Intellectual Property Rights: An Overview And Implications In Pharmaceutical Industry

Mr. Abhijit Rode R[1], Asst .Prof.Pagire D.M[2]
[1, 2] Dept of Chemistry
[1, 2] PratibhataiPawar College of Pharmacy, Shrirampur , Maharashtra, India

Abstract- *Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property. IPR provide certain exclusive rights to the inventors or creators of that property, in order to enable them to reap commercial benefits from their creative efforts or reputation. There are several types of intellectual property protection like patent, copyright, trademark, etc. Patent is a recognition for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial application. IPR is prerequisite for better identification, planning, commercialization, rendering, and thereby protection of invention or creativity. Each industry should evolve its own IPR policies, management style, strategies, and so on depending on its area of specialty. Pharmaceutical industry currently has an evolving IPR strategy requiring a better focus and approach in the coming era.*

Keywords- Drug, intellectual property, license, patent, pharmaceutical.

I. 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.

Historical Background

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

(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.

IP protection can be sought for a variety of intellectual efforts including

- (i) Patents

- (ii) Industrial designs relates to features of any shape, configuration, surface pattern, composition of lines and colors applied to an article whether 2-D, e.g., textile, or 3-D, e.g., toothbrush
- (iii) Trademarks relate to any mark, name, or logo under which trade is conducted for any product or service and by which the manufacturer or the service provider is identified. Trademarks can be bought, sold, and licensed. Trademark has no existence apart from the goodwill of the product or service it symbolizes
- (iv) Copyright relates to expression of ideas in material form and includes literary, musical, dramatic, artistic, cinematography work, audio tapes, and computer software
- (v) Geographical indications are indications, which identify as good as originating in the territory of a country or a region or locality in that territory where a given quality, reputation, or other characteristic of the goods is essentially attributable to its geographical origin

A patent is awarded for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial or commercial application. Patents can be granted for products and processes. As per the Indian Patent Act 1970, the term of a patent was 14 years from the date of filing except for processes for preparing drugs and food items for which the term was 7 years from the date of the filing or 5 years from the date of the patent, whichever is earlier. No product patents were granted for drugs and food items. A copyright generated in a member country of the Berne Convention is automatically protected in all the member countries, without any need for registration. India is a signatory to the Berne Convention and has a very good copyright legislation comparable to that of any country. However, the copyright will not be automatically available in countries that are not the members of the Berne Convention. Therefore, copyright may not be considered a territorial right in the strict sense. Like any other property IPR can be transferred, sold, or gifted.

Role of Undisclosed Information in Intellectual Property

Protection of undisclosed information is least known to players of IPR and also least talked about, although it is perhaps the most important form of protection for industries, R&D institutions and other agencies dealing with IPR. Undisclosed information, generally known as trade secret or confidential information, includes formula, pattern, compilation, programme, device, method, technique, or process. Protection of undisclosed information or trade secret is not really new to humanity; at every stage of development people have evolved methods to keep important information secret, commonly by restricting the knowledge to their family members. Laws relating to all forms of IPR are at different stages of implementation in India, but there is no separate and exclusive law for protecting undisclosed information/trade secret or confidential information.

Pressures of globalisation or internationalisation were not intense during 1950s to 1980s, and many countries, including India, were able to manage without practising a strong system of IPR. Globalization driven by chemical, pharmaceutical, electronic, and IT industries has resulted into large investment in R&D. This process is characterized by shortening of product cycle, time and high risk of reverse engineering by competitors. Industries came to realize that trade secrets were not adequate to guard a technology. It was difficult to reap the benefits of innovations unless uniform laws and rules of patents, trademarks, copyright, etc. existed. That is how IPR became an important constituent of the World Trade Organization (WTO).

