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PUBLIC HEALTH IMPLICATIONS OF IPR POLICIES IN PHARMACEUTICAL INDUSTRY WITH SPECIAL REFERENCE TO INDIA

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Abstract

Pharmaceutical industry, a promising sector constantly generating new intellectual property is third largest in terms of volume and thirteenth largest in terms of value. India is one of the largest providers of generic drugs contributing almost 20% of the worlds share. Due to flagship programmes such as Make in India substantial effect is reflected on innovation scenario as India has jumped the ranking this year in Global Innovation Index compiled by WIPO. Despite several health policies, India continues to lag several health indicators such as mortality rates and malnutrition. Home to 17.5% of the world's population, India accounts for 20% of all neonatal deaths and 21% of all child deaths (younger than 5 years).In such a scenario of increased burden of healthcare, a thriving generic drug supply at accessible costs and proper incentivization of the Pharma MNC's using PPP, providing them a good R&D environment with IP laws in sync with the TRIPS agreement is required.

Keywords: *Pharmaceutical industry, Intellectual Property, WIPO, Health policies, Healthcare, PPP, TRIPS.*

INTRODUCTION

'Intellectual Property' is a generic term covering assets that are created from the exercise of the human mind and have no physical existence as such hence the reference to "intellect". These assets are often referred to particularly by accountants, as 'intangible' assets and although frequently do not appear on a company balance sheet, can be extremely valuable. The assets generally belong to the creator, or a third party, such as an employer by virtue of a contract, and can be used in business to protect a market or to generate revenue by licensing, sale (by assignment) or even by being mortgaged. As one might imagine, intellectual property rights are by their nature very diverse, and with the relentless march of technology and the appetite of human beings to create, the list is increasing year on year. The strongest forms of rights are those which must be registered, such as patents, registered designs and registered trademarks.

The statutes which are in force to provide the framework for their protection set out clear standards and criteria for registration and procedures for enforcement. Intellectual property rights, have stretched the legislators, as they require their own form of regulation and do not merely 'fit' one of the existing statutes. Unregistered rights such as copyright, design right and database rights still benefit from the existence of a statute providing for their enforcement, whilst the rights of 'passing off' and protection for valuable know-how must rely upon common law for their protection, in the latter case by breach of contract. New forms of operational or technical rights such as domain names which are not strictly. In many cases a combination of rights building up a complex web through which the competition find it increasing difficult to navigate, can be a powerful deterrent, even where each particular right is not necessarily as strong as might be desired. This is a perfectly valid strategy; just as one does not rely entirely on either doors, guard dogs, locks or alarms to protect one's home, but often use all means available, so should a company look to all aspects of intellectual property to protect its products and processes as well as their position in the market.

IMPACT OF IPR RIGHTS ON HEALTH SECTOR

In India because of low level income of the people, most people prefer for the local medications and also the prices of medicines were raised too high so the common people can't afford to buy the modern medicines and antibiotics. Moreover, many of the new medical researchers are targeting developed countries with promising profits for medicines for lifestyle diseases whereas developing countries are still in need of basic health care except three sectors i.e., food processing, pharmaceutical and agrochemicals. The Indian patent act allows product patent only. Only in these three sectors process patent is allowed, as on today. India has only process patent regime with relation to pharmaceuticals product.

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RECENT CHANGES IN IPR LAWS IMPACTING PHARMACEUTICAL INDUSTRY WORLD OVER

"The commercial sector discovers and develops nearly all new drugs and vaccines, but this is expensive and risky; the patent system provides the incentive necessary to investigate thousands of new compounds and to invest an average of several hundred million dollars in R&D".

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA),
ASEAN Workshop on TRIPS, Jakarta, May 2000

The pre-Trade Related Intellectual Property Rights (TRIPs) era saw the world divided into group of nations i) allowing patent in all fields of technologies (products and processes) and ii) having restrictive patent laws providing for process patents in all fields except for product patents in selected fields such as pharmaceuticals and drugs, food etc. In addition, the term of patents, conditions for compulsory licensing, whether importation should be considered as working of patents, etc., varied based on existing national laws. TRIPs attempt to harmonize the IPR laws by bringing the disparities into focus.

