PATENTABILITY OF MEDICAL "PROS" - PRODUCT V PROCESS

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ABSTRACT

A patentee needs a legal instrument called a patent to prevent others from producing, utilising, selling, or offering for sale their "claims." Medical patents shall be defined as medications, methods of making and using them, medical treatment regimens, surgical procedures, medical equipment, and health care IT for hospital and health care administration systems for the purposes of this article. The problem of promoting medical research while keeping medical treatments cheap has yet to be overcome. The first thing this study does is look at the benefits of medical patentability. After that, it looks at how patents affect medical research and how the pharmaceutical industry's shift from process patent to product patent following the Patent Amendment Act of 2005 affects medical research and health-care access.

Keywords: Patent, Product patent, Process patent, Pharmaceutical industry, TRIPS

INTRODUCTION

If you're unfamiliar with the definition of patent, think of it as a government-granted statutory privilege given to inventors and others who assert their rights against the inventor for a set period a period of time in order to deter others from doing so from making, using, or selling patent-protected products or method. As a conclusion, a patent may cover both a technique and a product. Patent regimes for goods and methods differ considerably. The developed nations have a product patent system in place. The developing world, on the other hand, prefers the system of process patents. The two regimes differ in the degree of protection they provide for innovators[i].

A process patent protects a particular manufacturing method rather than a finished product. The identical product can be made by anybody else using a different PROCESS and altering numerous parameters. This point outs that there will be several manufacturers of the similar product due to the potential of using a different production technique to create it. Weakness of process patent regime: inventors are less protected under this system. Competitors often reengineer the original innovation by finding a new process that requires less effort and money. Using process patents has the advantage of lessening monopolistic power[ii].

A product patent gives the original creator of a product exclusive legal rights. This implies that the product can only be produced by the original producer using the same or a similar technique[iii]. As the product is protected by a patent, there will be no one to compete with the manufacturers. A product patent system protects the creator better since no one else will be granted a similar patent. TRIPs are in line with the patent-based system.

Before it was revised in 2005 to conform with WTO TRIPs requirements, India's 1970 Patent Act exclusively permitted patents for processes[iv].

Statement of Problem

1. After the implementation of TRIPs, India's sole option for manufacturing certain medicines is through compulsory licensing.
2. Patentability in medicines and chemicals is based on creative genius, novelty, and the presence of industrial use or economic importance of the new product or method, as demonstrated by the Patents Act modifications.

Research Questions

1. Should Intellectual Property Rights (IPR) be enforced?
2. What sector exists to alleviate poor and needy health issues, therefore providing inexpensive medications for the majority?

Hypothesis

Consumers and the public in general will gain greatly if incentives are provided to encourage extra research into this area since monopoly rights encourage corporations that make drugs to make big and risky expenditures in R&D. because of the numerous advantages of patenting medical inventions.

Research Objective

1. To Identify the Pros of Patentability in Medical and Parma Sector
2. To Analyze the patentability process before 2005 Amendment
3. To analyze the present legal framework of Patentability in Medical
4. To Examine the Product and Process patent post amendment

Literature Review

The purpose of a literature review is to identify research topics that require further attention. Through a literature review, the researcher has attempted to explore various parts and concepts of the current study's investigation. The vast amount of literature in the field of In order to gather knowledge, the study has been researched and analyzed. a better knowledge of the important parts of the research heading, so that the research may proceed on the correct path.

Patents, according to **Lilja (2008),** lead to monopolies that aren't conducive to innovation since they keep out new, more inventive businesses. Patents create monopolies that make it difficult for new, more inventive businesses to enter the industry, which reduces the likelihood of significant innovation.

Henry G. Grabowski, Joseph A. DiMasi, and Genia Long (2015) Researchers found that the "primary rationale for biopharmaceutical patent protection is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh

the relatively short-term restrictions on imitation cost competition associated with market exclusivity". Despite this, the entrance of other well-known drugs throughout the patent period will continue to be a major source of revenue of therapeutic rivalry.

Risa Kumazawa (2017) finds that pharmaceuticals' R&D returns on patenting will be significantly stronger on specific medicines for chronic illnesses like cancer and heart disease, resulting in higher profits.

Shilpi Kumari (2020) research shows that patents were initially designed to promote inventors and maximize the greater good, and if we want to assist people and make healthcare cheaper, we need a faster clearance procedure for generics. Branded pharmaceutical businesses must secure patent protection for their goods in order to attract investors. Because patents are a key driver of pharmaceutical and biotech innovation, they must be protected.

