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Intellectual Property Right (IPR) And Patent in Pharmaceuticals Industry in India

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Abstract

Patent is granting property right by the authority to the inventor. This grant provides the inventors exclusively right to the patent process. Design or inventions for a particular period especially in the pharmaceutical industry. Government agencies typically handle and approve the patent. In the United States the US patent and trademark office, which is the part of the department of commerce, handles the applications and grants the approval. Similarly in India the patents are controlled by the registrar of the patent department under the control of the central government. The pharmaceutical sector in India is a prosperous, high-tech sector that has grown steadily during the previous thirty years. Due to favourable government policies and little rivalry from overseas, an array of privately held Indian enterprises has seized a significant share of the domestic pharmaceuticals the marketplace, making them the contemporary industry players. However, when Indian businesses start expanding behind domestic markets and prepared for global competitiveness, the liberalization that has impacted the Indian economy continues to impact them.

India, an important player in the worldwide pharmaceutical sector, must strike an appropriate compromise between meeting the urgent demand for affordable pharmaceuticals and encouraging development by means of intellectual property protection. The study analyses the influence on the public's health, investigates important legislative structures, and digs into the lengthy history of pharmaceuticals patented in India. This essay seeks to add to the continuous conversation on finding an equilibrium between innovation and affordability in the drug sector by looking at case studies, global viewpoints, and viable solutions.

Key words: - IPR (intellectual property right), WTO (world trade organisation), TRIPS, Patent filling, Property, Pharmaceutical products, Protection.

Abbreviations

IPR – Intellectual Property Right

WTO – World Trade Organisation

TRIPS – Trade related aspect of Intellectual Property Right

MNC – Multinational Company

GATT – General Agreement on Tariffs and Trade

R & D – Research and Development

Introduction

A vital component of the international healthcare system, pharmaceutical patenting affects the harmony between encouraging innovation and guaranteeing the public's access to necessary medications. In India, where the pharmaceutical business is flourishing, this delicate balance is especially important. The complex relationship among intellectual property rights & healthcare is the main emphasis of this article's examination of the numerous problems concerning pharmaceutical patented in India.

Any material or immaterial item owned by an individual, a group of individuals, or a business, such as a corporation, is considered property. The owner of the property may devour, offer for sale, obtaining a license mortgage, exchange, trade in goods, or eliminate it, or they may be able to prevent others from doing so, contingent upon the type of ownership. Physical or physical assets, individual assets, private assets, governmental property, and intellectual or intangible resources are all generally accepted categories of assets, though the latter one is not necessarily as widely recognized.

A patent gives the grantee (Patentee) the sole right to manufacture, market, and use the idea for which it has been released, as well as the right to permit others authority to do so, for a specified period. A particular sort of personal property is a patent. Unless they obtain the patent holder's express consent, the holder of the patent has the authority to keep anyone from manufacturing, importation, trading, or promoting for trade the product covered by the patent. Through licensing agreements or the direct sale of the patent, the proprietor of the patent can delegate this right to other organizations. The intent of patent is safeguarding creative thinkers. It grants the patent holder the authority to forbid others from producing, utilizing, importing, or distributing their creations.

In the past few years, the Indian pharmaceutical industry has expanded extremely quickly. In India, we have seen numerous lawsuits and significant rulings. Following independence, the government appointed two committees to make some practical adjustments to India's pre-existing patent rules due to the lack of access to or availability of crucial life-saving medications. A new patent act of 1970 was subsequently introduced because of the recommendations. It only addressed pharmaceutical process patents. These procedure patents were only valid for seven years. Indian pharmaceutical companies were very excited by this new rule and began manufacturing generic versions of pricey imported medications. As a result, Indian businesses became proficient at "reverse-engineering." They began creating new medications, which benefited the Indian pharmaceutical industry. The Indian pharmaceutical industry's share increased from 15% to about 18%. It enabled India to become self-sufficient in the production of pharmaceuticals and to export active components in quantity. India rose to become a net exporter of pharmaceuticals, ranking third in terms of volume and fourteenth in terms of values.

