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An Overview of the Pharmaceutical Industry and Its Implications in Terms of IP Laws

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ABSTRACT

Intellectual property (IP) has been defined as ideas, inventions, and creative directions for which the public wishes to provide property. Intellectual property gives the creator or creator of that property certain exclusive rights, enabling them to profit commercially from their creativity or reputation. Intellectual property protection, patents, copyrights, trademarks, etc. includes. A patent is the recognition of an invention that is new, non-obvious, and satisfies its commercial application in the world. Intellectual property is a prerequisite for better identification, planning, marketing, presentation and therefore the protection of production or creativity. Every business has its own intellectual property rights, management methods, strategies, etc. should develop according to his own work. The pharmaceutical industry now has a shifting IP strategy that needs clarification and improvement in the future.

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

I. INTRODUCTION

Intellectual property (hereinafter referred as IP) relates to any authentic introduction of the human mind which includes artistic, literary, technical, or scientific creation. Intellectual property Rights (hereinafter referred as IPR) refers back to the felony rights given to the inventor or writer to protect his invention or advent for a certain time frame. those felony rights confer an different proper to the inventor/author or his assignee to absolutely make use of his invention/advent for a given period of time. it's miles thoroughly settled that IP play a important function inside the contemporary economy. It has also been conclusively established that the highbrow hard work related to the innovation must take delivery of due significance in order that public appropriate emanates from it. There has been a quantum jump in research and development (R&D) prices with an associated leap in investments required for putting a new era inside the marketplace location. The stakes of the developers of generation have become very high, and therefore, the want to guard the know-how from unlawful use has end up

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expedient, at the least for a period, that would make certain healing of the R&D and different associated prices and ok income for non-stop investments in R&D. IPR is a sturdy tool, to shield investments, time, money, effort invested with the aid of the inventor/writer of an IP, because it offers the inventor/writer an extraordinary proper for a certain time period for use of his invention/introduction. accordingly IPR, in this way aids the financial development of a rustic by means of selling healthful competition and encouraging industrial development and monetary growth. present review furnishes a quick evaluation of IPR with special emphasis on prescribed drugs.

II. BRIEF HISTORY

The legal guidelines and administrative methods relating to IPR have their roots in Europe. The trend of granting patents began within the fourteenth century. In contrast to other nations, in a few subjects England became technologically superior and used to attract artisans from someplace else, on unique terms. The first recognized copyrights appeared in Italy. Venice can be considered the cradle of IP device as maximum felony questioning on this place became completed here; laws and structures had been made here for the primary time inside the world, and other international locations accompanied in due course. Patent act in India is extra than 150 years vintage. The inaugural one is the 1856 Act, which is based at the British patent system and it has furnished the patent term of 14 years followed by numerous acts and amendments.

(A) Types of intellectual houses and their Description

In the beginning, most effective patent, trademarks, and commercial designs have been included as ‘commercial assets’, however now the term ‘intellectual assets’ has a much wider which means. IPR enhances generation development within the following ways:

- it presents a mechanism of coping with infringement, piracy, and unauthorized use
- it affords a pool of facts to the general public given that all forms of IP are posted except in case of trade secrets.

IP safety may be hunted for a spread of highbrow efforts along with

- Patents
- commercial designs relates to features of any form, configuration, floor sample, composition of traces and colors carried out to an editorial whether or not 2-D, e.g., fabric, or 3-D, e.g., toothbrush
- Logos relate to any mark, call, or emblem below which trade is conducted for any

products or services and through which the producer or the carrier issuer is diagnosed. Trademarks can be sold, bought, and certified. Trademark has no existence aside from the goodwill of the products or services it symbolizes

- Copyright relates to expression of ideas in cloth shape and includes literary, musical, dramatic, creative, cinematography work, audio tapes, and pc software program
- Geographical warning signs are symptoms, which identify as proper as originating within the territory of a rustic or a region or locality in that territory wherein a given exceptional, recognition, or different function of the goods is basically as a result of its geographical origin