M RAHMAH (2020) The study investigates whether or not pharmaceutical patents will provide societal benefits by spurring innovation, increasing consumer surplus, spreading knowledge, and boosting economic growth. The patent system, according to some, is based on the premise that the advantages of patents outweigh the costs of infringement. Patents on drugs that are uncontrolled and excessively protected, on the other hand, represent a significant burden on society. The exercise of exclusive rights and monopolistic power by patent holders has social costs, such as high drug prices, decreased output, less competition, less consumer surplus, etc. Patenting pharmaceuticals has social costs. A scarcity of low-cost medications in third world countries has resulted in significant deadweight as a result of pharmaceutical losses patents restricting public health. A medical invention patent may transform a miracle into a societal catastrophe. Adding additional funding to fundamental research, regulating the pricing of essential items like medicines, boosting education, and cultivating public perceptions of patent rights were all recommended by the author.

Avisha Barange and Alisha Thomas (2021) The Authors have critically analyzed the well-known Novartis case, which debateably sets a key paradigm for access to medications by bringing the pharmaceutical sector within the grasp of patent law. With respect to how rising nations opt to derive and implement the TRIPS Agreement, the Indian Supreme Court's decision may serve as a paradigm. This case shows how India views its worldwide intellectual property law duties while also ensuring that local the needs are taken into account by interpreting its legal obligations in a way that is significantly correct to domestic preferences.

The ruling favors social justice over commercial objectives while simultaneously benefiting Indian businesses at home. First time Indian legislation has been enacted to prohibit patents on pharmaceuticals with just minor changes to an already existing one is the present moment[v]. Patents will only be used to protect new and revolutionary medicines with a demonstrable therapeutic effect in the near future. To put it another what we're witnessing is a good example of that in India is a complex game that causes anxiety because of both global trade commitments and domestic public health concerns. The latter, in this instance, has clearly gained precedence.

Priyanka Rastogi (2014) the author Even in nations where such procedures are authorized to be patented, patents are seldom obtained, according to this research. This might be because enforcing these patents is extremely difficult. The patent holder would be required to keep tabs on the actions of a huge number of doctors and surgeons, who typically give their services under tight confidentiality regulations. If a small number of easily identified experts uses novel and sophisticated procedures, it may be easier to enforce. While patent law enables the award of patents for pharmaceuticals and medical equipment across the world, patentability for a technique of treating the same body is disallowed in some nations for a variety of public policy reasons Various legal systems exempt medical operations from patent protection due to ethical considerations. This is mirrored in the patent regulations of many legal systems, and it acts as a barrier to medical process patent protection. Medical treatment procedures are removed from the purview of patentable subject matter in most nations, with the exception of Australia and the United States, reducing the incentives offered by the patent system. A regulation like this was developed because of the inherent ethics in the practice of medicine.

Research Methodology

This study's researcher will take a doctrinal approach to coming up with the findings. For starters, the researcher utilized primary sources of data such as international and national statutes and case law to determine and analyze current legislation with regard to the concepts of Pros of Patentability and Product vs. Process Patent. The doctrinal approach will be used in the down mentioned way. After gathering and analyzing primary sources such as government reports and books written by well-known specialists in the subject of intellectual property, the The researcher has now shifted his focus. to secondary sources.

Scope and Limitation

In light of Patent Law, the study's scope is confined solely to product and process patents. An in-depth examination of patentability in medicine will be conducted as part of this investigation. The researcher will try to analyze the Patent Act by comparing it to the legislation of other countries. The study's primary goal is to better understand the present legal landscape and the effectiveness of patent grants.

DEVELOPMENT OF PATENT LAW

Libretto patenti (patent letters) refers to open letters in the patent system. The origins of Indian patent law may be traced back to the patent laws and practices in the United Kingdom. It is based on the British Patents Act 1949 that the Indian Patent Act 1970 was enacted. These two acts, however, are vastly different. The Indian Patent Act of 1970 granted the right to patent a process. Before the Act was further revised in 2005 in complete compliance with TRIPS standards mandating Product patents, no Product Patents had been awarded for food, medicine, or chemicals.[vi] The patent duration is legally set at 20 years, but in the case of medication patents, it is closer to 16-18 years because drugs must first satisfy FDA rules before they can be sold. Medicine patents expire, and there are several variants of the same generic medicine developed by competing businesses and sold at a much lower price. As a result, innovative firms strive to make their drugs last longer in order to remain competitive. This is taken to as an extension of a well-known medication to provide longer-term protection. “With the advantages of cost competitiveness, competence and experience in reverse engineering, availability of qualified scientific and engineering staff and the capacity to create raw materials for a wide range of pharmaceuticals from the basic stage, the industry offers the complete therapeutic range. According to McKinsey & Co., India's pharmaceutical industry might exceed USD 20 billion in 2015, making it one of the world's top 10 drug markets”.

