by filing new patent applications) of major pharmaceutical companies. Also, it will be difficult henceforth to get patent protection for nano-particles - today’s hot topics – as many of them are clusters of active molecules and already known.

7. **New added Section 11(A):** This section ensures that a patent obtained through the „mailbox” route cannot be used to initiate infringement proceedings against a generic manufacturer.

8. **Traditional System of Medicines:** Being a tropical country, India is indeed very rich in biodiversity. India is well known for its traditional systems of medicine like Ayurveda, Unani and various local folk and tribal medicine. Companies like Himalaya, Zandu, Sandu, Baidyanath, Dabur and Hamdard have been manufacturing and marketing these traditional medicines and also have developed their own formulations based on these systems of medicines. India has a clear advantage in these systems in terms of the knowledge that has passed down through generations. TRIPs will be a golden opportunity for getting protection for these products in India. Recent unsuccessful attempts made in the West to obtain patents for medicinal products being used in India over centuries like turmeric, Basmati rice, „karela” and neem” have alerted the government and industry to take steps to seek patent protection for innovations made in Indian systems of medicine. Attempts are being made by CSIR to prepare a Traditional Knowledge Digital Library (TKDL) and Traditional Knowledge Resource Classification (TKRC) so that such bio-piracies can be checked effectively in future.

9. **The issue of Patent length:** There are two welfare effects of extending the patent length. One is the growth enhancing effects: extending the patent length reduces economic growth by
raising the rate of return of R&D. The other is the static inefficiency effect: extending the patent length reduces the amount of output by increasing the proportion of monopolistic sector, and thus the amount of consumption. The length of the patent granted should not be of a fixed duration for all inventions. It should be linked to the actual expenditure on R&D and the degree of innovativeness. As long as the companies refuse to give information about their R&D costs, the incentive argument for patents only represents and ideology for supporting the monopoly power of the companies. If they really need extra profit to be willing to take the risk of R&D, the public has the right to demand to know how much they need, and how they calculate their „needed” profit. In fact, the exclusivity of a patent right needs to be supported by convincing arguments and by transparency in the calculations of the R&D costs to make it more than an ideology used to justify extra profit for some already very profitable companies. Foreign companies will look to bring their innovative products through existing subsidiaries or set up 100 per cent owned firms in the country. The industry will see further change in the form of foreign companies joining hands with Indian firms which have a strong distribution network. This again would aid both foreign and Indian firms.

II. (B) FINDINGS FROM THE SURVEY IN PHARMACEUTICAL SECTORS IN TAMIL NADU

The field analysis in pharmaceutical units in Tamil Nadu revealed that majority of the units (65%) were small scale unite and only 10% were large scale units. It was also found that public sector contributed 40%, private (30%) and partnership 20% from the selected sample. Regarding the nature of medicines manufactured 90% of them manufactured Allopathic medicine and marketed 60% in domestic market and 40% both in domestic and global market. When analyzed about the knowledge about IPR almost 60% were not aware of the issues and laws relating to Intellectual Property Rights and Patents and 80% were not aware of the cases prevailing regarding patents and their changes in the pharmaceutical units. About 70% were not aware of the institutions that were promoting IPR in India and Tamil Nadu.

It was interesting to find that 60% of the respondents expressed that it was not necessary to promote patents in the pharmaceutical sector in Tamil Nadu, and also felt that it has a negative impact on the pharmaceutical sector, while 35% felt there were benefit from IPR / Patents.
Regarding important issues, the result from the field analysis revealed that prices are very important factor, and 60% of the respondents felt that the introduction of product patent will increase the prices of drugs and 30% felt that it would decrease the prices, while majority 60% felt that it would affect the access of the drugs to the poor and 65% had no clear idea regarding the impact of patented drugs on people with HIV/AIDS and other serious health problem. Sixty percent of the respondents also felt that patented drugs may not be available to developing countries; and 60 expressed that patented drugs will be in favour of developed countries. Regarding the development of research and development, it was opined by 50% that research and development, innovations etc. will certainly develop in this sector. But majority of them (85%) expressed that their pharmaceutical companies were not able to invest in research and development. The cost for developing research and development in the pharmaceutical companies is very high. As far as the Foreign Direct Investment is concerned, it was found from 77% of the sample that FDI invest increase sharply after the introduction of Patents in the pharmaceutical sector.