A patent is provided for an invention, which satisfies the criteria of worldwide novelty, non-obviousness, and business or business application. Patents can be granted for products and strategies. As in keeping with the Indian Patent Act 1970, the term of a patent became 14 years from the date of filing besides for tactics for making ready tablets and food objects for which the time period turned into 7 years from the date of the submitting or 5 years from the date of the patent, whichever is earlier. No product patents were granted for capsules and meals gadgets. A copyright generated in a member us of a of the Berne convention is mechanically protected in all the member countries, with none want for registration. India is a signatory to the Berne conference and has an excellent copyright regulation akin to that of any use. But, the copyright will now not be robotically to be had in countries that are not the members of the Berne convention. Therefore, copyright won't be taken into consideration a territorial proper inside the strict feel. Like another belongings IPR may be transferred, bought, or proficient.

(B) Role of Undisclosed Information in Intellectual Property

Protection of undisclosed facts is least acknowledged to players of IPR and also least pointed out, although it is perhaps the maximum crucial shape of safety for industries, R&D establishments and other agencies coping with IPR. Undisclosed data, generally referred to as alternate secret or personal information, includes components, sample, compilation, programmer, device, technique, method, or technique. Safety of undisclosed records or exchange mystery isn't actually new to humanity; at each stage of development human beings have developed methods to keep important records secret, usually by way of proscribing the expertise to their family participants. Laws relating to all styles of IPR are at extraordinary stages of implementation in India, however there's no separate and special regulation for protective undisclosed information/change mystery or personal facts.

Pressures of globalization or internationalization were not excessive at some stage in Nineteen

Fifties to Nineteen Eighties, and many nations, consisting of India, were able to manipulate without working towards a sturdy device of IPR. Globalization pushed by way of chemical, pharmaceutical, electronic, and IT industries has resulted into massive funding in R&D. This method is characterized by using shortening of product cycle, time and excessive hazard of opposite engineering by using competition. Industries got here to comprehend that change secrets have been not ok to shield an era. It became hard to obtain the blessings of improvements unless uniform legal guidelines and guidelines of patents, trademarks, copyright, and so forth. Existed. That is how IPR became a critical constituent of the world trade employer (WTO).

(C) Rationale of Patent

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

Most countries have established country wide regimes to provide protection to the IPR inside its jurisdiction. besides in the case of copyrights, the protection granted to the inventor/author in a rustic (such as India) or a vicinity (along with European Union) is restrained to that territory where safety is sought and isn't always legitimate in other nations or regions. for instance, a patent granted in India is valid best for India and no longer inside the united states of America. The basic cause for patenting an invention is to make cash via exclusivity, i.e., the inventor or his assignee would have a monopoly if,

1. the inventor has made an critical invention after considering the modifications that the client, and
2. if the patent agent has defined and claimed the invention correctly within the patent specification drafted, then the resultant patent could provide the patent owner an special market.

The patentee can work out his exclusivity either with the aid of marketing the patented invention himself or with the aid of licensing it to a 3rd birthday celebration.

The following might not qualify as patents:

- i. An invention, which is frivolous or which claims whatever apparent or contrary to the properly mounted herbal regulation. An invention, the number one or intended use of which would be contrary to law or morality or injurious to public health
- ii. A discovery, scientific concept, or mathematical method

- iii. a mere discovery of any new property or new use for a acknowledged substance or of the mere use of a known technique, device, or equipment until such regarded procedure effects in a brand new product or employs as a minimum one new reactant
- iv. A substance obtained with the aid of a trifling admixture resulting most effective in the aggregation of the homes of the additives thereof or a method for producing such substance
- v. an insignificant association or re-association or duplication of a acknowledged tool each functioning independently of one another in its personal manner
- vi. a technique of agriculture or horticulture
- vii. Any manner for the medicinal, surgical, curative, prophylactic diagnostic, healing or other treatment of humans or any method for the same remedy of animals to render them freed from sickness or to boom their monetary price or that in their merchandise
- viii. An invention relating to atomic strength
- ix. An invention, that's in impact, is conventional know-how

(D) Rationale of License

A license is an agreement by which the licensor authorizes the licensee to carry out certain activities, which would in any other case had been illegal. For example, in a patent license, the patentee (licensor) authorizes the licensee to exercise described rights over the patent. The effect is to provide to the licensee a right to do what he/she might in any other case be prohibited from doing, i.e., a license makes lawful what in any other case might be illegal.