Literature review

1. Ajay Prakash et al. (2018) - The rights granted to the inventors of intellectual property, or works of art, are known as intellectual property rights (IPRs). These rights grant the creators exclusive use of the product or property for a predetermined amount of time. IPR can be broadly divided into two categories, according to the World Trade Organization (WTO): industry property and copyright.
2. S Bhattacharya et al. (2011) - The public's desire to grant property status to ideas, innovations, and creative expressions is the basis for intellectual property rights, or IPR. IPR gives the property's founders or inventors specific exclusive rights so they can profit commercially from their reputation or creative endeavours. Intellectual property protection comes in a variety of forms, including trademark, copyright, and patent. An innovation that meets the requirements of worldwide uniqueness, non-obviousness, and industrial use is recognized by a patent.
3. T Bazzle et al. (2010) - We investigate the connection between innovation and Trade Related Intellectual Property rights (TRIPS). This study uses export data to evaluate the relative effect of TRIPs on innovation, specifically the capacity of the Indian pharmaceutical sector to introduce new or old medications into new markets. It looks at whether India's choice to abide by TRIPS affected its innovation and creates a theoretical

model in which factors like demand and trade circumstances affect innovation, which is assessed by the possibility of exporting a single product from one designated country to partner countries.

4. R Basant et al. (2011) - Considering the TRIPS-mandated reforms to IP policy, some aspects of India's new IP framework have been the subject of intense discussion in recent years. Numerous arguments have been used to support or refute these aspects due to the intricate relationship between IP regimes and economic development. The article makes the case that an assessment of the intellectual property regime and regulations in developing nations must be conducted in light of how they support the development of capabilities, particularly through the involvement of local businesses in international scientific and technological systems.
5. K Satyanarayana et al (2007) - In India, specific laws passed by the Parliament address the many aspects of intellectual property rights. These laws function under the Indian Constitution's broad provision of the right to own property. The article addresses issues pertaining to how these rights intersect in real-world situations.
6. A Mehta et al. (2024) - This study looks at how the pharmaceutical patent system affects access to medications, specifically in light of the TRIPS Agreement and the Indian Patent Act of 1970. By safeguarding patent holders and enabling nations to protect public health, the TRIPS Agreement seeks to strike a balance between private and public interests. This balance has been controversial, though, particularly in developing nations where patent protections can result in exorbitant medicine costs and limited access to life-saving drugs.
7. J Sundaram et al. (2014) - The Patent (Amendment) Act 2005, which complied with the Trade-related Aspects of Intellectual Property Rights (TRIPS), changed India's legislation from a process patent regime to a product patent regime. India's generic medication manufacturing industry, which was established under the 1970 Act's process patent structure, has been directly impacted by the modifications. Since many developing nations have become heavily dependent on Indian generics, the ripple effect will soon be seen both domestically and internationally.

8. PD Krishna et al. (2022) - Concepts and creations—particularly artistic endeavours—about which the community is willing to grant the position of ownership are sometimes referred to as intellectual property rights, or IPR. Intellectual property protection comes in many forms, including trademarks, copyright, patents, and more. An innovation that satisfies the requirements of global originality, non-obviousness, and commercial utility is acknowledged with a patent. For better identification, organization, marketing, and rendering—and hence for overseeing innovation or creation—it is necessary.