Since the formation of the World Trade Organization (WTO) on January 1, 1995, several nations have made significant changes in their national laws governing IPR. Proper understanding and utilization of the IPR laws in various countries would help in the global positioning of pharmaceutical companies. The European Parliament on July 8, 1998, approved the biotechnology directive, which set the guidelines for legal protection to biotechnology products and processes within the European Union. This would markedly influence the pharmaceutical industry in Europe. It was implemented in the European Union by July 2000. However, there had been some opposition from Holland. The outcome of the opposition proceedings decided the future of the biotechnology directive in Europe. Since June 1995, USA changed the term of patents from 17 to 20 years. The practice of "first of invent'' as opposed to "first to file'' has been extended to all members of WTO. All patents in force on 8th June, 1995, will have a term of 20 years from the date of issue, whichever is longer. As per this provision, several patents received an extension of their term. This has had a significant effect on the pharmaceutical industry. In November 1999, the US introduced the system that a patent specification will be published 18 months after its filing.

The Japanese Patent Law was amended on December 14, 1994, with amendments falling into two groups, one effective from July 1, 1995 and the other from January 1, 1996. With effect from July 1, 1995 the term of patents was made 20 years from the date of filing. There were other features dealing with provisions for the restoration of lapsed patents, priority-based filing in WTO Member-countries, etc. The second category, effective from January 1, 1996, was the replacement of opposition proceedings to post-grant opposition and procedures for accelerated patent processing. A few landmark judgments related to "parallel imports'' into Japan and "research exemption'' in the area of development of generic drugs are of significance. Further amendments were introduced in 1999 that were made effective from January 2000. On March 10,1999, the Indian Parliament passed a Patent Amendment Bill, which regularized the transitory "mail-box provision" (with effect from January 1,1995) to file product patents for inventions relating to drugs, pharmaceuticals, agrochemicals and to grant "exclusive marketing rights'' in these selected fields only. Other changes in the Patent Act, 1970, have been introduced to meet the immediate obligations of TRIPS such as the withdrawal of Section 39 that required inventions in India to be first field in India before being filed elsewhere, considering importation as the working of an invention in India, etc. A second patent amendment bill (1999) was introduced in the Parliament in December 1999 to meet all the other obligations of TRIPs. This is presently under review. India also joined the Paris Convention and the Patents Cooperation Treaty on December 7, 1998.

In Spain, the patent law was amended in January 1998 to remove the requirement that pharmaceutical companies must make the patented product in Spain before an injunction would be granted against an accused infringer. Now it is getting easier to obtain interim injunctions from Spanish courts.

In Argentina, the 1995 Patent Law brought provisions in line with TRIPs to make the term of
patents 20 years from the date of filing, rather than 15 years from the granting date. The problems of where the old patent law ends and where the 1995 legislation starts have not been satisfactorily resolved.

The Australian Patent Act was changed on August 10, 1998, to give pharmaceutical patents an effective term of 20 years to bring them in line with the laws in USA, Japan and Europe. The most significant provision in Australia for pharmaceutical patent owners has been the extension of patents to give an effective term of 15 years, where product registration requirements have held up the introduction of the product to the market.

IPR AND INDIAN PHARMACEUTICAL INDUSTRIES

After the GATT changed into WTO, most of the developed countries were awakened to protect their

products. Initially most of the world leading pharmaceutical industries built a separate cell for IPR and regulated very well. So the profit of the companies was increased and IP played a major role in controlling the counterfeit and copycat drugs. But in India that time only Pharma companies were plan to set their IP cell some of the companies in India established the IPR cell in the year 1995. Majority of the companies started IPR cell after 2000 in India. By the end of year 2004, majority of companies started a separate department to look after the issues related to patents. It can be safely presumed that the patents that are granted to Indian pharmaceutical companies or applied by these companies are for either new processes or new drug delivery systems.