Patents Act 1970

In its initial form, the Patents Act of 1970 did not distinguish between process and product patents for pharmaceuticals, food, and chemical products. One of the Act's most notable provisions was the lack of product patents for the above described three industries. To make

sure life-saving medications are affordable, the Drug Price Control Order of 1970 set a price ceiling on the highest amount that may be charged. The Inventors' and Consumers' Rights Act of 1970 protects both parties' interests equally. The Act was passed in accordance with the Directive Principles of State Policy's socialist principles (Art 39 of the Constitution). For example, the 1970 Act of Parliament in India provided "patent protection solely to manufacturing methods, rather than to the final goods themselves, allowing Indian businesses to'reverse engineer' the production process and make generic copies of pharmaceuticals." To put it another way, an overly restrictive regulatory structure that solely focused on process patents made it possible for India's domestic pharmaceutical sector to become a world supplier of bulk pharmaceuticals and treatments at low rates for the common man in India and other developing countries. These regulations were enacted in response to nations' inability to offer appropriate security for pharmaceutical goods. Different patent offices in Delhi, Chennai, and Mumbai may handle the patent filing procedure[vii].

The Patents Act, 1970 is India's primary patent legislation. The terms of this legislation initially the awarding of product patents for inventions in the sectors of food and medicine was outlawed, medication, and chemical. In India, however, product patenting has been legal since 2005.

India, a WTO member, signed the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement in 1995. TRIPS established basic criteria for IP legislation that all member nations must follow. As a signatory to the TRIPS agreement, India has a contract based responsibility to change its Patents Law in order to comply with the agreement's terms. The Patents (Amendment) Act, 1999, was the first in a series of amendments to provide pipeline protection until the government began issuing product patents. It established procedures for submitting product patent applications in the fields of pharmaceuticals and agrochemicals as mailbox applications beginning on January 1, 1995, and it created the concept of Exclusive Marketing Rights (EMRs) for patents in these fields. The Patents (Amendment) Act, 2002, modified the Patents Act, 1970 to ensure compliance with the country's second set of TRIPS commitments. This legislation established a consistent 20-year patent term for all types of inventions. Additionally, the modification changed the meaning of the word "innovation" to be in line with the TRIPS agreement, and it included a provision per missioning the burden of evidence to be reversed in process patent infringement suits. It was the Patents (Amendment)

Act of 2005 that brought about the third round of revisions to the patent law. Product patents were established in India as a result of this legislation. “There were modifications to rules pertaining to pre-grant and post-grant oppositions and a new provision for the award of compulsory licenses for the export of patented pharmaceutical goods under specific situations that made the discovery of new forms, new properties, or new uses patentable.

Criteria of Patentability

Patents are issued to innovations that meet a set of requirements referred to as patentability criteria. In India, a patentable invention is defined as "a novel product or technique incorporating an innovative step and capable of industrial application" under the Indian Patent Act. As a result, the following are the essential conditions for the patentability of any invention:

a) “Newness: To be patentable, the invention's subject matter must be new at the time of patent filing. If an innovation hasn't been published or utilized anywhere else in the globe, it's called brand new[viii]”.
b) “For the purposes of this definition, an inventive step is any element of an invention that involves technological improvement above existing knowledge, or that has economic importance, or both, and makes the invention not obvious to someone versed in the art”.
c) “Industrial Applicability: The innovation must be able to be manufactured or utilised in industry. To provide an example, a new and innovative technique of eliminating cancerous cells from a patient's body is not industrially relevant and hence cannot be patented”.

PATENTABILITY OF MEDICAL “PROS”

As a result, the pharmaceutical industry is frequently embroiled in a debate about whether or not the sector exists to address the health issues of the poor and needy, therefore guaranteeing that medications are available to the general public at reasonable prices. First, let's take a look at the problems at hand before diving into the benefits and cons. In fact, the pharmaceutical industry invests enormous sums of money in the development of new medications, which are

then sold at prices that allow them to recover their costs while still making a profit. Current political and legal thought in the West holds that because Pharma spends a lot of money on R&D, it should be able to patent the medications it develops and prevent others from copying or producing them. This is the underlying legal stance in most countries, where the aim is to reward and encourage pharmaceutical firms to produce better medications by patenting their innovations and pricing them appropriately.

- Pharmaceutical firms make over 80% of their revenue from patents.
- The novel techniques employed by pharmaceutical businesses must be protected by securing patent protection.
- Drug patents assist in recouping R&D expenditures.
- Because rivals may readily copy a medicine's production process, drug patents can help protect an inventor from legal action.
- By helping to obtain venture capital, drug patents contribute to the overall economic growth of pharmaceutical firms.

