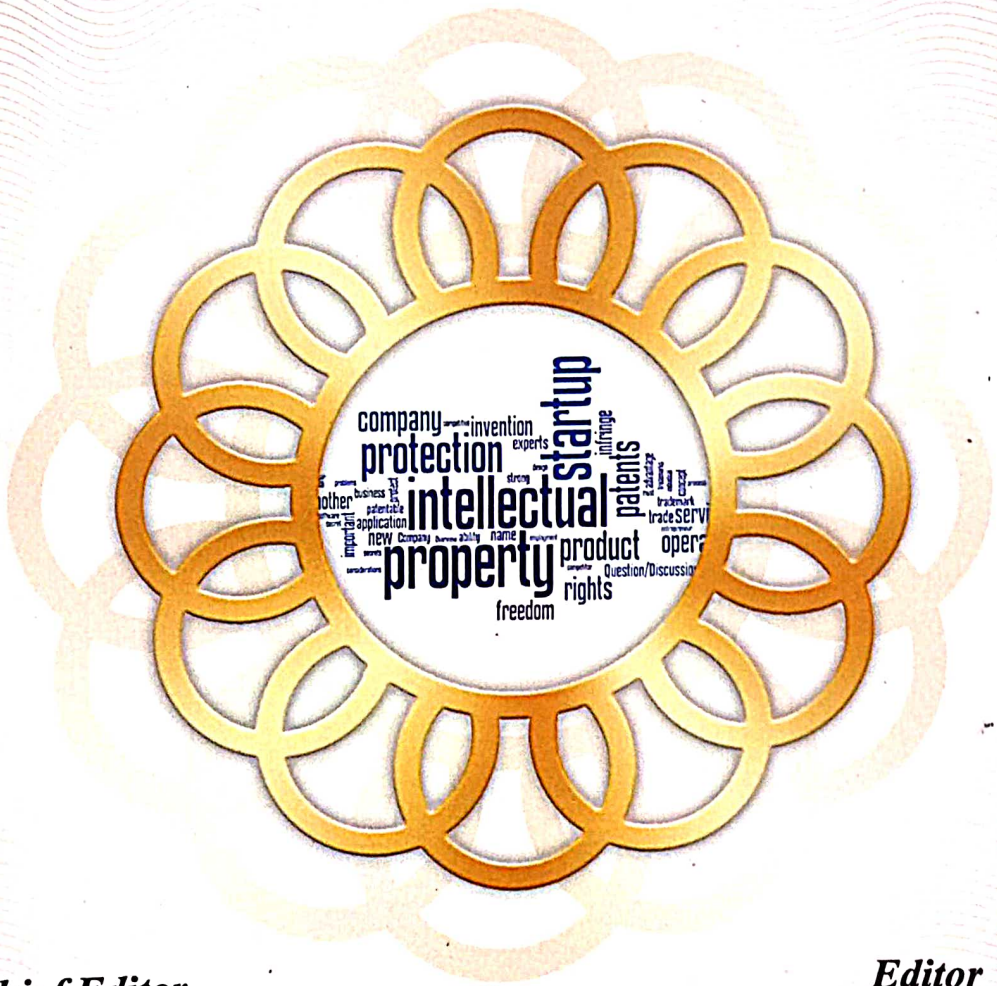
UGC TWO DAY NATIONAL SEMINAR ON

INTELLECTUAL PROPERTY RIGHTS CHALLENGES & ISSUES IN INDIA



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INTELLECTUAL PROPERTY RIGHTS: IMPACT OF PHARMACEUTICAL INDUSTRY IN INDIA

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Introduction:

Intellectual property (IP) pertains to any original creation of the human intellect such as artistic, literary, technical, or scientific creation. Intellectual property rights (IPR) refers to the legal rights given to the inventor or creator to protect his invention or creation for a certain period of time. These legal rights confer an exclusive right to the inventor/creator or his assignee to fully utilize his invention/creation for a given period of time. It is very well settled that IP play a vital role in the modern economy. It has also been conclusively established that the intellectual labor associated with the innovation should be given due importance so that public good emanates from it. There has been a quantum jump in research and development (R&D) costs with an associated jump in investments required for putting a new technology in the market place. The stakes of the developers of technology have become very high, and hence, the need to protect the knowledge from unlawful use has become expedient, at least for a period, that would ensure recovery of the R&D and other associated costs and adequate profits for continuous investments in R&D. IPR is a strong tool, to protect investments, time, money, effort invested by the inventor/creator of an IP, since it grants the inventor/creator an exclusive right for a certain period of time for use of his invention/creation. Thus IPR, in this way aids the economic development of a country by promoting healthy competition and encouraging industrial development and economic growth. Present review furnishes a brief overview of IPR with special emphasis on pharmaceuticals.