Technology transfer has become another important issue with the introduction of Patents in the pharmaceutical sector, but unfortunately 80% of the respondents, revealed that they did not have sufficient idea regarding this issue sixty percent of them expressed that the growth and competencies of pharmaceutical sector. When enquired about their views on profitability vs values, it was found that 80% of them had no idea to comment on this issue. Another significant aspect of the TRIPS Agreement is the flexibilities available, but again 70% of the sample informed that their knowledge regarding this aspect was not sufficient and 5% of each opined it as Compulsory Licensing, Bolar provision, parallel importation and 15% informed that it was all three. Regarding ‘Data Exclusivity’ 90% of the respondents did not have any idea.

Regarding the requirement of Product Patent in the company in Tamil Nadu, it was found that all the members (100%) expressed that it was not required for the development of the company. With respect to the procedure to be followed in patenting a product, only 20% of the sample had sufficient knowledge while majority has not much knowledge.

Eighty (80%) of the members in the sample revealed that copying the patent product (reverse engineering) is better that patenting a product. They also expressed that (50%) it requires huge capital above 500 crores in developing a product patent in the pharmaceutical sector. It was appreciatiable to note that majority (80%) of the members in the sample felt that the quality of
the product (drug) certainly increased in the patented product companied to the non-patented products; eighty percent of them informed that the patented product would be held for 20 years by the person to whom the patent was granted.

Regarding the benefits of the Patent, it was found that monopoly in the international market is the benefit by 20% while 40% felt that it could lead to huge sales (global) and 30% felt that it would enhance the profit level, and ten percent (10%) informed that high reputation would be a benefit that the company would enjoy.

It was found from the field analysis that the members in the sample gained knowledge to whatever extent it could be from books and journals (20%), through association and other meetings (25%), through discussion and with friends and other business men (20%), through internet information (15%) and through IPR cell (20%).

Regarding the user friendliness of IPR only 20% of the members expressed that it was user friendly in nature. Further it was found from the study that only 20% had an IPR cell in the Company. Eighty percent (80%) of the pharmaceutical companies did not have any IPR cell, because of which they were not able to acquire knowledge about IPR/Patent. Though trainings were undertaken through various sources it was very minimum and it was not conducted regularly to update the knowledge of IPR.

The respondents expressed their suggestions regarding improving their IPR knowledge. Nearly 30% of them felt that through organizing more seminars / conference / workshop, while 25% of them felt that government should organize more programmer and 20% of the members in the sample informed the media could be used as a good method of enhance, IPR knowledge while 25% of them felt that the company in which they were working should take special interest in disseminating information through trainings, awareness camps, meetings, exposure visits, special talks etc.
IX. III. PROBLEMS/CHALLENGES

1. Tie-ups: Multinational drug companies have a weak presence in India: their drug basket is small, their marketing structure is weak and their domestic operations are limited. Multinational companies may need to tie-up with Indian companies for effective marketing. This may result in greater affordability to Indian patients. There is already evidence that Indian and multinational companies are exploring opportunities for mutual benefits. It is, however, unlikely that new drug prices will be as low as currently enjoyed by the Indian public.

2. Compulsory licensing: The Indian government has reserved the right for compulsory licensing; that is, providing Indian companies the privilege to manufacture and market a drug even before the expiry of the patent held for that drug. Compulsory licensing will be resorted to if the patent holder does not make the drug available to Indian patients or if the cost to Indian patients is too high. Compulsory licensing for export will also be resorted to, on similar grounds, to supply drugs to poor countries to meet their acute public health problems as per the TRIPS agreement of the Doha Declaration on Public Health.

By way of example: the Brazilian Government recently announced that it would break the patent on several retroviral drugs to prevent the financial collapse of its successful public health program which provided free medication to HIV/AIDS patients.

Article 31 of the TRIPS agreement provides for compulsory licensing without the authorization of the patent holder in the case of a national emergency or other circumstances of extreme importance or in cases of public, noncommercial use. This idea is also embodied in Section 92 of the Indian Patents Act of 1970. It is, however, uncertain that circumstances will arise which will make the Indian Government resort to compulsory licensing for psychotropic medication.