Inventions are protected by patents. An innovation patent is a government-granted exclusive right. The inventor or anybody else to whom the inventor has assigned a patent application has the right to file for one. It's the right to keep others from manufacturing, using, selling, or importing the innovation without your permission. If you have the right to patent your invention, you can prevent or stop others from using it without your permission. This is known as a "negative patent right," because it does not give you permission to make, use, or sell your invention. Instead, it gives you the power to prevent or stop others from using your invention without your permission. A patent gives you the authority to provide licenses to others so they can make, use, or sell your patented innovation.

A patent is an agreement between the government and an applicant/inventor in which the government grants the applicant/inventor the right to protection of the innovation for a limited time after the invention has been fully disclosed. In other words, patenting is a way to safeguard inventions while at the same time making them public.

A patent gives a technological solution to a technical problem. Only innovations that meet specific requirements for patentability are given a patent. Patents are only valid for a period of 20 years after the date on which the patent application was filed. Patents are nation-specific rights, meaning they can only be enforced in the country where they were originally issued. As

a result, legal action against infringement or breach of patent rights may only be sought in the nation in question. To be eligible for patent protection in several countries, an invention must be submitted for patent protection in each of those nations. "The Patent Cooperation Treaty (PCT) offers a way to submit an international patent application, which may then be submitted in a large number of nations with a single patent application. However, after submitting a PCT application, the issuance of a patent is left solely to the whims of the individual patent office".

A patent is a government-issued legal document that grants an inventor the right to produce, use, and sell an invention for a certain length of time. It may also be used to make major enhancements to already developed items. Granting patents is based on the principle of incentivizing inventors to improve technology. UN definition: A patent is an exclusive right awarded by the government to the creator of a new and useful invention. Intellectual property rights are a broad legal area that includes patent law. Patent law revolves around the concepts of novelty and innovative, non-obvious inventions. It's essential that the innovation has some sort of practical application in the legal system. This innovation can't be used by copycats or independent distributors as long as there is a valid patent on it. Some innovations and discoveries are not covered by a patent. Despite being the first to discover gravity's principles, Isaac Newton would have been unable to secure a patent on them. Human health is commonly cited as a concern by those who oppose the WTO, especially in the world's most impoverished countries. The pharmaceutical and biotechnology industries rely heavily on patents because they provide a way to recuperate the exorbitant research expenses of new drugs and medical devices. In the first year after a patent expires, companies will see a 40% loss in market share. The pharmaceutical pipeline is also "drying up" (ie, fewer new drugs are entering the market). That is why pharmaceutical companies increasingly try to extend the patent on their drugs when their current one expires through innovative products like clinically superior formulations (like new delivery systems or controlled release) and chemico-pharmacological alterations (like sustained release) (ie, improvements in the pharmacokinetics or side effect profiles, single isomer drugs, prodrugs). The pharmaceutical business relies on patent protection to stay ahead of the competition. Patents provide innovative firms with the guaranteed term of market exclusivity they need to keep medicine prices stable, repay R&D costs, and fund the development of new treatments. International humanitarian organizations and health campaigners fear that India's proposed revisions to its 35-year-old patent rules may prevent millions of people in India and other poor nations from accessing low-cost generic medications.

The 1970 Indian Patent Act allowed patents on chemical processes but not on medicines. As a result, Indian pharmaceutical companies were able to reverse engineer molecules to create generic copies of copyrighted medicines. The revisions, according to health campaigners, would make it simpler for businesses to get patents on new uses of existing medications and on novel combinations of old treatments. Compulsory licensing, which now permits local firms to create generic versions of national brands, would be more difficult to enforce under the new law. As a WTO member, India attempted to make its patent legislation TRIPS compliant by implementing the Patents (Amendment) Act 2005 on January 1, 2005, which permitted for product patents, a hotly disputed topic both worldwide and nationally. The primary worry raised by these modifications is that medicine prices would rise, putting the poor at greater risk. Although resolving this issue would be difficult, additional regulatory measures may be implemented to keep medication prices under control. Considering that establishing pharmaceutical patents is likely to have more social and economic costs than benefits in most developing nations, it is prudent to approach intellectual property protection in the pharmaceutical industry with caution. There is much debate about whether pharmaceutical patents should be included in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights. Patent rights, according to its proponents, are vital for stimulating innovation since the virtual monopoly they establish allows companies to make more money from new medications they develop. Those opposed to patents, on the other hand, argue that increased prices are a result of them, making vital medications less accessible.