Importance of IPR

1. **It provides patent protection of drugs -** a patent provides drugs after it has been discovered and developed for the minimum period of 20 years. The capacity of a drug is possible with the help of reverse engineering and the competitor companies can create and develop the molecules. The IPR/ patent right provides power to the company to stop the competitors to reproduce the brand.
2. **Progressive economic growth -** IPR contributes the economic growth of the company as well as the nation, as a patent coverage providing the inventors company the benefits of monopoly. This gives additional economical advantage not only the company it provides the biggest boost to the countries.
3. **consumer protection-** the primary issue is the public safety and the IPR helps to protect the public interest when a patent is granted the safety and quality of drug is guaranteed. The inventors are the owner of the molecules and must prove the highest quality of drug before getting the patent that's why it helps in consumer protection.
4. **Safeguard against infringement-** the pharmaceutical industry is taking sea action against fraudulent pharmaceutical companies. It is possible only because of IPR. this right assists the government in the legal system as well as the inventor’s pharmaceutical company to initiate action against fake manufacturers or who are promoting marketing fake molecules in the market. In other words, the patent owner is given the full right to take necessary legal action against fake manufacturers.

5. **Time period: -** the inventory company of the molecules will be given a long period of 20 years to promote the product and to earn the profit. During these 20 years without the permission of the inventor the competitors are banned to promote similar molecules. Further the manufacturer also gave the right to use the medicine in different forms as well as different indications.

Role of IPR in business management

1. **Introduction -** the patent resume plays a vital role in the business management in the nation and multinational companies out of the cutthroat competition. Almost every company special in the pharma business has similar products in such scenarios the importance of patent as a big role to play. In the patent circumstances most of the product patents are expiring. Creating confusion in the pharmaceutical business the following parameters have an important role of having IPR in the pharmaceutical business.
2. **Securing competitive advantages:** - Company like Pfizer having around 8-10 patents given the extra boost to their overall sales. So, company securing their products from competitors to enhance their production and enhance profit.
3. **Enhancing brand value and recognition-** the companies like Johnson & Johnson, Sandoz, Russell, M.S.D. these all-Multinational company from US & Germany their companies are having maximum patent in the international market. These company are highly respected and regarded between the medical profession and physician used to prescribe some are other products from these company. Because of the good no. Of patent these non- essential drugs also start making in the market. Market of these companies introduce along with patent product antienzymes, protein, multivitamin, minerals products in the market as the medical science produce have not come under the category of essential drugs.
4. **Driving innovation and investment -** once the big MNC have been granted the patent the product is successful in the market in such condition the company is having a liberty to have for innovation. Example - Nimesulide launch essentially the molecule was promoted to the patent about 12 years. The company having good no of patent can generate lots of investment from the stakeholders. The company get number of financial partners which helps the company expand they're in the norms of state and countries.
5. **Creating revenue -** Another role of patent is generating revenue and profit. The leading top 10 pharmaceutical companies of the world is having around 70% of the patent. It indicates this companies out of their product patent generating huge revenue and profitability.
6. **Expanding new market –** Another important aspect of IPR in pharma industry is the expansion of the market the company like Johnson & Johnson, Pfizer, Glaxo are having their market operations in every part of the world. This are having good number of patent product at company having no of IPR it becomes easy process of them to promote a market licence and production licence in any country of the world. This create the market expansion is become very comfortable for the companies having greatest no patented product.
7. **Conduct IP Audits** - Every company dealing with pharmaceutical products must go for their production audit and sales audit this department under the control of central government agencies. It means the manufacturer must provide detail to the government agencies regarding their purchase of raw material, complete production of product their market strategy, total sales and what is the % of profitability. But if the company are having good number of patented products, they will be given benefits from regular assist of the company this will add number advantages for the organisation.
8. **File for protection -** Company is having no of patented product having a benefit internationally in all the market to file the protection against the fake drugs for the local company and the government are instructed to take a immediate action against the suspicious company.
9. **Employment satisfaction-** This has been observed a company is having good number of patented products because of quality of production, quality of product, quality marketing which led to more sales and more profit for the organisation. In such situations all the employees of the organisation are better paid, serving

under better work norms with generate employee satisfaction and their employees or committed for the organisation and other ready to serve organisation with fullest commitment.

Elements of national patent application

Indian patent: - All patent application must contain general detail with include applicant name, address and information provide to agent acting on behalf of the applicant as well as the technical information regarding the patents. Technical information consists of patent specification the mode of action. In short, the patent application will have the following elements.