If compulsory licensing is to succeed, some absurdities in the existent Patent Act require to be removed. One absurdity is that a compulsory license cannot be awarded during the first three years of the grant of a patent. Another absurdity is that the applicant for a compulsory license is required to state the nature of his interest in the matter and the existing patent holder is allowed to oppose the grant of the application. While this is correct on the grounds of natural justice, it defeats the needs of emergency licensing. A third absurdity is that compulsory licensing is possible only for drugs which are patented in the country and not for those which are
patented elsewhere. Pharmaceutical companies can therefore avoid compulsory licensing if they do not apply for a patent in India.

According to the provisions of the Patents Act of 2005, generic versions of patented drugs will be permitted to be manufactured and exported under a compulsory license to meet the major health needs of underdeveloped countries if the concerned countries issue a notification that the drug is required for the purpose.

Price control: The Indian Government has a list of drugs under price control. The exercise of this option may protect patients against exorbitant pricing. However, this option is unlikely to be exercised for newer psychotropic drugs unless the drugs have dramatic health benefits

1. When the mailbox applications are cleared and patents awarded, newly-introduced generics in the Indian market may have to be withdrawn. This, for example, is why Indian brands of tadalafil have disappeared from the shelves. And, newer antipsychotic, antidepressant, antiepileptic and other drugs will be permitted to be marketed only by the patent holder. Costs to the patient will then inevitably rise. This scenario is feared but is by no means certain to occur as the international patents for almost all currently available drugs had been awarded before January 1, 1995, the cut-off date.

2. New drugs that emerge in the international arena will be available to Indian patients only from the patent holder. Again, the cost is almost certain to be high.

**HEALTH PERSPECTIVE PROBLEMS:**

1. **First**, it is piecemeal, ambiguous and it is difficult to administer public safeguards and exceptions\[10\]. Developing countries do not always have the infrastructure to examine patents and resolve issues of questionable patent ownership; this and other factors are resulting in a chilling effect on developing countries implementing the safeguard measures in these provisions. Many countries do not act because they fear legal challenges by MNCs and trade sanctions that may result from an adverse ruling by the WTO dispute panels.

2. **Secondly**, the TRIPS delay the introduction of generic drugs and leads to higher prices for essential medicines, especially those discovered after 1995.

3. **Third**, the TRIPS–public health debacle is fundamentally about the cost of medicines for infectious diseases such as HIV/AIDS, malaria, and tuberculosis where there is restricted access, inflexibility in drug pricing and pharmaceutical firms balk at issuing licenses to The exhaustion
of an intellectual property rights (or ‘first sale doctrine) “the owner of intellectual property cannot control the resale of a legally purchased good.” generic manufactures. But there are potentially other public health aspects. For example, many women in developing countries die from gender specific illnesses for which the required medical drugs are very expensive and there may be no generic substitutes available. Though the numbers many not qualify as national emergency, it may be the case that a government may think the problem warrants governmental actions to provide cheaper drugs. Currently, there is a plethora of possible remedies for the TRIPS and public health problem. Some remedies aim at engendering systemic changes into the TRIPS agreement while others focus on measures to mitigate the most negative and often deadly impact of lack of access to affordable medicines
IX. IV. BENEFITS OF IPR

The strategic management and use of patents can significantly enhance a company’s success in three broad ways: by establishing a proprietary market advantage and by enhancing overall competitiveness.

Establish a Proprietary Market Advantage:

Patents enable companies to stake out and defend a proprietary market advantage. That is their most powerful benefit. Properly developed, patents can translate into category leading products, enhanced market share, and high margins. In some cases, they can even serve as the foundations for a new industry. (Chester Carlson’s original xerography patent comes to mind). This is true even in the emerging e-commerce industries, where it was once thought the advantage simply belonged to those who got to market first. The collapse of competitive barriers and blurring of industry boundaries on the internet suggest that patents may become one of the most effective – and sometimes event the sole – means of creating a proprietary, defensible market advantage.

Barnes & Noble, for example, discovers may that because it lacked any property advantage or patent defense against online rivals, its market share could be easily “Amazoned” by the upstart zon.com itself may have faced a similar thread from its ever widening circle of online competitors if it hadn’t received a patent for its “one-click” system for processing customer orders, which is now widely copied by other Internet retailers. In October 1999, Amazon deployed that patent as a competitive weapon; it filed an infringement suit against Barnes & Noble. Similarly, priceline.com is using its “name your own price” auction patents as a shield to keep rivals at bay, as its recent infringement suit against Microsoft demonstrates. Let’s look at three ways patents can help companies secure a proprietary advantage.