Types of Pharmaceutical Patents in India

There are few industries as intense as pharmaceuticals when it comes to "knowledge". The expense and outcome of pharmaceutical research are both high. New, innovative, and helpful products or processes can be the result of study. Pharmaceutical firms must safeguard their ideas from unlawful commercial usage in this highly competitive industry by obtaining patent rights for the created product or method. The following are the many types of pharmaceutical patents that are filed in India. According to the Indian Patent Office's online list of Pharma patents, this categorization was created[ix].

a) Drug compound patents

These patents assert ownership of a medicinal molecule based solely on its chemical structure. Markush type claims are the common name given to these patent claims. A Markush claim is one in which several "functionally equivalent" chemical entities are permitted in one or more portions of the medicinal molecule.

Since other businesses are not permitted to create or produce/sell any formulation using this medicine before the expiration of the stated patent, drug compound patents give the most protection for the company's product.

b) Formulation/ composition Patents

These patents claim a specific technique for the preparation of a formulation and/or the quantity of its main constituents. Patent no. 203986 in India claims an ayurvedic anti-retroviral compound for treating AIDS ("Acquired Immuno Deficiency Syndrome").

"5 mg to 2 grams of Guduchi or Giloe (cordifolium) Two milligrams to five grams of Panash or Kathal Tulsi, also known as Krishna Tulsi (Holy Basil), 5 mg-5 g Kuda or Kutaja (Kurchi): 2 mg-2 gm Bhui Amla or Bahu Patra (Gooseberry): 5 mg-2 gm in conjunction with pharmaceutically approved excipients."

c) Synergistic combination Patents

When two or more medicines interact in such a manner that one or more of the effects of those drugs are enhanced or magnified, drug synergy occurs. New synergistic medication combinations may qualify for patent protection if they are covered by existing patents.

Roflumilast and salmeterol were claimed to work synergistically in Indian patent no. 206328, as follows:

"A medicament comprising a PDE inhibitor, which is to be administered orally, from the PDE4 inhibitors group combined with a G2 adrenoceptor agonist in fixed or free combination, wherein the PDE inhibitor is roflumilast, a pharmacologically tolerable salt of roflumilast and/or the N-oxide of roflumilast and the G2 adrenoceptor agonist is salmeterol or a pharmacologically tolerable salt thereof".

d) Technology Patents

These patents are based on methods for resolving certain technological issues including stability, flavor masking, and increased solubility, among others.

An illustration of this is Indian patent no. 227933, which claims the following taste-masked composition.

The flavor masking persists after administration of the formulation, particularly in the form of a suspension in an aqueous vehicle, and is defined by the presence of at least one of the following components in the pharmaceutical formulation with a masked taste: The active component must be dispersed evenly and in the molecular state in the mixture, which takes the form of an atomized matrix, and the mixture must be homogenous and comprise an organic alkaline agent or an alkaline salt suitable for pharmaceutical application.

e) Polymorph Patents

Polymorphs are a compound's several physical or crystal structures that are not yet known. Polymorphs are frequently produced to eliminate impurities or improve the stability of a chemical.

For example, “Indian patent no. 237261 claims the crystalline form B4 of atorvastatin magnesium, which is characterized by an X-ray powder diffraction pattern. This crystalline form has a purity rating of over 98 percent”.

Section 3(d) role in polymorph patenting

“To grant a polymorph patent, one must comply with section 3(d) of the Indian Patents Act, 1970 (the "Act"). The Patents (Amendment) Act of 2005 made changes to this provision. The section states: "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. This clause considers salts, ethers and esters of known substances to be the same substance unless they differ significantly in properties with regard to efficacy in polymorphs and metabolites, pure form and particle size of known substances, isomers, mixtures of isomers and complexes, combinations and other derivatives”.

By limiting patentability to pharmaceutical derivatives that have significantly improved "efficacy," section 3(d) aims to prevent "ever greening of patents". By limiting patentability to truly meritorious forms, the section 3(d) assures that new forms will not be awarded patent protection simply because they are novel. It sheds light on the Indian government's strategy of rewarding innovators and researchers for their genuine intellectual endeavors while also protecting the public interest and making vital commodities like pharmaceuticals readily available at low cost.

f) Biotechnology patents

Living organisms or biological materials are used when making pharmaceuticals thanks to biotechnology. Patents in biotechnology cover a wide range of diagnostic, therapeutic, and immunological products.

It's possible that the “Interferon-alpha in Indian patent no. 234072 is an aqueous, human serum albumin-free solution that also contains non-ionic detergent, a buffer for pH adjustment, and possibly an isotonicizing agent”.

In fact, the aforementioned “Indian patent no. 234072 was the first product patent awarded by the Indian Patent Office after the implementation of the product patent system in 2005. F. Hoffmann-La Roche Ltd., a Swiss company, holds the patent rights”.

g) Process patents

While a product patent claims a specific product, a process patent simply covers a novel and innovative way to make that product.

