**Intellectual Property Management in Chemical, Biological & Pharmaceutical Science**

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**ABSTRACT**

Creating a new kind of formulation, coined any novel use of any chemical compound, any alteration in the step of a process – chemical engineers and pharmacists are continuously revolutionising these above-mentioned things. This revolution is proving helpful in creating the intellectual property- inflatable benefits whose advantage can be taken by an enterprise to add more values. The IPR’s are impalpable in nature and are confidential to the creator or inventor. In this era of globalisation, global trade practises are now focusing on IPR’s throughout the world. These rights provoke the creator and provide him/her confident. Strong Intellectual property rights impart funding in developing the knowledge and ultimately provoke innovation. Five types of IPR have been recorded which includes copyrights, trademarks, patents, trade dress & trade secrets. A patent is related to all the uses of that particular concept. In simple words, it conveys how that particular article works and how it is made. A patent provides the legal ownership for an article and also a monopoly in relation to enhance the innovation of a product or process. Pharmaceutical companies are much indulging themselves in obtaining durable and sustainable patents to secure their products that can be copied by other easily once known.

**Key words: -**Intellectual Property Right, copyrights, patents, trademarks legal ownership,

**Introduction**

The term "intellectual property" pertains to the special privileges that the government grants over individual’s cognitive creations, specifically inventions, literature and artistry works, address a variety and styles being used for commercial activity. Industrial copyrights, that include patent rights, service marks, trade names, utility models, commercial secrets, innovative varieties of plants, as well as geographic location evidence, are separated into two categories: publishing rights and associated rights, which pertain to literary and artistic works. [1]

Industrial property (IP) privileges are critical in the pharma companies. The adoption of the IP system through Small and medium enterprises in the pharma companies is heavily influenced by a business strategy, dimensions, assets, capacity for innovation, challenging context, and area of expertise. Companies that seek to develop pharmaceutical medications, enhance or modify new substances, or build innovative pharma machinery or operations depend heavily upon that patent system to guarantee they rebound their investment in research and development. [2] Businesses that are dependent on licensing in or licensing out of medical drugs must understand the intellectual property system in order to bargain fair and equitable licencing agreements. SMEs in the drug sector may utilize the plethora of data embedded in filings as a critical input to one‘s Research and innovation work, to somehow get ideas for future advancement, to guarantee their "right to operate," or even to discover out if a patent is scheduled to expire, allowing the competition to enter the market. [3]

Many organizations value sensitive information, which is shielded as proprietary information, as well as precious understand or undeclared test information related to new or significantly improved drugs. Acknowledging the trademark framework is critical for businesses that sell branded goods. Industry's average, plant variation safety, and digital rights and associated rights are normally less meaningful to most SMEs in the healthcare companies, but this may fluctuate widely on each company's products or services and strategic plan. [4]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes least rules and expectations for the succeeding intellectual property rights categories: -

a. Copyrights and related rights

b. Trademarks

c. Geographical Indications

d. Industrial Designs

e. Patents

f. Lay out designs of integrated circuits

g. Protection of undisclosed information (trade secrets)

This has also been consistently documented that perhaps the intellectual labour associated with technological advancement must be taken into account in order for public good to result. The expenses of research and development (R&D) have risen dramatically, as have the investment is expected to introduce a new technology to the marketplace. [5] The risks for application developers are now extremely significant, and thus the really have to safeguard awareness from unauthorised use has already become necessary, at least for a short time, to guarantee the retrieval of R&D as well as other costs involved, as well as sufficient profit for ongoing R&D investments. [6] IPR is a powerful tool for protecting the innovator of an IP's invested money, duration, finances, and effort, because it permits the innovator the exclusive entitlement for using his innovation and technology for a specified period of time. Thus, IPR contributes to an economy's growth by encouraging healthy contest and inspiring production growth and development.