Protect core technologies and business methods:

To the extent that they have a patent strategy, most companies focus it on protecting the proprietary technologies that give their products and services an advantage over those of competitors. The aforementioned seminal xerography patents, for example, allowed Xerox to legally monopolize the copier market for nearly 20 years; double – digit margins and earnings growth were the result. But when Xerox was forced to license those copier patents under the terms copier patents under the terms of a federal consent decree in 1975, the company saw its
market share, margins, and industry dominance quickly erode. (Court rulings later overturned the presumptive view at that time that patents were inherently anticompetitive.

Dell computer owes its success in the PC business not to the technological superiority of its produces – though of good quality, they are made mostly with off – the – shelf components – but rather to its innovative “build to order,” direct – sales business model. In other words, Dell’s advantage lies not in its computers but in its system for selling, distributing, and providing after – sales support for those computers. In similar fashion, Wal – Mart owes its $138 billion – a – year retailing success not to its products but to the sophisticated purchasing, marketing, and distribution systems that enable the company to operate more efficiently, maintain lower prices, and achieve higher rates of customer satisfaction than its competitors do.

It is important that companies must ensure that they protect and leverage whatever it is that adds the most value to their business and whatever represents the most vital source of their competitive advantage.

**Boost R&D and branding effectiveness:**

Patents can help companies build category – leading products as well as enhance the branding efforts devoted to those products. Hitechi, for example, tries to develop only those products for which patents can help it establish market dominant share. These aren’t necessarily the most technically complex products, either. Hitachi’s automotive airflow sensor would be easy for rivals to copy, for example, but the company has built such as effective patent wall around it that rivals were forced to look for more complex and expensive – and therefore less competitive – design approaches in their own airflow sensors.

Smart biotechnology and pharmaceutical companies also think about the potential strength of patents when setting their research and development priorities. The biotech firm genetics Institute decides which version of a drug to develop partly based on which iteration shows the best results in clinical trials but also according to which version can command the strongest patent protection. Genetics Institute’s patent counsel says the strength of the potential patent position is “a leading factor” in deciding what research to pursue.

But few companies (and certainly no consumer product company) can top Gillette’s use of patents to secure and sustain a market choke hold, as the development of its Sensor shaver a decade ago demonstrates.
Building a patent wall around a product – clustering, as it’s sometimes called – is not the only way to hamper competitors. Sometimes it’s possible to use patents to hem in a competitor’s initial market lead through a process called bracketing. Imagine that your competitor has invented a new, high-intensity light and has patented the filament. But it turns out that the filament requires a more durable glass bulb and socket housing to absorb the added heat, as well as more heat-resistant shade construction and electrical connectors. New manufacturing processes are required, as is new packing, because the new-style bulbs can be ruined by the oils from human hands. Your competitor may have patented the filament, but if you patent everything else, then the competitor is locked out of much of the market. That’s the essence of bracketing.

**Anticipate market and technology shifts:**

Even the best-laid product development plans and market strategies won’t prevent loss of market share and margin erosion if a company is unprepared for shifts in technology or market demand. A patent strategy can help companies anticipate those shifts and then respond with new products and services.

That is precisely what Texas Instruments did in 1997 when executives realized that demand for higher speed Internet communications made a technology called Digital Subscriber Line (DSL) a leading contender for next-generation modems. TI moved quickly to acquire a small company called Amati Communications for $395 million, which TI believed held the seminal DSL patents. That was an unprecedented price to pay for Amati, which lost $30 million on barely $12 million in sales. But in buying Amati’s patents, TI gained more than just the exclusive rights to the technology. One advantage of owning intellectual property is that it lets companies develop favourable partnerships and licensing relationships (as Dell and IBM have done recently with their patent portfolios). Another advantage is that it helps to keep costs down, which TI will need to do to develop affordable DSL modems.