As an illustration, “Indian patent no. 206678 claims a method for synthesizing L-lactone with the formula 3,6-dialkyl-5,6-dihydro-4-hydroxy-2h-pyran-2-one”

Medical Innovation

New medical innovations continue to be developed by physicians and granted medical patents. When disputes arise between companies involved in obtaining and commercializing surgical methods covered by a health-care patent, the actions of physicians and surgeons have also been implicated. Legal protections exist that shield physicians/surgeons from patent infringement liability and other types liability in some circumstances. When a U.S. court ruled in Warsaw Orthopedic Inc. v. NuVasive, Inc. (decided on June 2, 2016), for example, a U. The Court of

Appeals considered whether NuVasive could be held liable for infringing Warsaw Orthopedics' patent by instructing doctors/surgeons on how to perform the procedure covered by Warsaw's existing patent. A charge of patent infringement was brought against NuVasive based on evidence that the surgeons had been instructed by the company on how to perform the patented surgical procedure developed by Warsaw[x].

If a medical or surgical procedure performed on the body violates a patented medical procedure, the practitioner is immune from liability under 35 U.S.C.A. 287. (c).

Under 35 U.S.C.A. 287, medical practitioners are immune from patent infringement liability if they perform a medical/surgical procedure on a body that infringes on a patented medical procedure (c). Medical practitioners, on the other hand, are not immune from liability when performing a medical procedure with a patented machine or medical device, such as a pharmaceutical device. If device manufacturers direct or influence doctors to infringe on another company's patent, they may be found guilty of an inducement to infringe under 35 U.S.C. 271(b). Companies that offer patent-infringing tools/devices and instructions to physicians for their use may be held responsible for the infringing conduct of those physicians. Hence, giving directions on how to carry out a patent-protected technique may be considered infringement-inducing behavior. Also, physicians who become owners in pharmaceutical and/or medical device firms should exercise caution to ensure that their exemption from responsibility for patent infringement remains intact under the legislation.

PHARMACEUTICAL PRODUCT PATENTS: AN INTRODUCTION

Scenario Pre-TRIPS

It is estimated that the Indian pharmaceutical sector is the fourth-largest in output and the thirteenth-largest in terms of domestic consumption value worldwide. India's pharmaceutical sector has grown from near extinction to global leadership in the manufacturing of generic pharmaceuticals during the last 30 years. Since the Patents Act of 1970, Indian pharma manufacturers have become specialists in reverse engineering and have boosted their supply of lower-cost replicas of the world's best-selling patent-protected medicines. This was only feasible due to the absence of a medication and medicinal product patenting system. As a result,

while Section 5 (which was removed by the amendment of 2005) of the Patent Act of 1970 initially distinguished between product patents and process patents, it now only offers a process patent for food, medicine, or drug substances and excludes product patents for the same. As a result, India was able to duplicate foreign-patented medications without having to pay a licensing fee, and make them available to the general public for a tenth of their original cost. It also set a ceiling on the highest price that could be charged, and this helped to make life-saving medications more affordable. Inventors and consumers benefit equally from the 1970 Act, which is one of the most forward-thinking pieces of legislation. Keeping in mind the Directive Principles of State Policy, the Act was signed into law. con Enactment The 1970 Indian Patents Act is the cornerstone of Indian patent law. Patents on "substances intended for use, or capable of use, as food, medicine, or medication" are specifically prohibited". "Post-TRIPS Scenario The intellectual property component of the Uruguay Round of the GATT Treaty, known as TRIPs, has sparked a bitter dispute between rich and developing countries (LDCs) The inclusion of pharmaceutical product patents was the most significant change required by the amendment of 2005 to bring India's current patent regime into compliance with TRIPS". TRIPS now encompass food, pharmaceuticals, and medicine as well, according to a 2005 amendment. When the 1970 Patent Act was in place, it stipulated that patents were only to be awarded for chemical methods that resulted in the manufacturing of a specific medicine. Additionally, the pharmaceutical industry will benefit from the new law because the length of a patent protection has been increased from seven years under the 1970 legislation to twenty years now. The new amendment does not impact pharmaceuticals on the market before 1995 since it was made applicable to all member nations and therefore eliminates all variations in patent protection that existed between countries. For medications created between 1995 and 2005, manufacturers will be able to keep making them as long as they pay a set royalty to the patent holder. The major issue is with medicines that are now being developed and patented. Compulsory licenses are the only method to produce certain medicines in India. With this in mind, keep Article 39 of the Constitution, which makes it mandatory. As a result, the Indian pharmaceutical industry has evolved from an import-dependent one in the 1950s to a low-cost maker of high-quality pharmaceutical goods with an annual export turnover of more than $1.5 billion dollars, all while operating under a strict price control framework. Many developing countries with capable pharmaceutical businesses, who previously competed in selling generic versions of

patented medications to least developed countries, completed their transition phase in 2005. (LDCs).