1. **Patent title: -** Provide detailed information in the application name, assigned to your patented invention for examples- in the case of pharmaceuticals patent the new name of the molecules will be the patent title. If the company is introducing 6th and 7th generation antibiotic the molecule name must be mentioned as a patent title.
2. **Field of invention: -** Important element in the national patent is patent filling must mention the field of invention, like in the case of pharmaceutical industry their name of field should be pharmaceutical or healthcare system. In the case of technology related patent where a new device in the field of healthcare is applied for patent the detail must be given.
3. **Background of invention:** - Background of invention should be mentioned in the application in nutshell if pharma company is trying to get patent for their arithmetic range, the company must provide detail about, how many no. of patients, what are the effects, side effects, and contraindication of product which include the background of the product, life style of the patient, generic order of the family of patients, blood group of the patients.
4. **Statement of invention: -** Under this category it is important to mention what is the usage of the product to the society, how your product will serve the society. In pharmaceutical industry how your product is effective, how it can cure diseases, how the patients will be benefited.
5. **Drawing: -** The drawing is the one of the important factors in the patent application. The patent applier must give accurately describe drawing regarding the invention.in pharma industry the drawing means consist of various factor like- how the medicine act in the site of injection, the line diagram must be attached with the application, and how the medicine mix with blood and what is the rate if excretion.
6. **Abstract: -** Complete abstract regarding the product must be submitted to the concern patent office, the abstract must consist of: -
   - Why the product is introduced
   - The product is manufacturing for what kind of disease
   - How the product act
   - What is the cell life or half-life of the product
   - Possible side effects
   - Contraindications
   - What is the prescribed schedule of the product
   - Detail must be given in the space provided for abstract.
7. **Description: -** Description means complete explanation regarding the molecule's operational principle, depending how product manufactured, what kind of specific technology used in the process of manufacturing, what are the various process of technology, whether the manufacturing technology. As per the Indian law the description plays the important role in many of the patent application filling.
8. **Patent claims: -** It is one of the important sections in patent application the patent claims will consist of the use of the molecules is effective.
   - Name of the disease
   - The success of cure rate in %
   - The side effect of the product with %

- Route of application of molecule or product
- Contraindication to the product
- Detail about milligram applied for patient in the case of capsule or tablets like 100ml, 500ml, 1000ml in the case of injection intramolecular or intravenous and the route of medication oral, vein, muscles or anal etc.

Patent life cycle management

A patent is a legal right provider for the investor for the inventions that must be unique, utility and must have some kind of different features while registering a patent it has the following life cycle of a patent.

1. Ideation
2. Patent search
3. Patent filling
4. Patent examination
5. Patent grant

1. **Ideation: -** Ideation is the 1st stage in patent lifecycle where the idea is generated through technical workshop or brainstorming session. Idea is a part of initial research. If patent is registered by a single person under ideation focus will collect opinion from the experts.
2. **Patent search: -** Under this stage it is important to check patentability of the product weather the product has been selected in the stage of ideation is suitable for patent or not.
   - Is my idea unique
   - Is my product unique
   - Is my invention worth filling the application and
   - What is the scope of getting patents
3. **Patent filling: -** It is an important phase in the life cycle management is the patent filling process which help the application to secure the right of an invention.

Provision application: - provision application that does neither required any specific application format nor complete specification and information. It can be file if a inventor does not have neither very specific information about the product but the person is confident of getting the patent. In such condition one can fill up the provision application.

While filling the provisional application what must five are given the following information: -

- Title of invention
- Abstract
- Reference regarding the product
- Background of the product
- Summary about the product
- Summary about the description of product
- Claims

4. **Patent examination: -** file patent application will be the published 18 month after the date of filling till that it will be kept at confidential by the patent officers. Once the examination is cleared and if the product patent satisfies the criteria of product patentability the officer of patent will do prepare for the exam of patents. It consists of 6–8-member board.
5. Patent grant: - final step in the patent life cycle management process over the patent get granted the application has to wait for minimum period of 60 days, the patent authority will publish some details of patent in various magazine or publications to see any protest, any claims will arise from any party. Once 60 days over the patent will be granted to the inventor as per the norms of life cycle of patent is 20 years it means for this 20 year there is no competitors will copy the brand.