WHO perspective on access to medicines:

•Access to medicines is a human right

•The affordability of essential medicines is a public health priority

•Essential medicines are not simply another commodity

•Patent laws should be managed in an impartial way and strike a balance between the incentives provided to stimulate innovation and public health needs

•WHO supports the incorporation of TRIPS flexibilities in national legislation, in order to protect public health (WHO. Globalization, TRIPS and access to pharmaceuticals, WHO, Geneva, 2001.)

TRIPS, THE DOHA DECLARATION AND PUBLIC HEALTH

"We are all aware that the text of the TRIPS is a masterpiece of ambiguity, couched in the language of diplomatic compromise, resulting in a verbal tight-rope walk, with a prose remarkably elastic and capable of being stretched all the way to Geneva."

Former Commerce and Industry Minister Murasoli Maran

A majority of members of the WTO already had some form of intellectual property protection in existence prior to the TRIPS Agreement. For example, as of January 1995, fewer than 20 of the current WTO developing country and least-developed country members excluded pharmaceutical products *per se* from the grant of patents. The key difference that came about after the adoption of the TRIPS Agreement in 1995 was that countries were bound to certain minimum universal standards of patent protection. Thus TRIPS prevents countries from changing their laws to suit national interests if such interests are at variance with the Agreement. Further, as TRIPS is part of the WTO system, there is now also the possibility of cross-sectoral retaliation in the event of noncompliance by any country of its provisions. This implies that any member country failing to bring its patent law into conformity with TRIPS, if challenged by another member country, is subject to the WTO dispute settlement system. If the dispute settlement system were to rule against it and the country still insists on not changing it law, other WTO countries can retaliate with trade sanctions.

The TRIPS Agreement covers two categories of intellectual property;

1) Industrial property (trademarks, patents, geographical indications, industrial designs and trade secrets); and 2) literary and artistic works (copyright and neighboring rights). It establishes universal minimum standards, which WTO member countries are required to adopt in their national laws.

Thus, TRIPS requires countries to provide patents to protect inventions in all fields of technology, and for both products and processes. To be patented, inventions must meet three criteria: novelty, inventive step and industrial applicability (TRIPS Article 27). Before the TRIPS Agreement entered into force in 1995, countries did not have to grant patents for inventions in the pharmaceutical field if they did not wish to. This had allowed diversity in national approaches to patent protection in terms of what could be patented (scope), patent term, exceptions to patentability, etc. It must, however, be underlined that countries have some leeway in implementing TRIPS. For example, countries can choose whether or not to allow parallel importation, and whether to apply strict or lenient standards for patentability.

IMPLICATIONS OF PATENT CASES

What these patent cases demonstrate is that the MNCs have been aggressively asserting their patent rights and filing infringement cases against generic companies and that they invariably challenge any adverse decision and appeal to higher bo dies.They havethe right to do so under the Indian law.

But what is important for us in this context is to see wh at the implications are for generic companies and gener ic competition. The generic companies are required to bear not only the huge legal expenses for pr otracted cases; they also run the risk of damages to be paid to the MNCs if they lose the infringement cases. These act as a deterrent for the generic companies. Not surprisingly only few generic companies such as Cipla, Natco, Glenmark are involved in patent challenges in India.

In the Novartisc ase, Cipla fought till the last but in the erlotinib case, Cipla has agreed to mediate rather than to continue to fight. In the sitagliptin case too, Glenmark has agreed to mediate. Interestingly MSD and Sun filed six other infringement suits against companies such as Aprica Pharmaceuticals and WinBioz Remedies and obtained injunctions in each of these. In fact in four of these cases the

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generic companies did not pursue the matter opting to settle it mutually including in one case after paying for token damages (Anand 2014). As several cases show MNCs have lost the patent cases (as for example in the Novartis case) or have opted for mediation (as in the cases of erlotinib & sitagliptin). Thus in view of such litigation if generic companies desist from opposing the MNC patents, then what the patent cases actually imply is that MNCs will be able to enjoy patent monopoly even when they are legally not supposed to have these patents.

PATENTABLE ENTITIES OF RELEVANCE TO THE PHARMA INDUSTRY

The following classes of invention are of relevance here:

• Compositions of matter - whether new chemical or biological entities including for example isolated cells, genetically engineered animals and plants, combinations and formulations.