**Improve Financial Performance:**

Companies biggest assets today are intangible ones like patents. And that’s not true just in technology intensive industries. The asset base of U.S. manufacturing firms has also shifted dramatically during the past 20 years. In 1982, physical assets such as plants, factories, and equipment constituted 62% of manufacturing companies’ market value. Today they represent less than 30% of their market value, according to economists at the Brookings Institution. Thus
even for manufacturing firms, the bulk of their value now lies in their intellectual assets. Given that fact, it’s appropriate to ask how well these assets are being managed and used. The answer, in most cases, is not very well at all.

Given the pressures on companies these days to maximize shareholder return, this underutilization to technology assets represents either a stinging indictment of corporate myopia regarding intellectual property or the greatest opportunity to be handed to chief financial officers in a generation. Indeed, the current run up in intellectual asset values – demonstrated not least by the growing gap between the book and market values of public companies - suggests that patent rewards may be as great as the rewards the leveraged buyout kings obtained 20 years ago when they capitalized on the undervalued real estate and pension holdings of corporate America. Let’s look at ways to realize the hidden financial value of patents.

**Tap patents for new revenues:**

Revenues from the licensing of patent rights have skyrocketed in the last ten years, increasing from $15 billion in 1990 to more than $110 billion today. Companies are slowly realizing that intellectual property can be among their most valuable and flexible assets. And the licensing market is still in its infancy; remain completely unaware of the earnings potential of their patent holdings. Those few that do begin licensing efforts tend to do so only when pressed to the wall financially or when struggling to turn around their competitive fortunes. That was certainly the case for IBM when, in the midst of its early - 1990s restructuring and revitalization efforts, it began to systematically mine its patent portfolio for revenues. (as we noted earlier, it now nets nearly $1 billion a year from the effort.

Some companies take more enlightened approach and treat portfolio mining for revenue as a business in its own right. Under Rick Thoman’s leadership, for example, Xerox has established a new business unit to create profit and competitive advantage from the company’s patent assets. “if you only use your patents to protect your products, which is the old paradigm, you’re missing all manner of revenue – generating and Jaferian, vice president of intellectual property at Xerox.

The critical point here is that once issued, a patent becomes a sunk cost. One can either leverage that sunk cost as a source of R&D funding or bottom – line revenue, or one can simply
ignore it. We believe patents just like any other business asset, should be required to generate returns.

**Reduce costs:**

The proper management of patent assets can also yield significant savings in the form of reduced portfolio maintenance costs and taxes. Perhaps the best known example of reducing costs through patent management involves Dow chemical. In 1994 as part of corporate cost–cutting effort, Dow initiated a year–long audit of its IP assets an audit that become somewhat legendary in intellectual property circle. (New automated technology tolls can now do this in days). Each of the company’s patents, 29,000 at that time, was valued and assigned to one of 15 major business units. The units thereafter assumed financial responsibility for the patents use. “Intellectual – asset managers” from each business unit met regularly to review patent activity company wide and to identify licensing, commercialization, and joint venture opportunities for individual patents or groups of patents.

As result of its audit, Dow achieved immediate savings of $50 million in taxes an maintenance fees on unneeded patents that were pruned from the portfolio and donated to universities and nonprofit organizations. (Last year DuPont followed Dow’s example and earned a $64 million tax write – off when it donated 23 patents to universities). Licensing revenues have also risen since the audit, from $25 million to more than $125 million. And according to Gordon Petrash, the former director of Dow’s Intellectual Asst Management terms, if one factors in the commercial befits of more effectively aligning the company’s technology assets with its business goals, the audit probably produced “billions and billions” in new revenues. (For more on patent audits, see the sidebar “Auditing Your Patent Portfolio.”)

**Attract new Capital and enhance corporate value:**

By thinking creatively, companies can often repackage their patents to be highly attractive to investors. The aerospace firm Lockheed Martin, for example, over the years had assembled a large cache of 3-D flight simulator patents that gathered dust in the corporate legal office. But in 1997, the company used those patents as the foundation for a new venture called Real 3 D that it spun off to compete in the PC graphics and video game business. Real3D attracted investments from Intel and Silicon Graphics, and it’s currently valued at several hundred million dollars. Lockheed was able to take a group of fallow patents valued on its books
at exactly zero and transform them into a strategic presence in a potentially lucrative new market. It also gained a 40% stake in a high-flying start-up.