- Patent law in the Indian pharmaceutical industry

The law that regulates patents in India is given under the Patent Act, 1970. India is a signatory to both the Paris Convention of 1883 and the Patent Cooperation Treaty (PCT) of 1970. The Patents Act details out the prerequisites of a patent which are necessary to be satisfied for it to be granted protection:

- It should be new
- It should not be obvious
- It should be useful which can be the subject matter of a patent.

There are some non-patentable inventions under the Act which includes:

- Methods of agriculture or horticulture
- Processes for the medicinal,
- Processes of surgical, curative, or prophylactic

Or other treatment of human beings, animals or plants or substances which are just due to mere admixture which results in the aggregation of the properties of the components

With regard to pharmaceuticals in India, the substances which are intended to be used or capable of being used as food compounds, drugs compounds, or even medicines or products which are produced by way of chemical processes and such processes are granted protection. Patents

are granted for the processes or methods of manufacture of such products of chemical processes and not the whole compound product itself. Hence, pharmaceutical "products" are currently not given patent protection under Indian patent law due to the reasons mentioned below:

- Heavy dependence on the importing system.
- Bulk importing is costly and gives a more advantageous position to profit-making companies.
- Local brands are not encouraged to make these products as branded drugs have a better standing in the market.
- If the products are given protection, the costs will inflate.
- Cost inflation will reduce the affordability, and the consumer base will be disease-prone, and only higher economic strata consumers will be able to afford it.
- Research and Development of the local brands will suffer in the country.

Earlier, the product patent was protected under the Patents and Designs Act, 1911. However, in the year 1970, the government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from getting patent protection. They were excluded only to break away India's dependence on importing system of drugs and making a self-reliant drug discovery system that helps the economy from within and not creating a monopoly market by a profit-making company only.

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 were 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 pharma companies or applied by these companies are for either new processes or new drug delivery systems

Evergreening Strategy In Pharmaceutical industry:

So many number of strategies have been followed by the innovator companies to extend the term of patent, like methods of treatment, mechanism of action, packaging, derivatives, isomeric forms, delivery profiles, dosing regimen, dosing range, dosing route, combinations, screening methods, biological targets and field of use. These strategies involve skilled addition of patents to the product by the innovator companies that force the generic manufacturer to maintain forbearance for all the patents to expire and applying for marketing authorization bearing the risks of litigation and associated penalties and delays .The innovator companies in the name of life-cycle management maximize revenues from their so called evergreen products and also choke their generic competition at the outset of product life-cycles. Even though strict strategies are followed still most of these companies represent misuse of pharmaceutical patents and regulations governing authorization. Ever greening strategies that have been usually followed by the pharmaceutical industries involve: a) redundant extensions and creation of next generation drugs which result in superfluous variation to a product and then patenting it as a new application, b) prescription to OTC switch, c) exclusive partnerships with cream of generic players in the market prior to patent expiry thus significantly enhancing the brand value and interim earning royalties on the product, d) defensive pricing strategies practice wherein the innovator companies decrease the price of the product in line with the generic players for healthy competition and e) establishment of subsidiary units by respective innovator companies in generic domain before the advent of rival generic players .

PATENTING AND PHARMA RESEARCH COST:

Pharmaceutical organizations pour resources into R&D of various molecules for the benefit of mankind. The development of a pharmaceutical goes through a series of permutations and combinations resulting in uncertainties which could be many and substantial. Maximizing the certainty that a research-based manufacturer can obtain enforce, defend, and make full, legitimate use of IP rights is essential to maintain the cycle of innovation for the benefit of public health. In the absence of strong IP rights at each stage of the innovation cycle, promise of pharmaceutical innovation could be lost . Pharmaceutical products often rely on substantial amounts of upfront investment and technical knowledge and for the resources involved, companies eventually secure patents for every product they develop. The pharmaceutical companies screen large number of molecules and out of the thousand potential drugs screened, only 4-5 reach clinical trials stage form, of which finally one is approved for marketing. It costs on an average around 800 million dollars to develop and test a new drug before it is approved for use. In the case of pharmaceutical companies, monopolies over the fruits of their R&D efforts are vehicles