• Processes - for the preparation of compositions of matter whether new or old. New processes for manufacturing known drugs can radically reduce cost of production and therefore worth protecting.

• New uses -many compounds exist on the shelves of pharmaceutical companies and provide new leads when screened against targets for which they were not originally prepared. Screening libraries of known compounds to identify new uses and therefore new leads is big business.

• Devices - physical devices for the administration of compounds can also turn otherwise non-viable treatments into a realistic proposition. In some cases new means of delivery can radically improve treatments and devices for depot delivery, sustained delivery, transdermal delivery etc., can all provide useful protection.

• Business methods - as the Internet takes over, even the pharma industry have to consider whether the traditional ways of marketing and distributing their products and services will need to evolve. Business methods, which have traditionally been granted only in the USA, are being considered as potential subject-matter warranting protection in Europe and elsewhere.

• Enabling technologies/ research tools - these bridge a number of the categories above but cover for example the host cells, vectors and vector components as well as methods for biological production of chemical and biological entities. Research tools patents per se have been controversial in obtaining patent protection as they can potentially block the very basis of research. However protection on a particular target for example, whether the receptor or the gene could be important in justifying the expense of the investment in the research to have identified in the first place.

FUTURE SCENARIO OF THE INDIAN PHARMACEUTICAL INDUSTRY

The current economic scenario indicates that the impact of IPR will largely depend on the developmental status of the economy such as the availability of technical manpower and infrastructure, capacity of the domestic industry, and so on. A country with a base of strong domestic industry such as India is in a relatively advantageous position than a country where domestic industry does not have much presence and depends on multinationals. The present WTO regime has been successful in stimulating the much needed R&D investment in India but at the same time the many of the big research firms have internally invested in their R&D department and constantly strive to make their breakthroughs as patentable. There is some evidence available regarding the mergers and amalgamations to pool the human and financial resources (CMIE, 2000) to strengthen the R&D in new product development. These organizations will definitely benefit by the stronger protection provided to them. Some of the R&D and manufacturing facilities set up in these firms meet the international standards, and they have already been approached by multinationals for conducting research and undertaking manufacturing on their behalf. At present many of the R&D firms are looking for breakthroughs in biotechnology research. With TRIPS allowing the patenting of the living organisms, research in biotechnology is the latest buzzword in the pharmaceutical industry. Significant breakthroughs have already been madein the area of stem cells and cloning which have potential cure for some of the dreaded diseases like cancer, Parkinson disease, Alzheimer's and nervous disorders. Cloned animals have been patented and are being used for research purposes.

India biotechnology research is concentrated in the areas of vaccines, diagnostics, molecular and cellular biology, cell culture, fermentation and hybridoma technology. Lalitha (2001) observes that some of the research based pharmaceutical firms have ventured into biotech research since the late '90s. Some of the important areas where research is being currently carried out are in the field of recombinant vaccines (for typhoid, rabies and hepatitis B), HIV 1&2 diagnostic test kit and gene probe test for TB are. It is also observed that though simple diagnostic kits, were the first to arrive in the biotech market elsewhere, in India only a handful of companies are engaged in the production of TB diagnostic kit. In the case of DNA or r-DNA research, research is at a basic level, for two reasons. First being that India does not recognize patenting living organisms and second because of the moral and ethical issues concerning the human stem cells and embryonic research, R&D firms tread

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cautiously in this area. As part of trade liberalization though most of the drugs were delicensed yet, bulk drugs produced by the use of recombinant DNA technology and bulk drugs requiring in vivo use of nucleic acid as the active principles and formulations based on use of specific cell or tissue targeted formulations shall continue to remain under compulsory licensing (Government of India, 2000). Also a committee set up under the Department of Biotechnology scrutinizes each research application concerning embryos and only embryos discarded in the fertility clinics can be utilized for research purposes. Though this area is being highly researched and resource intensive currently very few firms are engaged in this research.