Pharmaceutical patents and the world trade organization's effect

WTO was established in 1995 by replacing GATE (general agreement on trade and tariff) in 1948 with 23 countries as a member to serve as a multinational trade agreement by giving a fair chance to conduct the business among the member countries. In addition, it mission is to increase stock and trade services to assure maximum trading of pharmaceutical products of world resources and to preserve the environment.

The WTO deals include trade in commodities as well as services to promote international trade which can be bilateral or multilateral though the elimination of entering country taxation as well as on tariffs obstacles and implementing greater Market place access to all the members nation. As an influencing member of WTO India is at the lead of building fair global laws and to improve global market by expanding India companies at global level.

Indian pharmaceutical giants like sun Pharma, mankind, torrent, Cipla, lupin they improved their business volume after 1995 when WTO was established. India has fulfilled its promise towards liberation of trade made by WTO and following WTO norms.

Objectives of WTO

- To set rules for international trade and to convince all the members countries to follow the objectives.
- To present a panel for negotiating and controlling additional trade liberalisation. It means the WTO continuously works to create favourable conditions for liberal trade.
- To solve all types of trade conflicts between the member countries.
- To improve the clarity of business and to provide decision making power to all its member countries.

India is thereby required to meet the minimum standards under the TRIPS Agreement in relation to patents and the pharmaceutical industry. India's patent legislation must now include provisions for availability of patents for both pharmaceutical products and processes inventions. Patents are to be granted for a minimum term of 20 years to any invention of a pharmaceutical product or process that fulfils established criteria.

To comply with the TRIPS Agreement, the statutory licensing requirements under Indian law need to be restricted and contingent. The government of India will only give those licenses based on the merits of every instance after providing the owner of the patent with a hearing. In addition, in the case of process patents, the responsibility of proof will fall on the party performing the infringement, and there will absolutely no distinction made between local and imported goods. India has chosen to take advantage of the entire transition time for developing nations, and it has until January 1, 2005, to give pharmaceutical goods patent protection. India has begun the process of enhancing the Patents Act in accordance with the TRIPS commitments by granting exclusive marketing rights (EMRs) and establishing up a mailbox system for applications for patents for a duration of five years, or until the patent is issued or denied, whichever comes first.

TRIPS agreement

TRIPS (Trade Related Aspects of Intellectual Property Rights) a significant international agreement administered by the WTO (World Trade Organisation). TRIPS agreement came into effect on January 1, 1995, and provides an insight about IPR on the platform of WTO. TRIPS agreement covers various forms of IP, including copyright, trademark, patent, industrial design, geographical indication and trade secrets. TRIPS is an international legal agreement between all the member nations of WTO.

Major Features

1. Gender provision and basic principle was introduced in the article 1-8 which confirms the slope and application of IPR must be uniform and equal to all the nations.
2. TRIPS also covers number of act resolution to solve the conflicts regarding the IPR among the member countries.
3. IPR is applicable in all types of industries individual dealing with product, design, art.
4. Agreement deals with all kinds of commercial and non-commercial product services.

5. TRIPS agreement is applicable to all the 164 nations who are part of TRIPS agreement as well as the member of WTO.

Objectives

- To faster the technical innovation.
- To facilitate transfer and distribution of technology.
- Promote innovation and creativity.
- Global IP laws.
- Balance IP rights and public interest.
- Protect IP rights fairly and transparently.
- Promote trade and economic growth.