HISTORY OF IPR:

The laws and administrative procedures relating to IPR have their roots in Europe. The trend of granting patents started in the fourteenth century. In comparison to other European countries, in some matters England was technologically advanced and used to attract artisans from elsewhere, on special terms. The first known copyrights appeared in Italy. Venice can be considered the cradle of IP system as most legal thinking in this area was done here; laws and systems were made here for the first time in the world, and other countries followed in due course.Patent act in India is more than 150 years old. The inaugural one is the 1856 Act, which is based on the British patent system and it has provided the patent term of 14 years followed by numerous acts and amendments.

Types of Intellectual Properties and their Description

Originally, only patent, trademarks, and industrial designs were protected as 'Industrial Property', but now the term 'Intellectual Property' has a much wider meaning. IPR enhances technology advancement in the following ways:

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a) It provides a mechanism of handling infringement, piracy, and unauthorized use

b) It provides a pool of information to the general public since all forms of IP are published except in case of trade secrets.

Rationale of Patent:

Patent is recognition to the form of IP manifested in invention. Patents are granted for patentable inventions, which satisfy the requirements of novelty and utility under the stringent examination and opposition procedures prescribed in the Indian Patents Act, 1970, but there is not even a prima-facie presumption as to the validity of the patent granted.

Most countries have established national regimes to provide protection to the IPR within its jurisdiction. Except in the case of copyrights, the protection granted to the inventor/creator in a country (such as India) or a region (such as European Union) is restricted to that territory where protection is sought and is not valid in other countries or regions.[1] For example, a patent granted in India is valid only for India and not in the USA. The basic reason for patenting an invention is to make money through exclusivity, i.e., the inventor or his assignee would have a monopoly if, the inventor has made an important invention after taking into account the modifications that the customer, and if the patent agent has described and claimed the invention correctly in the patent specification drafted, then the resultant patent would give the patent owner an exclusive market.

Nature of Pharmaceutical Industry:

The race to unlock the secrets of human genome has produced an explosion of scientific knowledge and spurred the development of new technolc gies that are altering the economics of drug development. Biopharmaceuticals are likely to enjoy a special place and the ultimate goal will be to have personalized medicines, as everyone will have their ow n genome mapped and stored in a chip. Doctors will look at the information in the chip(s) and prescribe accordingly. The important IP issue associated would be the protection of such databases of personal information. Biotechnologically developed drugs will find more and more entry into the market. The protection procedure for such drug will be a little different from those conventional drugs, which are not biotechnologically developed. Microbial strains used for developing a drug or vaccine needs to be specified in the patent document. If the strain is already known and reported in the literature usually consulted by scientists, then the situation is simple. However, many new strains are discovered and developed continuously and these are deposited with International depository authorities under the Budapest Treaty. While doing a novelty search, the databases of these depositories should also be consulted. Companies do not usually go for publishing their work, but it is good to make it a practice not to disclose the invention through publications or seminars until a patent application has been filed.

While dealing with microbiological inventions, it is essential to deposit the strain in one of the recognized depositories who would give a registration number to the strain which should be quoted in the patent specification. This obviates the need of describing a life form on paper.

Depositing a strain also costs money, but this is not much if one is not dealing with, for example cell lines. Further, for inventions involving genes, gene expression, DNA, and RNA, the sequences also have to be described in the patent specification as has been seen in the past. The alliances could be for many different objectives such as for sharing R&D expertise and facilities,

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utilizing marketing networks and sharing production facilities. While entering into an R&D alliance, it is always advisable to enter into a formal agreement covering issues like ownership of IP in different countries, sharing of costs of obtaining and maintaining IP and revenue accruing from it, methods of keeping trade secrets, accounting for IP of each company before the alliance and IP created during the project but not addressed in the plan, dispute settlements. It must be remembered that an alliance would be favorable if the IP portfolio is stronger than that of concerned partner. There could be many other elements of this agreement. Many drug companies will soon use the services of academic institutions, private R&D agencies, R&D institutions under government in India and abroad by way of contract research. All the above aspects mentioned above will be useful. Special attention will have to be paid towards maintaining confidentiality of research.

The current state of the pharmaceutical industry indicates that IPR are being unjustifiably strengthened and abused at the expense of competition and consumer welfare. The lack of risk and innovation on the part of the drug industry underscores the inequity that is occurring at the expense of public good. It is an unfairness that cannot be cured by legislative reform alone. While congressional efforts to close loopholes in current statutes, along with new legislation to curtail additionally unfavorable business practices of the pharmaceutical industry, may provide some mitigation, antitrust law must appropriately step in. While antitrust laws have appropriately scrutinized certain business practices employed by the pharmaceutical industry, such as mergers and acquisitions and agreements not to compete, there are several other practices that need to be addressed. The grant of patents on minor elements of an old drug, reformulations of old drugs to secure new patents, and the use of advertising and brand name development to increase the barriers for generic market entrants are all areas in which antitrust law can help stabilize the balance between rewarding innovation and preserving competition.