The Indian Patents Act of 1970 established the foundation for patent protection in India. Patents on "substances intended for use, or capable of use, as food, medicine, or medication" are specifically prohibited".

Scenario Post-TRIPS

TRIPs, the Uruguay Round's intellectual property treaty, has sparked a bitter controversy between the developed and developing worlds (LDCs) The inclusion of pharmaceutical product patents was the most significant change required by the amendment of 2005 to bring India's current patent regime into compliance with TRIPS. TRIPS now encompass food, pharmaceuticals, and medicine as well, according to a 2005 amendment. Because of this, it needs patent protection to be extended to goods as well, whereas before, only chemical processes that resulted in the manufacturing of a specific medicine were covered by patents. The following are the new act's additional consequences for the pharmaceutical industry: Since the Patent Act of 1970, the duration of a patent has been increased to twenty years. Thus, all disparities in patent protection across nations are eliminated. The new amendment did not apply to medications that were already on the market when it was passed in 1995[xi]. For medications created between 1995 and 2005, manufacturers will be able to continue making them as long as they pay a set royalty to the patent holder. The major issue is with medicines that are now being developed and patented. Compulsory licenses are the only method to produce certain medicines in India[xii]. Compulsory permits are issued by the government for a variety of reasons, including a lack of supply, excessive pricing, and the general interest. In theory, the method should be straightforward and uncomplicated, but the new Act leaves a lot of room for ambiguity in the process. TRIPS compliance and the adoption of the new Act of 2005 will have the largest and most immediate impact on India's healthcare industry. The patients are the true winners in the pharmaceutical R&D race. By refusing to recognize product patents, India will be able to promote low-cost generic medicine manufacture in large quantities. However, generics aren't the only answer to the problem of affordable medicine. Generic drug production may not always lead to the development of new and more effective pharmaceuticals, and by refusing to acknowledge innovation, India risks losing access to future medications, which

might have a negative influence on public health. We cannot solve the problem of providing medication to patients who are unable to afford it by denying patents and allowing generic firms unfettered access to the new medications. The real issue is that product patents not only raise the price of medications and therapies, but they also prevent much-needed research and development in areas such as neglected illnesses from being done. The majority of deaths from HIV/AIDS in underdeveloped nations were caused by a lack of cheap medication. While the implementation of product patents will, on the one hand, aid in the development of new and more effective drugs, the problem remains that drug manufacturers' research and development efforts avoid neglected diseases and diseases that are region-specific, such as medicines for malaria and tuberculosis, which are prevalent in developing countries such as India. Due to the absence of medical insurance penetration, people in developing nations are more vulnerable to price increases, which reduces their capacity to pay healthcare. People in developing countries, who make up the vast majority, are unable to live normal lives because of the patent system. With a product patent system, India will be completely reliant on multinational corporations for both technology and permission to manufacture the patented medicine. Indian pharmaceutical companies will be forced to compete with MNCs on the basis of exorbitant prices. They will be demoted from the position they gained as a result of the Act of 1970.

Patents Amendment Act (2005)

"The Patent Amendment Act of 2005, approved by Parliament in its 2005 budget session, brings the Indian Patent Act completely in line with the intellectual property system". This ordinance took the place of one that had been passed in December 2004 in order to satisfy WTO commitments. the defining clause in "Section 2(j) defines innovation as a novel product or method involving an innovative step and capable of industrial application, as amended by Sections 2 and 3 of the Patent Act. Inventive step (ja) refers to a feature of an invention that involves a technical advance over existing knowledge or has economic significance or both and makes the invention not obvious to a person skilled in art[xiii]. Thus, for an invention to be patentable, it must include the following elements: I an inventive step with industrial application; (ii) technical advancements over prior art or economic significance; and (iii) be obscure to a person skilled in the art. Section 3 discusses various circumstances in which an invention (properly referred to) may be patentable but not commercially exploitable. It was necessary to amend Section 3(d) of the Patents Act of 1970 under the new Act to specify a

class of discoveries that cannot be protected by a patent". "New form of an existing substance that does not result in the enhancement of the known efficacy of that substance; discovery of any new property or new application for an existing substance; or use of an existing process, machine or apparatus unless that process produces a new product or uses at least one new reactant". Product, it is now possible to obtain a patent for a drug, food, or chemical under certain conditions (Section 3(d)), but this is still restricted. This clause prohibits the patenting of insignificant innovations. The amendments to the Patents Act demonstrate that creative creativity, originality, and the presence of an industrial application or economic importance are all significant components of patentability in medicines, chemicals, and new processes. Patents are used in a variety of ways by various businesses. However, in the pharmaceutical, chemical, and biotechnology sectors, the patent usually equals the product and protects the significant investment in research and clinical testing necessary before releasing it to the public.