Pharmaceutical outsourcing has been on the rise and it may be expected that contract research and manufacturing would increase still more with the vertical disintegration of activities by the multinationals as they review their core competencies. Henceforth, R&D could take place in one country, manufacturing in another and marketing rights could be given to a totally different country. The maximum benefit may be reaped by domestic units with proper infrastructure, research facilities and standards which meet the international standards. Such domestic units can flag off the foreign direct investment in sectors of manufacturing and R&D. This segment that has been able to export its products to both developed and developing countries can widen the market further in the universal patent regime provided the manufacturing practices and the quality standards match the standards at the export destination. While the medium and big units can adopt any of the combination of strategies that were mentioned above, at present the future of the thousands of small units is not very clear. Indian companies and local pharmaceuticals which are mainly thriving by making the generic drugs should not be affected as these drugs do not come in the purview of patent laws but it may face market competition in case of manufacturers providing the same drugs at a lower cost. In a classical case from Jordan, the local industry had to suffer in terms of investment and production and even many small local firms had to close their operations as they could not face the brunt of competition (Correa, 2000).

Some theories suggest that the strength of the Indian pharmaceutical industry is in reverse engineering and as such upcoming local pharmaceutical companies and private research organizations can exploit the provisions under compulsory licensing, exceptions to exclusive rights and the Bolar exception and should aim to produce the generic version of the patented products as well as keep an eye on the drugs which are approaching patent expiry dates and still are needed in the market. Such firms can also engage in research leading to unravelling new drug delivery mechanisms and in identifying new uses of existing drugs as well. Evenson (Siebeck et.al, 1990) and Watal (1997) suggest that in order to develop domestic innovations, developing countries require utility models or petty patents. These petty patents can act as tool to make the innovation profitable and garner funds for long term research as well as such patents will be available for a shorter period of time for process innovations made over existing products. The TRIPS agreement leaves members to introduce such legislation, as there are no specific rules on this subject. Such patents will encourage the small firms.

One of the major concerns in regards to product patents is the ease of access to patented products. Some of the provisions within the TRIPS agreement clearly indicate that price controls could be imposed on the patented products but even then some exemptions from price controls have been suggested by the government for the products that are produced domestically using the domestic R&D and resources and are patented in India. Such exemptions will keep the prices high and will continue to make access to the drugs difficult. It appears that stakeholders going for patenting are given more weightage then the actual products which are being patented. In the Doha meeting, a separate declaration on the TRIPS agreement has clarified that members have the right to grant compulsory licence in the area of pharmaceuticals and that they have the freedom to determine the ground upon which such licenses are granted (Economic Times, 21stNovember, 2001) which can have a considerable impact on the availability as well as on their prices. Parallel trade in pharmaceuticals may facilitate access to medicine, yet compulsory licence will be the only course of option to facilitate flow of technology and R&D. Scherer and Watal (2001) suggest that tax concessions should be provided to the pharmaceutical manufacturers to encourage them to donate the high technology drugs to the less developed and developing countries which is a viable option.

A majority of the population does not have access to the essential medicines (most of which are off patent) either in the government or private health care systems because they are not within their capacity to reach. Though the percentage of drugs under price control has been drastically reduced, it is essential to keep the prices of the essential drugs under check, especially those concerning the common diseases.

Currently only a handful of pharmaceutical firms in India invest in R&D which needs to be improved. The suggestions of the Pharmaceutical Research and Development Committee (1999) were to have a mandatory collection and contribution of 1 per cent of

MRP of all formulations sold within the country to a fund called 'Pharmaceutical R&D support fund' for attracting R&D towards high cost-low return areas and be administered by the Drug Development Promotion Foundation. The domestic universities and other academic institutions can play the role of research boutiques or contract research organisations (CRO), which can supply the technical know-how and manpower. Units already having such infrastructure can also function as a CRO for other firms as well.

In the post TRIPS era, the government needs to probe into factors that contribute largely to the widening gap between the proposed FDI and the actual FDI and rectify these bottlenecks. Similarly a study can be taken out to understand the reasons for the difference between the number of patents filed and the patents granted and understand the areas where the Indian firms are lacking.