The licensor may license 'bdd5b54adb3c84011c7516ef3ab47e54' referring to the execution of the licensed patent right which include information, system, or device taking place or applied in a business interest can also be covered together with the patent right in a license settlement. Some examples of bdd5b54adb3c84011c7516ef3ab47e54 are:

- i. technical facts which include formulae, techniques, and running strategies and
- ii. industrial information inclusive of consumer lists and sales information, advertising and marketing, professional and management processes
- iii. certainly, any technical, exchange, industrial, or other records, can be able to being the difficulty of protection.

a. Advantages to the licensor:

- Opens new markets

- Creates new areas for revenue technology
- allows triumph over the challenge of organizing the era in specific markets specifically in foreign international locations – lower costs and hazard and savings on distribution and advertising and marketing costs

b. Advantages to the licensee are:

- Financial savings on R&D and elimination of risks associated with R&D
- Short exploitation of market requirements before the marketplace interest wanes
- Guarantees that merchandise are the contemporary

III. THE ROLE OF PATENT COOPERATION TREATY

The patent cooperation treaty (PCT) is a multilateral treaty entered into force in 1978. via PCT, an inventor of a member united states of America contracting kingdom of PCT can simultaneously reap priority for his/her invention in all or any of the member international locations, without having to record a separate application inside the international locations of hobby, via designating them within the PCT software. All sports related to PCT are coordinated by using the sector highbrow assets company (WIPO) located in Geneva.

On the way to guard invention in other nations, it's far required to file an unbiased patent utility in every use of hobby; in some instances, inside a stipulated time to gain precedence in these nations. This will entail a big investment, within a quick time, to meet fees toward submitting prices, translation, lawyer prices, and many others. In addition, it's far assumed that because of the quick time available for making the choice on whether to record a patent utility in a country or no longer, may not be well based.

Inventors of contracting states of PCT then again can simultaneously acquire priority for their inventions while not having to file separate application within the countries of hobby; for this reason, saving the initial investments in the direction of submitting charges, translation, and so on. In addition, the gadget gives lots longer time for filing patent utility within the member international locations.

The time available below Paris conference for securing priority in other nations is twelve months from the date of initial filing. Under the PCT, the time available will be as a whole lot as minimum 20 and most 31 months. In addition, an inventor is likewise benefited through the hunt document organized underneath the PCT machine to make sure that the claimed invention is novel. The inventor can also opt for initial exam before submitting in different countries to be doubly sure about the patentability of the invention.

IV. MANAGEMENT OF INTELLECTUAL PROPERTY IN PHARMACEUTICAL INDUSTRIES

More than every other technological place, tablets and prescription drugs in shape the description of globalization and need to have a strong IP gadget maximum intently. understanding that the fee of introducing a brand new drug into the market may cost a business enterprise anywhere between \$ 300 million to \$1000 million along with all of the associated dangers on the developmental stage, no company will like to hazard its IP turning into a public assets without good enough returns. Creating, acquiring, shielding, and dealing with IP have to end up a company interest within the identical manner as the raising of sources and finances. The expertise revolution, which we are certain to witness, will call for a special pedestal for IP and remedy in the typical selection-making process.

Opposition within the global pharmaceutical industry is driven with the aid of scientific know-how rather than manufacturing bdd5b54adb3c84011c7516ef3ab47e54 and a company's fulfillment may be in large part dependent on its R&D efforts. Therefore, investments in R&D in the drug industry are very excessive as a percentage of general income; reports propose that it is able to be as an awful lot as 15% of the sale. One of the key troubles on this enterprise is the management of revolutionary dangers whilst one strives to benefit a competitive advantage over rival companies. There may be excessive value attached to the hazard of failure in pharmaceutical R&D with the development of ability drugs that are not able to meet the stringent safety requirements, being terminated, once in a while after many years of funding. For the ones drugs that do clear improvement hurdles, it takes approximately eight-10 years from the date when the compound turned into first synthesized. As product patents emerge as the primary tools for protecting IP, the drug agencies will need to shift their focus of R&D from improvement of recent methods for producing recognized capsules toward improvement of a brand new drug molecule and new chemical entity (NCE). All through the Eighties, after a length of efficaciously treating many sicknesses of quick-term length, the R&D consciousness shifted to long period (chronic) sicknesses. Even as searching out the global market, one has to make certain that necessities extraordinary regulatory authorities must be glad.