**Brief History**

IPR laws and standard operating procedures have one‘s origins in Europe. The practice of approving the application began in the 14th century. In certain ways, England was technically sophisticated in comparison to other European nations, and it was able to capture artisans from many other nations on favorable terms. The very first recognized copyrights were established in Italy. Venice can indeed be regarded the origin of the IP rights because it was the site of most lawful thoughts in this area; regulations and processes were created here for the very first time around the world, as well as other nations followed suit in timely manner. [7] The first is the 1856 Act, that is premised upon that British patent system and establishes a 14-year intellectual property phrase, which is accompanied by countless actions and adjustments. [8]

**Rationale of Patent**

A invention is acknowledgement for such form of intellectual property exhibited in creation. Design patents for patentability that satisfy the requirements of uniqueness and functionality under the rigorous investigation and dissent phases of the research process in the Indian Patents Act, 1970, however there is no facts of the case insinuation as to the authenticity of the patent was granted. [9] Most nations have developed nationwide norms to safeguard IPR within their borders. Other than in the particular instance of copyrights, the safeguarding awarded to the innovator in a nation (such as India) or area (such as the European Union) is limited to the region where safety is desired and it is not legitimate in the other regions or nations. [10] A intellectual property conferred in India, for instance, is now only legitimate in India and not across the United States. The main cause for patent protection an innovation is to profit from uniqueness, i.e., the creator or his transferee was granted a stranglehold if

(a) The patentee created a significant innovation upon taking into consideration the improvements that the client requested, and

(b) The patent representative accurately stated and asserted the innovation in the patented invention conscripted; therefore the subsequent patent might well grant the intellectual property owner an exclusive industry.

The patent holder can use his distinctiveness by promoting the patentee personally or licensing it to a 3rd person.

**The Role of Patent Cooperation Treaty**

The Patent Cooperation Treaty (PCT) is a multilateral agreement that was signed in 1978. A patentee from a PCT participating country can concurrently obtain preference for his/her innovation over all or some of the participating countries besides labelling them in the PCT proposal, without being required to file a formal application with in countries of involvement. The World Intellectual Property Organization (WIPO) in Geneva coordinates all PCT-related operations. [11] To safeguard a creation in other regions, it is necessary to file a separate provisional patent for each nation of interest; in certain cases, inside a certain time frame to acquire preference in these nations. This might necessitate a considerable investment in a short time frame to cover costs such as legal costs, transcription, lawyer fees, and so on. Furthermore, it is supposed that because of the limited available time for deciding if or not to document a provisional patent in a region, the judgement might not be well established. [15] Creators from PCT signatory countries, on the contrary hand, can acquire preference for their innovations without being required to file multiple applications in the regions of interest, and save the upfront outlay in submitting fees, interpretation, and so on. Furthermore, the system gives signatory nations much more time to file patent applications. [12,13]

The Paris rules allow 12 months from the time of first filing to secure preference in all other nations. The resources duration under the PCT may be as little as 20 months and as long as 31 months. Furthermore, the lookup report published underneath the PCT system helps an innovator ensure that the patented invention is innovative. To be certain that the innovation is patentable; the patentee could request preliminary study before submitting in other nations. [14]

**Management of Intellectual Property**

Substances and pharmaceutical drugs, unlike any other field of research and development, intimately match the definition of globalization and require a strong IP system. Recognizing that the expense of putting a new product onto the market can range from $300 million to $1 billion, not to mention the uncertainties that come with the research stage, no corporation wants to risk its intellectual property to become public land without additionally guarantees. Creating, acquiring, defending, and managing intellectual property (IP) should be a procedure in the same way that increasing funds and resources is. The impending knowledge transformation will necessitate a special place for intellectual property and therapeutic interventions in the as a whole choice procedure. [15] Modern science, instead of producing know-how, drives competition in the worldwide pharmaceutical companies, and a team's growth is heavily reliant on its Research and development efforts. As a result, expenditures in the pharmaceutical industry are indeed very significant as a percentage of overall sales; sources claim that it may be quite so much as 15% of overall sales. Among the most critical topics in this market is managing creative risks while attempting to gain a competitive edge over rival organizations. The danger of failure in pharmaceutical Research and development comes at a high cost, with the development of promising medications that fail to meet strict regulatory standards being ended, occasionally after several years of effort. It takes approximately 8-10 years from the time the substance was first synthesized for therapies to clear advancement hurdles. As merchandise patents become the primary tool for safeguarding intellectual property, drug manufacturers will need to transition their R&D concentrate from creating innovative methods for generating recognized drugs to developing a new therapeutic agent and novel chemical entity (NCE). After such a timeframe of proven methodology many brief diseases, the R&D emphasis moved to long-term (chronic) illnesses in the 1980s. When going to look for a world market, one should guarantee that the necessities of various regulatory agencies are met. [16]