Governments should take active part at various levels in disseminating knowledge about the IPRs and the possible strategies that can be adopted by the industry. This will remove some of the impediments. Lessons can be drawn from the Chinese experience wherein systematic efforts were taken to educate the bureaucrats, policy makers and the industry about the WTO and product patents in the pharmaceutical industry. India will have to strengthen the patent examination process and speed up the processing procedures and reducing the paperwork as well making way for dedicated online portals can make the process less cumbersome as well. Such steps can help in checking the products entering the country utilising the import monopoly route provided by the Exclusive Marketing Rights (EMR). Besides a strong institutional and judicial framework will have to be set up for monitoring the prices, to prevent infringement and trade dress cases of patented products respectively.

In the present WTO regime various options can be exercised by India's pharmaceutical industry. These are to: (a) manufacture off patented generic drugs, (b) produce patented drugs under compulsory licensing or cross licensing, (c) invest in R&D to engage in new product development, (d) produce patented and other drugs on contract basis, (e) explore the possibilities of new drug delivery mechanisms and alternative use of existing drugs, and (f) collaborate with multinationals to engage in R&D, clinical trials, product development or marketing the patented product on a contract basis and so on. Besides these strategies, India's strength lies in process development skills. This expertise utilised within the WTO framework with emphasis on quality standards will provide India a competitive advantage over other Asian countries. In brief, all the stakeholders viz. government, research organizations , pharmaceutical industries and academia and legal fraternity making the IPR as agents of innovation and entrepreneurship and not as hindrance to technology. The profits and products generated should while making the business profitable, at the same time should keep the greater interest of research making the products affordable and accessible to the people who deserve it.

CONCLUSION

Pharmaceutical industry is one of the most promising sectors constantly generating new intellectual property. Indian Pharmaceutical industry is the third largest in terms of volume and thirteenth largest in terms of value as per a report of equity master. India is one of the largest providers of generic drugs contributing almost 20% of the worlds share. Indian Pharma market is expected to grow up to US$20 billion by 2020 with government allowing up to 100% FDI. Though Indian IP laws have been in cross-strings particularly due to Supreme Court judgements against Novartis and with respect to policies of Pharma MNC"s regarding drug pricing and consequent accessibility to India"s huge population. The Pharma industry takes huge risk perse in drug development and research where there are huge monetary investments involved right from drug molecule search and designing to marketing and the chances of failure of experiment or denial of licenses. Section 3(d) of the Indian Patent Act has been under controversy with Pharma industry where - mere discovery of a new form of a known substance without enhanced efficacy is not granted a patent otherwise termed as a form of patent ever-greening employed by Pharma MNC"s to employ monopoly over the market. Due to governments flagship programmes such as Make in India, substantial effect is reflected on the innovation scenario as India has jumped from the ranking of 81st in 2015 to 66th this year in Global Innovation Index compiled by WIPO, a clear indicator of the change coming through. Though many developed and resource rich countries adopted product patents to reward the innovators, some developing countries realising the difference of needs adopted process patents with a view to let domestic industries thrive the market as well. New IPR policy has been made by present government keeping up the hopes of reviving the home sector entrepreneurship and follow up the SDG as well and the pharmaceutical sector plays an important role in the same. Despite of several health policies in line, India continues to lag several health indicators such as mortality rates and malnutrition. Home to 17.5% of the world's population, India accounts for 20% of all neonatal deaths and 21% of all child deaths (younger than 5 years).According to a study in Lancet, India has seven structural problems in healthcare system i.e. a weak primary healthcare sector,

Unequally distributed skilled human resources, large unregulated private sector, low public spending on health, fragmented health information systems, irrational use and spiralling cost of drugs and weak governance and accountability. In such a scenario of increased burden of healthcare the need of a thriving generic drug supply at accessible costs becomes more of a need than ever before. The need of the hour is proper incentivization of the Pharma MNCs using PPP. Allowing them use the wide market base instead of increasing the price of drugs and more effort to incline them to CSR activities. At the same time provide them a good research and development environment with IP laws in sync with the TRIPS agreement and export of Indian made drugs as well to cover the cost-benefit ratio can be a possible solution to look forward.

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