Patents are also useful in bolstering corporate financing efforts. In the first-ever use of patents as vehicles for off-balance-sheet financing, a San Francisco–based investment banking boutique called Global Asset Capital last year said it intended to securitize the future royalties of drug company patents and sell the notes to investors. IP securitization is unlikely to become widespread until risk factors are more easily quantified, but this example is indicative of the expanding role that patents are playing as financial instruments.

Patents can help companies communicate their asset picture and earnings potential to investors and the financial community. Indeed, Wall Street is slowly waking up to the asset value of patents, spurred in part by research from economists such as Professor Baruch Lev at New York University’s Leonard Stern School of Business. Lev and doctoral student Zhen Deng recently studied the stock performance of hundreds of companies over a ten-year period. They found that companies whose patents were more frequently cited in the patents of other companies saw their stock prices rise far more rapidly than those of companies with less frequently cited patents. As Lev recently told Forbes, “Hardly any financial analyst on Wall Street takes patents into account when they study a company, (but) if they knew about the correlation between patents and profits, they might change their approach.

**Enhance Competitiveness:**

The value of patents as competitive weapons and intelligence tools becomes most evident in the day-to-day transaction of business. Indeed, whether a company is trying to block a competitor’s product development plan, gain entry into a hotly contested new market, find the most attractive acquisition opportunity, or reduce the risks involved in a high-stakes merger, patents can be potent weapons – and quite possible the greatest source of competitive intelligence on earth. Let’s look at some ways that companies are bolstering their competitiveness by using patent strategies.

**Outflank competitors:**

In early 1998, S3 was a small chip-design firm with a big problem. The company knew that Intel’s patent wall would eventually stall its high-performance graphic chip business. So S3 hatched a plan to fix the problem. Acting anonymously, S3 outbid Intel to acquire the patents of bankrupt chip maker Exponential Technologies for $ro million. In doing so, S3 obtained a
patent that predated Intel’s Merced chip patents and, according to analysts, could potentially hold Intel’s next-generation processor business hostage. S3’s bold IP gambit paid off when it revealed itself as the buyer and forced Intel to cross-license its patents to S3 in exchange for the rights to that “hostage” patent.

Over in the tool sector of the chip business, meanwhile, Quick turn Design Systems also had a problem. The company had sued rival Mentor Graphics for patent infringement and had gotten an injunction that blocked U.S. sales of Mentor’s key product. Quick turn then faced a hostile bid by Mentor to acquire the company and thereby scuttle Quick turn’s injunction. Quick turn resisted, of course, and the two companies battled through the summer and fall of 1998. Quick turn knew it could not fend off Mentor’s advances forever, so it dropped its intellectual property hankie (as it were) in front of white-knight Cadence Design Systems, which responded with a $253 million buyout offer that the much-relieve Quickturn happily accepted. Its flanks no longer exposed to hostile M & A action from Mentor, Quickturn continued to press its infringement case until Mentor agreed last June to withdraw its SimExpress product from the market.

**Exploit new market opportunities:**

Patents can also give companies patent-protected entry into lucrative new markets. The $3.5 billion Avery Dennison Corporation offers a case in point. In 1994, one of Avery’s embryonic business units developed a new film for use in product labeling. The film unit had already won an important contract to provide the labels for Procter & Gamble shampoo bottles, and corporate managers thought the unit had considerable growth potential. But an analysis of patent activity indicated that Dow Chemical was also beginning to move into the business. Should Avery commit the huge resources needed to exploit the market opportunity for the film unit, especially when it looked like Dow might become a formidable competitor?

**Paul Germeraad:**

The former vice president and director of corporate research at Avery Dennison, describes what happened: “We saw that we had the more fundamental patents in this area, “he recalls, “and we strengthened those with additional patent filings. Then, with the support of the CEO, we went to Dow and basically told them that they couldn’t manufacture that film anymore. They had to shut down their team, dismantle it, and withdraw from the market. And that’s exactly what Dow did. Thanks to the strength of our patents — and to our CEO’s willingness, based on that IP strength, to bet our total resources on building the unit-we were
able to stop Dow in the market and have it basically all to ourselves. As a result, that unit became one of the fast-growing, highest EVA units in the company”.