THE GLOBAL INSTITUTIONS RESPONSIBLE FOR ADMINISTERING THE PATENT SYSTEM

Every country with a patent system keeps a public record of inventor claims at the national patent office. As previously said, several countries require inventors to first pass an examination. Patent claims are recorded in other countries, but comprehensive investigation is not done until a dispute over infringement develops. However, in these nations, the registration procedure frequently involves a prior art search, and the search results are disclosed so that members of the public may evaluate the registrant's claims. The "World Intellectual Property Organization (WIPO)" is based in Geneva and acts as the secretariat for the bulk of international intellectual property treaties. It is the principal forum for new patent treaties to be negotiated, as well as the largest source of intellectual property rights technical support to poor nations. WIPO was established in 1967 as the successor organization to the International Bureau for the Protection of Intellectual Property, which had existed since the nineteenth century. "The World Intellectual Property Organization (WIPO) now has 179 member countries. Following the successful conclusion of the Uruguay Round of Trade Negotiations in 1994, the World Trade Organization (WTO) was established in Marrakech. The World Trade Organization heard the General Agreement on Tariffs and Trade (GATT) (WTO). The

Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, was a significant reform of the Uruguay Round, incorporated as an appendix to the treaty creating the WTO. It is critical to remember that the TRIPS Agreement was designed to establish a more equal international trading system". Wealthy countries agreed to decrease import barriers for competitively priced foreign goods, while developing countries agreed to open their markets to industrialized nations' high-value-added exports. These high-value exports are dominated by intangible assets such as technology, which must be protected by powerful intellectual property laws before they can be effectively exploited. Pharmaceuticals account for a sizable percentage of the high technology sector. The following essential clauses are outlined in the TRIPS agreement:

- "WTO Member States must provide a level of rights equal to those provided in the major global intellectual property treaties administered by WIPO, including the Paris Convention on Industrial Property".
- "Patent exclusions for pharmaceutical items must be abolished in many countries since WTO members can't discriminate among technologies while offering patent protection".
- "WTO members must offer patent protection for at least 20 years after the date of submitting a patent application".
- "Intellectual property rights must be effectively enforced by WTO member states".
- "A TRIPS Council was created to coordinate WTO policy in the area of intellectual property rights and to manage the resolution of disputes among states on implementation of TRIPS obligations".

CONCLUSION AND RECOMMENDATION

A patent is a legal instrument that gives the patentee the only right to produce, use, sell, or offer for sale the subject matter of the patent "claims." Medicinal patents will be defined broadly in this article to cover pharmaceutical patents, methods of production and use of them and medical treatment regimens, surgical procedures, medical equipment and health information technology for hospitals and health care institutions.

Every year, millions of people around the world benefit from medical patents and health care innovations that improve medical care delivery, as well as quality of life. There are still difficulties in determining the most cost-effective way to make these advances available to those who need them the most. It is time consuming and expensive, but it provides a measured framework within which the societal health care benefit from medical patent-created products can be realized that governs innovation and the implementation of medical patents in balance with commercial interests and safety/efficacy concerns. "Patentability must be aligned with public health objectives, and governments must understand that extending the breadth of what may be patented could distort competition and restrict access to medications. Patents over minor developments can be effectively used to discourage or block competition, as generic producers, purchasing agencies, and consumers, particularly in developing countries, generally lack the substantial technical and financial resources required to challenge incorrectly granted patents or defend against infringement claims".

"The primary worry raised by these modifications is that medicine prices would rise, putting the poor at risk. Solving this issue would be difficult, but additional regulatory measures might be implemented to keep medication prices in check. Price restrictions, bargaining power as a big purchaser, and obligatory permits can all be used by the Indian government in the meanwhile to keep the process from moving too rapidly. The absence of Indian jobs may have an impact on Indian pharmaceutical companies as well". "This worry is not unfounded, but there are several grounds to believe that Indian business will be able to compete with global firms. For example, the present thriving Indian pharmaceutical sector relies on a highly educated and well-trained scientific staff. India's government may ensure that funding for the country's emerging biotechnology industry, which has the potential to make major contributions to India's economic growth and public health, will be accessible by adopting laws that stimulate the development of venture capital".

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