It is believed that the number of records that must be provided to government regulators has nearly tripled over the last 10 years. Furthermore, regulatory authorities are now taking significantly longer to approve a new drug. As a consequence, the time frame of patent rights is lowered, necessitating additional efforts to obtain sufficient profits. The scenario may be worse in the case of pharmaceuticals developed through the biotech route, especially those that involve gene utilization. It is probably that the industrialized world will soon begin lobbying for increased drug safety. It is also feasible that several governments will use price controls to achieve community goals. This might emphasize the requirement for relatively low drug discovery, manufacturing, and marketing expenses, while also necessitating planning for reduced profit margins in order to regain costs above a longer time frame. As a result, it is clear that the pharmaceutical industry must navigate a maze of competing regulations. Numerous strategies for controlling costs and exchange benefit have emerged in the past 10 to 15 years. Companies outsource R&D efforts, formation R&D collaborations, and formulating strategic partnerships are a few of these. [17]

Biotech is a discipline of applied genetics that deals with the utilization of living creatures in mechatronics, future technologies, pharmaceutics, as well as other useful fields. The phrase is now used to refer to genetically engineered in addition to cell and tissue culture innovations. The idea embodies a broad range of techniques (and past) for changing living organisms for human benefit, dating all the way back to domestication of animals, vegetation cultivation, and "adjustments" to all of these via conventional breeding that use illusionary which is indeed choices and interspecific. Biotechnology is defined by the United Nations Biological Diversity Convention as "any technical method that employs biochemical pathways, living beings, or derivative products of its use, to create or adjust products or procedures for particular use." Biotechnology is based solely on biomedical sciences (genetics, microbiology, animal cell culture, molecular biology, biochemistry, embryology, cell biology). [18]

Breakthroughs in biological sciences, on the contrary hand (including ideas such as biochemical ecology), have been intrinsically tied to and dependent on biotech and the biomedical market. Biotech is growing rapidly in sub-sectors such as bio-informatics, production bioengineering, agriculture and agri research programs, bio-suppliers, and, most particularly, among the most important applications of bio-technologies, bio-pharmaceuticals. Because of advancement of a growing biotech industry may be ignored, massive investment is required to achieve the required goal of Research and Development (R&D) in this section.

The pharmaceutical sector in India was among the first industries to benefit from biotechnology. Consumer health biotech brands represent about 60% of the home market, with bio-drugs, vaccines, and diagnostic tools also having major market shares. As a result, Indian pharma is starting to reap the benefits of improved IP protection for their goods. Ranbaxy's NDDS for ciprofloxacin, for example, was licenced to Bayer for $65 million plus royalties. [19] Other Indian research-based industries have earned approximately $70 million from R&D advancement and enabling technology transfer. In terms of encouraging the possibility and significance to societal needs, the Department of Biotechnology (DBT) has greatly contributed to the development of all. In comparison, most developing nations lack strong intellectual property norms and landmark payments. Intellectual property (IP) is crucial to the field of biotechnology and adds an element to collaboration process, whether it involves drug finding, clinical or business trials. [20] Primarily, cooperative activity is a fusion between India's capacity supply circumstances for research, clinical studies, and advancement, as well as technological edge and availability of capital in advanced nations. The productive translation of such synergies into economically viable implementations and tradeable items is critically dependent on the suitability of restrictions dealing with intellectual property enrollment and protection derived from the cooperative effort. Policies that encourage a harmony between incremental innovation and enabling technology transfer have made significant advancements in terms of research and development, human capital production, and infrastructure building.

Over the last decade, India has demonstrated effectiveness in scientific effectiveness, as exemplified by the number and reliability of articles published made in scientific publications every year. However, as determined by the number of patent applications issued per component of R&D investment, its commercial and technological performance is poor. [21]

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