Key Features

- Standards
- Enforcement
- Dispute settlement
- Protection of geographical indication
- Encouragement of technology transfer
- Coverage of IP rights
  a. Copyright
  b. patent
  c. trademark
  d. layout design
  e. industrial design
  f. geographical indication

Doha deceleration and significance for Indian pharmaceutical industry.

The Doha agreement is declaration which held on Doha on 14-09-2001. Doha deceleration has proved the WTO is the only interactive institute that oversees the global trade rules in between various nation. The multilateral trading system was discussed in the meeting especially in pharmaceutical export & import with member countries during this Doha meeting there where 146 countries are registered as the members. The Doha deceleration refers to the Doha deceleration on the trade related aspects for IPR (TRIPS) and public health.

1. Multilateral trading system - WTO has contributed significantly to economic growth development and employment generation in all the members country in future with special reference in the pharmaceutical business.
2. The international trade can play a major role in the promotion of economic development in the third world country and the obligation of poverty along with it will bring back health of all majority of WTO members and form developing countries the bilateral agreement as per the WTO norms will enhance the market access by rules and will target sustainability finance, technical assistance, capacity building program. where declare to promote the pharmaceutical industries in the WTO members and most of the members are from developing countries to allow export and import of product among the countries to make availability of medicines to improve the life especially of population in the country.
3. Further the Doha conference also suggested to improve the business or trade especially in pharmaceutical industry from developing countries to the least developing countries with special taxation systems for export and import to least developing countries. The country also suggested we are most committed to organised and least

develop countries specific into trade to improve their countries by third world countries like India, China, Korea, Japan etc.

4. During the 4th sessions of Doha meeting the World Trade organisation also prepared several policies regarding global trade and liberalisation. There were sudden major points discussing regional trade agreements It means creating a small association of neighbouring countries and keeping them or giving them a platform for export and import to expand that trade.

5. In the rapidly changing international environment there is an urgent need to deal licence various product to promote global businesses because licensing is a major hurdle in expanding the business in very countries the licences system especially global trade export import is a big hurdle in international businesses. The conference highly recognises those licensing problems and improves. The Government of concern countries must create economic policy that should align with the global economic policy with the help in the global trade.

6. The forum also discusses various objectives of sustainable development, how the procedure of development must uniform to all the countries which comes under developing and under develop Nation.

7. Committee also discuss to make the availability of life saving medicines to all the member countries of World Trade organisation.

8. The committee also discusses medicines for diabetic, hypertension, anti-cancer must be available to the under develop countries by the third world countries India also give the responsibilities to expand their pharmaceutical businesses to various parts of under development Nation. The Doha meeting also create a work program to implement the policy which has been discuss and at the same time to provide solution to the problem in implementation so the major discussion of Doha conference to following topics and they are-

- Pharmaceutical related matter
- agriculture related matter
- service sector related discussion
- primary on healthcare banking insurance and education
- market access for agriculture products related aspects of IPR discussions also conducted on relationship between trade and investments.
- Meeting also conducted regarding trade and competition policy. transparency of trade between nations.
- discuss the dispute settlement between member countries involve in the trade transactions.
- To improve an environment of trade. For example, by relaxing the regulation, by relaxing of taxation policy, by relaxing the licensing policy.
- Apart from Pharma agriculture the other important topic was electronic and commerce.
- Small economic or small countries where per capita income was very low how to involve them in international trade this point has been discussed.
- WTO rules also relaxed especially in case of export and import and procurement of raw materials.

Patent mapping

Patent mapping is the method of visualising the patent data and graphics with the help of software. Patent mapping is based on data which are collected during the time of the research that's why research procedure is authentic and approved by the authority. Ex- especially in the case of pharmaceutical patent the patent mapping can be done by following methods -

1. Mode of action - the mode of action of a molecule it should be preserved in the form of visual effects like how the molecules Move in the body where the molecules release its substance. The point the molecules substance mixes with blood, visual must carry complete detail about the visual effects of mode of action of the molecules.