Its miles understood that the files to be submitted to regulatory government have nearly tripled within the remaining ten years. Similarly, regulatory authorities now take an awful lot longer to approve a new drug. Therefore, the duration of patent safety is reduced, ensuing in the need of putting in more efforts to earn sufficient income. The scenario may be greater severe inside the case of medicine advanced through the biotechnology course particularly the ones regarding

utilization of genes. It is more probable that the industrialized world could soon begin canvassing for longer safety for capsules. It is also feasible that many governments would work out increasingly rate control to fulfill public desires. This would on one hand emphasize the want for decreased price of drug development, manufacturing, and advertising, and understanding, necessitate planning for lower income margins so that you can get better charges over an extended period. It is therefore apparent that the drug enterprise has to wade through many conflicting necessities. Many specific strategies have been evolved during the last 10 to 15 years for value containment and exchange benefit. Some of those are out sourcing of R&D activity, forming R&D partnerships and establishing strategic alliances.

(A) Nature of Pharmaceutical Industry

The race to liberate the secrets and techniques of human genome has produced an explosion of scientific understanding and spurred the development of recent technologies that are changing the economics of drug improvement. Biopharmaceuticals are likely to reveal in a special location and the ultimate intention could be to have customized drugs, as everybody could have their own genome mapped and stored in a chip. Docs will take a look at the data in the chip(s) and prescribe for that reason. The vital IP problem associated would be the protection of such databases of private data. Biotechnologically evolved tablets will locate more and more access into the market. The safety manner for such drug can be a little unique from those conventional capsules, which are not biotechnologically developed. Microbial traces used for developing a drug or vaccine wishes to be special within the patent document. If the strain is already known and suggested in the literature normally consulted through scientists, then the scenario is simple. However, many new lines are determined and advanced continuously and those are deposited with international depository government below the Budapest Treaty. While doing a novelty search, the databases of those depositories must additionally be consulted. Organizations do not normally cross for publishing their paintings, but it is ideal to make it a practice no longer to disclose the discovery thru courses or seminars until a patent application has been filed.

Whilst coping with microbiological innovations, it's more crucial to deposit the strain in one of the diagnosed depositories who could give a registration quantity to the strain which should be quoted inside the patent specification. This obviates the need of describing a life form on paper. Depositing a strain also costs money, however this isn't always a good deal if one isn't always coping with, for instance cell traces. Further, for innovations regarding genes, gene expression, DNA, and RNA, the sequences also have to be described within the patent specification as has been seen in the beyond. The alliances may be for plenty special goals along with for sharing R&D understanding and centers, using advertising networks and sharing production facilities.

whilst moving into an R&D alliance, it's miles continually beneficial to enter right into a formal settlement masking problems like possession of IP in one-of-a-kind nations, sharing of costs of obtaining and keeping IP and sales accruing from it, strategies of keeping trade secrets and techniques, accounting for IP of each organization before the alliance and IP created throughout the challenge but now not addressed inside the plan, dispute settlements. It need to be remembered that an alliance might be favorable if the IP portfolio is more potent than that of involved accomplice. There will be many different factors of this settlement. Many drug groups will soon use the offerings of academic institutions, personal R&D organizations, R&D institutions underneath authorities in India and abroad by means of way of contract research. All the above elements referred to above will be beneficial. Special attention will have to be paid toward keeping confidentiality of studies.