through which they could recoup huge investments. The costs of research done on screening out the molecule and taking into clinical trial stage are recovered through appropriate pricing mechanisms from the patients who receive the patented drugs. Providing market exclusivity to an inventor through patent protection can encourage the initial outlay of resources needed to develop the products Capital investment by the innovator companies in the development of new molecules which have reached the stage of marketing also encourage the challenge to invest more in further research, development and refinement of related innovations to expand and improve therapies and cures. Moreover due to innovation in providing products of medicinal importance, patent protection on the same creates a platform wherein generic companies compete with research oriented innovator companies following the expiration of IP rights. After the patent on a drug expires, any pharmaceutical company can manufacture and sell that drug. Since the drug has already been

The Role of Patent Cooperation Treaty

The patent cooperation treaty (PCT) is a multilateral treaty entered into force in 1978. Through PCT, an inventor of a member country contracting state of PCT can simultaneously obtain priority for his/her invention in all or any of the member countries, without having to file a separate application in the countries of interest, by designating them in the PCT application. All activities related to PCT are coordinated by the world intellectual property organization (WIPO) situated in Geneva.

In order to protect invention in other countries, it is required to file an independent patent application in each country of interest; in some cases, within a stipulated time to obtain priority in these countries. This would entail a large investment, within a short time, to meet costs towards filing fees, translation, attorney charges, etc. In addition, it is assumed that due to the short time available for making the decision on whether to file a patent application in a country or not, may not be well founded.

Inventors of contracting states of PCT on the other hand can simultaneously obtain priority for their inventions without having to file separate application in the countries of interest; thus, saving the initial investments towards filing fees, translation, etc. In addition, the system provides much longer time for filing patent application in the member countries.

The time available under Paris convention for securing priority in other countries is 12 months from the date of initial filing. Under the PCT, the time available could be as much as minimum 20 and maximum 31 months. Further, an inventor is also benefited by the search report prepared under the PCT system to be sure that the claimed invention is novel. The inventor could also opt for preliminary examination before filing in other countries to be doubly sure about the patentability of the invention.

Management of Intellectual Property in Pharmaceutical Industries

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.

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. There is high cost attached to the risk of failure in pharmaceutical R&D with the development of potential medicines that are unable to meet the stringent safety standards, being terminated, sometimes after many years of investment. For those medicines that do clear development hurdles, it takes about 8-10 years from the date when the compound was first synthesized. As product patents emerge as the main tools for protecting IP, the drug companies will have to shift their focus of R&D from development of new processes for producing known drugs towards development of a new drug molecule and new chemical entity (NCE). During the 1980s, after a period of successfully treating many diseases of short-term duration, the R&D focus shifted to long duration (chronic) diseases. While looking for the global market, one has to ensure that requirements different regulatory authorities must be satisfied.

It is understood that the documents to be submitted to regulatory authorities have almost tripled in the last ten years. In addition, regulatory authorities now take much longer to

approve a new drug. Consequently, the period of patent protection is reduced, resulting in the need of putting in extra efforts to earn enough profits. The situation may be more severe in the case of drugs developed through the biotechnology route especially those involving utilization of genes. It is likely that the industrialized world would soon start canvassing for longer protection for drugs. It is also possible that many governments would exercise more and more price control to meet public goals. This would on one hand emphasize the need for reduced cost of drug development, production, and marketing, and on the other hand, necessitate planning for lower profit margins so as to recover costs over a longer period. It is thus obvious that the drug industry has to wade through many conflicting requirements. Many different strategies have been evolved during the last 10 to 15 years for cost containment and trade advantage. Some of these are out sourcing of R&D activity, forming R&D partnerships and establishing strategic alliances.

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 technologies 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 own 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, 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.

Difference between weak and strong intellectual property regime in the pharmaceutical industry

From the intellectual perspective regime, the generic drug manufacturers imitate the bio-pharma innovations due to a lack of investment in research and development of new drug discovery in the weak IPR regime. The results are decremental for both branded as well as for the customers of the drug. The innovation is compromised in a weak IPR regime.