2. Contraindications - through visual effects it is important for patent mapping why the molecules lead to contraindications consumed with some other product in other words the visual graphic must prove the reason of contraindications with visual effects.
3. Side effects of the molecules- through the side effects are not common in all the patient, the side effects may be occurring among the few people but to secure patent it is important to demonstrate visually, reason for side effects or may be skin rashes, allergies, weight gain, nausea, vomiting, loss of appetite, hair fall, blood vision etc.
4. Dosage schedule - in most of the cause the dosage schedule is decided by the body weight of the individual, this must prove visually the authentication for a particular dosage schedule.
5. Trail phase - there must be a visual process of visual trail research specially in the final stage when the drugs are being used in the human body.

Research scope

Since the modified Indian Patents Act offers certain protections against the misuse of patent and monopoly rights, Indian pharmaceutical enterprises have the chance to thrive under the goods patent framework. It was found that several respondents' answers contained ambiguity due to the technical nature of the survey responses which somewhat impacted the study's findings. The study has primarily focused on pharmaceutical businesses with their registered offices located in Mumbai alone. Many multinational pharmaceutical corporations have their patent departments located outside of India, making it impossible to obtain adequate data from different organizations.

The future of the Indian pharmaceutical industry and patents

Numerous international companies have restricted their portfolios to either a small number of patented items or products that have lapsed due to the lack of patent protection for products for pharmaceuticals and agrochemicals. As a result, their market share declined as local producers used reverse engineering to introduce the most cutting-edge medications. Although Indian companies could benefit from patent protection for their goods to support research into creating low-cost pharmaceuticals that fit the Indian ailment profile, foreign companies had a responsibility to pay royalties for foreign products.

The existing patent application will be eligible for a patent on a product when India amends its patent laws to comply with WTO recommendations. If the paperwork is considered suitable, the person submitting it will be awarded EMRs in India for a duration of 5 years, or until such patent gets issued or rejected, whichever is shorter. The provision that forbade Indian inventors from obtaining the most recent molecules from throughout the globe and reorganizing them for the purpose of sale in their own country is also removed from the modified Patents Act, which also provides for mandatory licensing for the EMR along the same principles as patents. As a result, patent protections for pharmaceutical goods in India were systematically weakened, and numerous multinational pharmaceutical companies that relied on development left the country.

India's prosperous bulk and formulation-focused pharmaceutical sector will be greatly affected by the duties placed on it by the TRIPS Agreement. To remain competitive with the international corporations, Indian businesses must concentrate on medicine discovery and create their own unique goods. As an alternative, Indian businesses might concentrate on making proprietary pharmaceuticals under license from foreign companies or make revenue by making medicines that are generic.

For Indian pharmaceutical companies, increasing R&D spending exponentially is essential to their existence. To support research into creating affordable medications that fit the disease profile of India, Indian businesses want commercial protection through patents.

Conclusion

In the pharmaceutical industry, patents are the mainstay of innovation protection. It is impossible to overstate how crucial patent protection is. Patents are appropriately referred to as "currency of research" since the revenue that an organization receives from them can be utilized to fund other R&D initiatives. Acquiring medication patents is crucial for long-term innovative drug development and research, even though it may appear like a "money taking" tactic. Even though the pharmaceutical industry produces many patent applications, there has been very little clinical translation of these requests. It makes explanation that the generic market currently dominates most of the Indian pharmaceutical sector, with inventiveness contributing very little to its growth. Segregated work in each discipline, improper multidisciplinary collaboration between experimental and clinical trials scientists, insufficient resources, diverse interests of the concerned industries, a lack of structured workforce training, and a lack of leadership seem to be the primary root causes of this. In this sense, industry-academia interaction and the creation of quality control agencies can be advantageous.

Since the pharmaceutical industry is a knowledge-intensive sector, as it already exists, this will hinder its expansion. Large sums of money are needed to put into R&D and later phases to create more advanced medications. However, having adequate protections is also crucial to ensuring that every individual in a nation has simple availability of medications.

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