Traditional medicine dealing with natural botanical products is an important part of human health care in many developing countries and also in developed countries, increasing their commercial value. The world market for such medicines has reached US $ 60 billion, with annual growth rates of between 5% and 15%. Although purely traditional knowledge based medicines do not qualify for patent, people often claim so. Researchers or companies may also claim IPR over biological resources and/or traditional knowledge, after slightly modifying them. The fast growth of patent applications related to herbal medicine shows this trend clearly. The patent applications in the field of natural products, traditional herbal medicine and herbal medicinal products are dealt with own IPR policies of each country as food, pharmaceutical and cosmetics purview, whichever appropriate. Medicinal plants and related plant products are important targets of patent claims since they have become of great interest to the global organized herbal drug and cosmetic industries.

Management of Intellectual Property in Pharmaceutical Industries in India:

More than any other technological area, drugs and pharmaceuticals match the description of globalization and need to have a strong IP system most closely. Knowing that the cost of introducing a new drug into the market may cost a company anywhere between $ 300 million to $1000 million along with all the associated risks at the developmental stage, no company will like to risk its IP becoming a public property without adequate returns. Creating, obtaining, protecting, and managing IP must become a corporate activity in the same manner as the raising of resources and funds. The knowledge revolution, which we are sure to witness, will demand a special pedestal for IP and treatment in the overall decision-making process.

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Competition in the global pharmaceutical industry is driven by scientific knowledge rather than manufacturing know-how and a company's success will be largely dependent on its R&D efforts. Therefore, investments in R&D in the drug industry are very high as a percentage of total sales; reports suggest that it could be as much as 15% of the sale. One of the key issues in this industry is the management of innovative risks while one strives to gain a competitive advantage over rival organizations.

Important Aspects of Drug Patent Specification:

Writing patent specification is a highly professional skill, which is acquired over a period of time and needs a good combination of scientific, technological, and legal knowledge. Claims in any patent specification constitute the soul of the patent over which legal proprietary is sought. Discovery of a new property in a known material is not patentable. If one can put the property to a practical use one has made an invention which may be patentable. A discovery that a known substance is able to withstand mechanical shock would not be patentable but a railway sleeper made from the material could well be patented. A substance may not be new but has been found to have a new property. It may be possible to patent it in combination with some other known substances if in combination they exhibit some new result. The reason is that no one has earlier used that combination for producing an insecticide or fertilizer or drug. It is quite possible that an inventor has created a new molecule but its precise structure is not known. In such a case, description of the substance along with its properties and the method of producing the same will play an important role.

Combination of known substances into useful products may be a subject matter of a patent if the substances have some working relationship when combined together. In this case, no chemical reaction takes place. It confers only a limited protection. Any use by others of individual parts of the combination is beyond the scope of the patent. For example, a patent on aqua regia will not prohibit any one from mixing the two acids in different proportions and obtaining new patents. Methods of treatment for humans and animals are not patentable in most of the countries (one exception is USA) as they are not considered capable of industrial application. In case of new pharmaceutical use of a known substance, one should be careful in writing claims as the claim should not give an impression of a method of treatment. Most of the applications relate to drugs and pharmaceuticals including herbal drugs. A limited number of applications relate to engineering, electronics, and chemicals. About 62 per cent of the applications are related to drugs and pharmaceuticals.

Conclusions:

It is obvious that management of IP and IPR is a multidimensional task and calls for many different actions and strategies which need to be aligned with national laws and international treaties and practices. It is no longer driven purely by a national perspective. IP and its associated rights are seriously influenced by the market needs, market response, cost involved in translating IP into commercial venture and so on. In other words, trade and commerce considerations are important in the management of IPR. Different forms of IPR demand different treatment, handling, planning, and strategies and engagement of persons with different domain knowledge such as science, engineering, medicines, law, finance, marketing, and economics. Each industry should evolve its own IP policies, management style, strategies, etc. depending on its area of specialty. Pharmaceutical industry currently has an evolving IP strategy.

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Since there exists the increased possibility that some IPR are invalid, antitrust law, therefore, needs to step in to ensure that invalid rights are not being unlawfully asserted to establish and maintain illegitimate, albeit limited, monopolies within the pharmaceutical industry. Still many things remain to be resolved in this context.

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