The current state of the pharmaceutical enterprise suggests that IPR are being unjustifiably reinforced and abused at the expense of competition and consumer welfare. The shortage of chance and innovation at the part of the drug industry underscores the inequity that is taking place on the price of public right. Its miles an unfairness that cannot be cured by legislative reform alone. even as congressional efforts to shut loopholes in modern statutes, at the side of new rules to curtail additionally negative business practices of the pharmaceutical industry, may provide some mitigation, antitrust regulation ought to as it should be step in. whilst antitrust laws have correctly scrutinized positive business practices hired with the aid of the pharmaceutical industry, such as mergers and acquisitions and agreements not to compete, there are several different practices that need to be addressed. The furnish of patents on minor elements of an antique drug, reformulations of vintage tablets to comfy new patents, and using advertising and logo call development to increase the obstacles for frequent market entrants are all regions wherein antitrust law can assist stabilize the balance between profitable innovation and keeping opposition.

Conventional medication dealing with natural botanical products is an important a part of human fitness care in lots of growing international locations and also in developed countries, growing their commercial fee. The sector marketplace for such drug treatments has reached US \$ 60 billion, with annual growth fees of between five% and 15%. Even though in basic terms traditional know-how primarily based medicines do now not qualify for patent, human beings regularly claim so. Researchers or companies may also declare IPR over biological resources and/or conventional information, after slightly editing them. The short increase of patent applications associated with natural medicinal drug indicates this fashion virtually. The patent packages within the discipline of herbal products, traditional natural medicinal drug and natural

medicinal merchandise are treated personal IPR regulations of each country as food, pharmaceutical and cosmetics purview, whichever suitable. Medicinal vegetation and associated plant products are crucial objectives of patent claims due to the fact they have end up of notable hobby to the worldwide organized natural drug and cosmetic industries.

(B) Some Special Aspects of Drug Patent Specification

Writing patent specification is an incredibly expert skill, which is obtained over a time frame and wishes an excellent combination of scientific, technological, and felony expertise. Claims in any patent specification constitute the soul of the patent over which criminal proprietary is sought. Discovery of a new assets in an acknowledged material isn't always patentable. If you can put the belongings to a practical use one has made an invention which can be patentable. A discovery that a recognized substance is capable of withstand mechanical surprise could no longer be patentable however a railway sleeper made from the cloth may want to well be patented. A substance might not be new but has been discovered to have a new assets. It can be feasible to patent it in combination with a few different regarded materials if in combination they showcase some new result. The reason is that nobody has in advance used that mixture for generating an insecticide or fertilizer or drug. Its miles quite possible that an inventor has created a brand new molecule but its particular structure isn't regarded. In one of these case, description of the substance at the side of its properties and the approach of manufacturing the same will play a crucial role.

Combination of recognized substances into beneficial merchandise can be a subject rely of a patent if the materials have some working relationship whilst blended together. In this case, no chemical reaction takes area. It confers most effective a confined safety. Any use through others of man or woman components of the aggregate is beyond the scope of the patent. as an instance, a patent on aqua regain will no longer limit anyone from blending the two acids in distinct proportions and obtaining new patents. Strategies of remedy for human beings and animals are not patentable in most of the international locations (one exception is u.s.) as they are now not considered capable of business application. In case of new pharmaceutical use of a known substance, one must be careful in writing claims because the declare must no longer supply an impression of a technique of treatment. Most of the applications relate to tablets and prescription drugs which includes natural capsules. A limited wide variety of packages relate to engineering, electronics, and chemicals. About 62% of the programs are related to pills and pharmaceuticals.

V. CONCLUSIONS

It is obvious that control of IP and IPR is a multidimensional assignment and calls for many

unique movements and strategies which need to be aligned with national laws and global treaties and practices. It is no longer driven basically by a national angle. IP and its related rights are severely influenced by using the market needs, market reaction, value worried in translating IP into business challenge and so forth. In other words, alternate and commerce concerns are important in the management of IPR. Specific forms of IPR call for special remedy, handling, planning, and techniques and engagement of humans with distinctive area know-how including technology, engineering, drug treatments, regulation, finance, advertising and marketing, and economics. Every enterprise have to evolve its personal IP regulations, control fashion, techniques, and so forth. Depending on its location of distinctiveness. Pharmaceutical industry currently has an evolving IP method. because there exists the elevated opportunity that some IPR are invalid, antitrust regulation, consequently, needs to step in to make sure that invalid rights aren't being unlawfully asserted to set up and preserve illegitimate, albeit limited, monopolies in the pharmaceutical enterprise. Nonetheless many things remain to be resolved in this context.

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