Whereas, on the other hand, a strong IPR regime does not necessarily mean that it is beneficial for the country. A stronger IPR regime helps to emerge branded pharma companies in protecting their innovation from the research to the development stage of the drug. IPR not only protects but proves beneficial in creating, managing, and protecting intellectual property as it becomes an important source of funding as it helps in becoming an important source of raising funds. These funds can also be used for investment in R&D.
Intellectual property rights have an impact on the industry which ranged from discovery, pricing, development, and even distribution of the drug. With stronger intellectual property rights protection regimes in developed countries, pharmaceutical companies are growing at a rapid rate. Developing countries criticize the patent system as it creates a monopoly in the market and leads to higher prices of drugs making it difficult for the consumers to buy at affordable rates. In the Indian market, the product cannot be granted a patent, which means that drugs when reverse engineered and the method by which they are formulated can only be patented, if novel.

Some Special 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% of the applications are related to drugs and pharmaceuticals.

Importance of Intellectual Property Rights in Pharmaceutical Company

Protection of invention

If there has been a discovery or development of a drug, a patent helps in the protection of the drug. It can be reverse engineered, and the drug can be protected by inventive methods. But the novel process by which that drug company manufactures that particular drug is protected. A patent gives better protection than trade secrets law. In India, trade secrets law is not codified, so the only protection drug has is patent protection.

Incremental economic growth and competitiveness amongst the Companies

Intellectual Property Rights help fund the growth of the economy of the country. Awarding the rights to the inventor helps him gain profits as well as invest that in the research and development of drugs to create more drugs and develop the already discovered ones. That is not only cost-effective but also consumer-friendly. Research and development in a country help the economy to grow and on the other hand, the market also becomes competitive.

Protects consumers and families

Public safety is the main concern and IPR helps to safeguard the interest of the people. While granting protection of a patent the safety of a product and the quality is assured which puts the mind of the consumer at ease. It helps the consumer to make the right choice. Also in Indian market where the product is not granted protection and the process is, the Companies compete and help to reduce the price of the product which helps the customer base at large.

Protection against the potential infringement of the drug discovery and development

Intellectual property rights allow pharmaceutical companies to take strict actions against fake drugs. These rights help countries across the globe to ensure safety in their medical inventions. The potential infringers who make counterfeit drugs are penalized for fraudulent behavior towards the consumers for the sake of creating profit only which the authorities prohibit.

Recent Changes In IPR laws Impacting Pharmaceutical Industry: 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 pregrant 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.

Global Market Intellectual Property Rights

Software intellectual property, commonly known as software IP, is a computer program or code that is protected by law from unauthorized copying, theft, or other uses.Global Intellectual Property Software Market is estimated to witness a rise in revenue from US$ 6,508.6 Mn in 2021 to US$ 22,658.5

Mn by 2030. The market is registering a CAGR of 15.78% during the forecast period 2022-2030.The corporation that generated or obtained the rights to that code or software owns the intellectual property (IP) associated with it. Intellectual property rights play an important role in promoting innovation and protecting investment, in particular in the digital and green economy. In-house IP management is a time-consuming operation that recessitates significant investment. Whereas outsourcing IP management aids businesses in lowering costs, Increasing productivity, and increasing profits Moreover, individuals and corporations can avoid the expenditures of purchasing Installing, and maintaining expensive gear and software by using cloud computing

Choose License Type
O Single User Licence O
Multi User Licence O
Corporate User Licence O

The major factor responsible for the growth of the global intellectual property software market includes the rising awareness of Intellectual property rights. The expansion of the intellectual property software Industry is fueled by an increase in demand for a secure and well-documented system within a company. Moreover, the increased demand for secured and well-documented systems in organizations creates a lucrative growth trend in the market. Furthermore, the expansion of the intelectual property outsourcing industry is fueled by the rising demand for ostinctive IPs for goods. However, complexity in maintaining me software fagh cost of Investment, poor rate of awareness, and data security are expected to hider the market growth during the forecast penod As copynght protection is applicable to a computer source code and is not limited to a single language, the comprexity of maintaining the software increases

The Global Intellectual Property Management Software market was valued at USD **6.97 Billion** in 2021, and it is expected to reach a value of USD **18.54 Billion** by 2027, registering a CAGR of **17.27%** over the forecast period (2022-2027).