One might also consider the Machiavellian M & A maneuverings over patent rights in the stent business. Stents are tiny wire – mesh medical devices that keep a coronary artery open after it has been cleaned out through angioplasty. Until 1997, three companies – Johnson & Johnson, Boston Scientific, and Arterial Vascular Engineering – had divided the spoils in this $r.3 billion-per-year market.

But all that changed in October 1997, when Guidant Corporation received FDA approval for its new Multi-Link stent. Horrified at the thought of having to divide $ r.3 billion by four instead of three, Johnson & Johnson filed a patent infringement suit. Guidant responded three days later with a surprise maneuver; rather than file a patent countersuit, Guidant bought Endo Vascular Technologies. The deal surprised analysts because Endo Vascular doesn’t even make stents. But reporter Herb Greenberg, then writing for the San Francisco Chronicle, revealed Guidant’s logic in his October 8, 1997, column: “What nobody talks about is patents, (Guidant) will also be getting its hands on potentially lucrative patent that could give (it) control over the superheated U.S. coronary stent market.”

It seems the Guidant deal was really aimed at acquiring an unused endo Vascular stent patent that may prove to be a legal bombshell. The patent in question was issued two years before Johnson & Johnson’s patent was issued. Does Guidant now hold a winning weapon in the stent wars? It remains to be seen, But doubtless Guidant already feels that the $170 million it paid for Endo Vascular and its key stent patent was money well spent; in its first six months in the stent business, the company sold $ 350 million worth of the devices.

IBM has chosen a slightly different and very enlightened approach to seizing an opportunity in the telecommunication components industry. Because of users voracious need for routers and networking equipment, this market is exploding. But rather than spend buckets of cash to enter the market or cut component prices to rock bottom in the hopes that users would buy its products, IBM used its patents to structure a win-win deal with Cisco, the market leader. The $2 billion pact guarantees the sale of IBM’s components to Cisco for two years and gives IBM a substantial foothold in a new market for its products.
Reduce risk:

As a vital source of competitive intelligence, the information contained in patents can also help companies steer their R & D and M & A programs around infringement and due diligence potholes.

The most famous example where a company failed to use patent information to reduce its risk involves the great patent war between Polaroid and Eastman Kodak over the instant photography business. Kodak ignored the “patent thicket” that its much smaller rival Polaroid had erected around its fast-growing instant-camera business. In 1975, Kodak launched a line of instant cameras and films that many people—including key Polaroid executives—felt bore too close a resemblance to Polaroid technology. The patent case that resulted finally concluded in 1990 with a judgment that Kodak had indeed infringed on Polaroid’s patents.

The total cost to Kodak of its misguided patent strategy? The company was ordered to pay Polaroid a staggering $925 million in damages. Kodak was also forced to shut down its $1.5 billion manufacturing plant, lay off 700 workers, and spend nearly $500 million to buy back the 16 million instant cameras it had sold to consumers between 1976 and 1985. Legal fees during the 14 year-long court battle cost Kodak and additional $100 million, and a decades-long R & D effort had to be written off as a total loss.

Many executives consider it unnecessary to spend the time and money to map out the patent landscape and avoid infringement dangers. After all, they say, in today’s fast-paced economy, the life span of a new product may be shorter than the time required to obtain a patent for it.

Another consideration is the emerging threat of board liability and shareholder lawsuits regarding patents. Failing to make best efforts to steer R & D away from potential infringement problems could be seen as the intellectual property equivalent of negligently building a factory atop a seismic fault. In-deed, the prospect of shareholder lawsuits over “IP wasting” is very real, according to Steven Bochner, an attorney at Wilson Sonsini Goodrich & Rosati, the California-based law firm that represents more silicon Valley boards of directors than any other.

Besides protecting research efforts, patent mapping can also reduce the Risks inherent in mergers and acquisitions. And here, unfortunately, may managers would be surprised to
discover just how abysmal most due diligence efforts regarding intellectual property actually are.

Most investment banks have teams of accountants, tax advisers, management consultants, and regulatory affairs experts to structure their deals to a company’s greatest advantage. But one would be hard-pressed to find a major investment bank that employs even one individual with experience in evaluation patent portfolios.