Intellectual property is a legal approach for the preservation of ideas or inventions for commercial benefits by providing its creators or inventors with certain exclusive rights. The incremental increase in the adoption of outsourcing services by larger enterprises contributes significantly to the growth of the IP management software market.

Managing the organization's intellectual property portfolio is as important as managing the business. It is a big piece in almost any enterprise's value puzzle. Additionally, anyone operating a business primarily understands the importance of maximizing the return on investments related to employees, equipment, products, and services. However, multiple organizations overlook or short-change intellectual property.

Intellectual property is not just a collection of rights that lawyers alone should care about; this property is primarily a collection of many valuable business assets that help businesses maintain a competitive edge over their competitors. It includes patents, copyrights, trademarks, and trade secrets. Therefore, it becomes critical to review, organize, and manage the IP as its value driver.

Managing all the potential intellectual property assets has become one of the most crucial parts of securing a place in the market as the business grows. Vendors in the market can significantly help companies in protecting their competitive advantages from infringements. Making the use of a wealth of experience, IP management software and services providers guide the development of a smarter IP portfolio that may align with the business strategy and maximize the IP assets.

The outbreak of the COVID-19 pandemic impacted the market studied. A prolonged pandemic crisis heightened by the COVID-19 may push the intellectual property and legal services domain downwards, like other sectors and industries. However, the possibility of significant growth in the intellectual property domain cannot be ignored once the COVID situation ends, as a post-COVID world will more likely push tech companies to go after the licensing of their existing IP portfolio to incentivize their financial reserves. This will increase the demand for the market studied.

II. CONCLUSION

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. 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.

REFERENCES

[1] Biopharmaceutical Research & Development: The Process Behind New Medicines, Pharma(2015),http://phrmadocs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

[2] See Thomas Sullivan, A Tough Road: Cost To Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%, Policy & Medicine (last updated Mar. 21, 2019), https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html.

[3] See Ana Swanson, Big pharmaceutical companies are spending far more on marketing than research, Wash. Post, Feb. 11, 2015, https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-thanresearch/?noredirect=on&utm_term=.fb51ba7da933.

[4] See Renu Lal, Patents and Exclusivity, FDA/CDER SBIA Chronicles (May 19, 2015), https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM447307.pdf.

[5] See Fabian Gaessler & Stefan Wagner, Patents, Data Exclusivity, and the Development of New Drugs, Northwestern University Pritzker School of Law (June 3, 2018) (unpublished manuscript) (on file with the author).

[6] Anonymous. The Copyright Act 1957 as amended up to 1999 along with Copyright Rules 1958 and International Copyright Order 1999. New Delhi: Commercial Law Publisher (India) Pvt. Ltd.; 2005.

[7] Abbott F, Cottier T, Gurry F. The international intellectual property system: Commentary and materials. Part I. London: Kluwer Law International; 1999.

[8] Mrudula BS, Durgadevi NK, Madhavi BR, Tejeswi B, Durga PV. Intellectual property rights pinpoint at IPR spotlights coveted R and D. Drug Inv Today 2009;2:197-201.

[9] Glasgow LJ. Stretching the limits of intellectual property rights: Has the pharmaceutical industry gone too far? IDEA J Law Technol 2001;41:227-58.

[10] Kartal M. Intellectual property protection in the natural product drug discovery, traditional herbal medicine and herbal medicinal products. Phytother Res 2007;21:113-9