That is sometimes true even in the drug industry, where companies live or die on the strength of their patent holdings. According to Cynthia O’Donohue, principal information specialist at global drug company Allergan, Businesses don’t always look closely enough at the patent issues involved in a merger or acquisition. “A company may see that the firm it wants to buy has all these wonderful patents,” she explains, “but sometimes they don’t ask when those patents expire. And especially if they’re acquiring a smaller firm, executives have to ask if the company has maintained its patents.

Tapping the financial and competitive rewards of patents will require top-level involvement and enterprisewide organizational muscle, that means building a structure in which patents and the information they contain are available thought out the organization and are managed by senior executives as strategic assets of potentially enormous value to the enterprise. Companies that treat their patent portfolios as a strategic asset and a new core competence will enjoy a big advantage over those that don’t.

The effort is made easier now by technological advances in patent asset management. There are now automated systems that provide platforms for organizing, analyzing and visualizing patents across and industry, for conducting patent audits, and for uncovering competitors, strategies. Patent – mapping efforts that used to take months can now be done in hours or days. Once –unintelligible text documents can now be presented in 3-D reports that highlight patterns and relationships in technology development. The scope of change that these new tools make possible is comparable to the changes we saw when electronic spread-sheets were introduced to the public two decades ago.

If patents are the “smart bombs” of tomorrow’s business wars, then companies that fail to develop offensive and defensive strategies for their use will do so only at their peril. (Kevin G.Rivette and David Kline)

INDIRECT BENEFITS OF THE NEW PATENT REGIME:
1. It will force the Indian pharmaceutical sector into greater efforts in research and development. Many of the pharmaceutical majors in India have already made large outlays in this area and have even applied for patents, though not necessarily for psychotropic drugs or even chemicals with therapeutic potential.

2. Outsourcing of laboratory research and clinical trials to India will increase, thereby facilitating the domestic processes for the approval of the marketing of a new drug. Even more importantly, outsourcing to India will lower research costs, thereby reducing the costs which will have to be recovered through pricing mechanisms. Finally, even bulk drug manufacture may be outsourced to India, which would further reduce the costs of the marketed product.

3. Small companies, many of which manufacture and market generic drugs of doubtful quality, will fold up.

4. Competition will eventually change from brand vs brand to drug vs drug

UPDATE ON EVERGRENING
At present, there is a strong lobby trying to persuade the government to allow evergreening; that is, the patenting of molecules which differ slightly from the parent molecule. The argument is that molecules are patented very early during the process of drug discovery, but unique clinical characteristics or benefits are not discovered until much later, when clinical trials are conducted, if at all. Therefore, it is unreasonable to ask that unique characteristics of a slightly altered molecule be described at the time of the application for the patent, itself. Evergreening is not necessarily a disadvantage to India. For example, if evergreening is permitted, Indian companies may be able to develop and patent incremental advances on patented drugs.

1. On a related note, the patents act does not define how unique the new molecule must be; therefore, an element of subjectivity enters the decision-making process for the grant of a patent. In this context, the pharmaceutical industry is concerned that the officials involved in the grant of patents may not be sufficiently qualified to understand the nuances in molecular behavior that justify novelty and hence the grant of a patent. (Chittaranjan Andrade)

- The value of intellectual property (IP) is often not adequately appreciated and its potential for providing opportunities for future profit is widely underestimated by small pharma units. However, when IP is legally protected and there is demand for the IP-
protected products and/or services in the marketplace, IP can become a **valuable business asset**.

- IP may generate an income for small pharma section (SPU) through the licensing, sale, or commercialization of the IP-protected products or services that may significantly improve an enterprise's market share or raise its profit margins.
- IP rights can enhance the value or worth of your SPU in the eyes of investors and financing institutions.
- In the event of a sale, merger or acquisition, IP assets may significantly raise the value of the enterprise; and at times may be the primary or only true assets of value.
- The strategic utilization of IP assets can, therefore, substantially enhance the competitiveness of your SME. SMEs should make sure that they are ready to face the challenge and take measures to exploit their IP and protect it wherever possible. Like physical assets, IP assets must be acquired and maintained, (see “How can Your SME Acquire and Maintain Intellectual Property Protection”), accounted for, valued, monitored closely, and managed carefully in order to extract their full value (see Managing the Intellectual Property Assets of Your SME). But before this can be done, SMEs must first acknowledge the value of IP and begin to see it as a valuable business asset.