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# ISSUES RELATED TO PATENTS IN THE PHARMACEUTICAL SECTOR, AND PROTECTION OF MEDICINAL PLANTS

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## ABSTRACT

*In-depth analysis of the intricate interactions between intellectual property rights, concerns with patents in the pharmaceutical industry, and the vital subject of safeguarding medicinal plants is provided in this comprehensive research paper. The importance of intellectual property rights in encouraging innovation, advancing research and development, and guaranteeing fair competition is highlighted in the initial portions of the paper. By allowing people to profit from their creative endeavours and forbidding others from using, copying, or distributing their work without permission, it seeks to uphold the rights of innovators, creators, and inventors. It also emphasizes the importance of patents as the main tool for securing inventions and encouraging investment in the pharmaceutical sector. It then investigates the problems with licenses in the pharmaceutical industry. The difficulties brought on by patentability standards, the patentability of pharmaceutical formulations, and the effects of patent term extensions are all covered in this study. The development of a new treatment may be a time-consuming, expensive, and risky process, thus pharmaceutical companies seek patents to safeguard what they have invested in development and research and to encourage progress in the field of medicine. For a short time patents offer protection and exclusivity, allowing inventors to recoup their costs and generate income. Pharmaceutical firms are given a window of market exclusivity, during which time they are the only ones permitted to produce, use, and distribute the patented medication. To get approval from regulators for a new drug, patents are frequently necessary. As part of the approval procedure, regulatory authorities often demand proof of intellectual property rights. Patents prove that the pharmaceutical*

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*corporation has the legal authority to create and market the medication. The article next turns its attention to the problem of safeguarding medicinal plants, considering the moral, cultural, and environmental implications of their use. It covers the numerous safeguards used to protect customary wisdom and the environment, such as adoption of patent rules that acknowledge the value of conventional medical practices and guarantee fair benefit-sharing. The study also looks at how international initiatives safeguard medicinal plants, such the Nagoya Protocol and the Convention on Biological Diversity, have affected the global market. It emphasizes the significance of developing efficient systems for gaining access and making use of genetic resources while upholding the rights of indigenous people and conventional healers. In addition, it examines case studies that illuminate the relationship between patents, intellectual property rights, and the preservation of medicinal plants. It investigates cases of biopiracy, the difficulties indigenous populations have in defending their rights, and effective examples of cooperation between pharmaceutical firms, researchers, and communities at large. The report finishes with recommendations and future directions. It emphasizes the significance of supporting knowledge transfer, harmonizing patent laws around the world, and sustainable practices that strike a balance between access to life-saving medications and innovation. To secure the preservation and effective use of medicinal plants for everyone, it also advises incorporating traditional medical knowledge into contemporary research and development projects.*

**Keywords:** Intellectual Property Rights, Patents, Pharmaceutical Sector, Medicinal Plants, Legal Protection.

## Introduction

The pharmaceutical industry is essential to advancing global healthcare and treating a range of illnesses. In this context, patents are crucial legal tools that provide inventors exclusive rights to their creations, guaranteeing that they can make money off of their breakthroughs and keep spending money on R&D. The patent system in the pharmaceutical industry is not without its difficulties and conflicts, though. The safeguarding of therapeutic plants is a crucial issue that merits consideration in addition to patents. The preservation and sustainable use of these resources are essential for both cultural heritage and pharmaceutical research as many traditional and indigenous people rely on the use of medicinal plants for their healthcare requirements.

The possible influence on access to necessary medications is one of the most important issues with regard to medical patents. Particularly when patented treatments are life-saving or

necessary for widespread conditions, patents can generate monopolies that result in high drug prices. As a result, vulnerable populations in emerging economies may not be able to buy medications, limiting their access to life-saving therapies.[3]

Pharmaceutical corporations occasionally participate in a practise known as "patent evergreening," which entails making modest adjustments to an already-approved treatment in order to prolong its patent protection, even if the adjustments provide little to no therapeutic benefit. This tactic hinders the availability of cheap medications by delaying generic competition and maintaining drug costs high for an extended length of time.

The term "biopiracy" describes the unlicensed commercial use of indigenous or local people' genetic resources and traditional knowledge. Some pharmaceutical businesses are alleged to have taken advantage of traditional medical procedures and plant knowledge without paying the communities who possess this expertise fairly or giving them any advantages.[4]

As wealthier countries have easier access to copyrighted medications while poorer countries find it difficult to afford them, the patent system frequently exacerbates global health inequities. Uneven health outcomes can result from this discrepancy in access to medicines around the world. Medicinal plants make a substantial contribution to biodiversity, and it is essential to protect them in order to maintain the fragile equilibrium of the environment. Many indigenous and local populations have deep knowledge of the therapeutic benefits of plants. However, excessive harvesting and destruction of habitat for commercial interests have the potential to cause the extinction of valuable medicinal plant species. Sustainable harvesting and cultivation practises are necessary to guarantee that medicinal herbs are available for future generations. By protecting their traditional knowledge, they have the ability to utilise and reap the benefits of their cultural treasures while preventing unauthorised exploitation by outside parties. Fair and equitable sharing benefits mechanisms must be established that compensate communities and nations who offer genetic resources and conventional wisdom for drug development and research. Unrestricted harvesting or gathering of these plants can result in their extinction or degradation, negatively affecting biodiversity as well and human healthcare. By doing this, you can make sure that these communities are properly acknowledged and rewarded for their work.

[3] R., Thakur H. S. Puri and A. Husain, “Major medicinal plants of India”, (1989), Central Institute of Medicinal and Aromatic Plants; Lucknow

[4] GANDHI, M.K. Young India Journal (1919-1932), Ahmedabad, India, 1924

**The Role of Patents in Innovation in the Medicinal Sector**

The pharmaceutical industry plays a crucial role in the development of innovative, efficient medicines for a variety of medical diseases. The advancement of medical knowledge and raising the standard of living for people all over the world depend heavily on innovation. Patents are crucial legal tools that provide creators exclusive ownership of their discoveries, encouraging further study and development. Patents have been a major factor in supporting innovation, encouraging investment in drug research, and boosting medical advancements in the field of medicine.[5] The foundation of the intellectual property system is the patent, which grants pharmaceutical companies and scientists a window of exclusivity for their ideas. This exclusivity serves as a powerful motivator for spending significant amounts of money, time, and effort on research and development (R&D) projects.[6] The process of creating a new drug or medical therapy is time-consuming, expensive, and frequently involves years of testing and study. Many businesses would be hesitant to take on such substantial risks and investments without the protection and potential financial rewards provided by patents.

Patents give creators the opportunity to recuperate their R&D costs and make money during the exclusive period. These earnings can then be used to fund more R&D initiatives, fostering an ongoing cycle of innovation in the pharmaceutical industry. This framework encourages businesses to venture into uncharted therapeutic territory and take calculated risks when creating novel medicines that might not be immediately profitable.

The patent system fosters competition and innovation by giving inventors a significant market edge over their rivals. To ensure that only really creative discoveries are granted exclusivity, an invention must be novel, non-obvious, and beneficial in order to receive a patent. This motivates scientists and pharmaceutical firms to concentrate on revolutionary discoveries and cutting-edge treatments rather than gradual gains.

This desire for innovation has resulted in the development of game-changing medicines that have altered the course of medical history and greatly improved patient outcomes. Antibiotics, vaccinations, and specialised treatments for different diseases are among examples.

In the pharmaceutical industry, patents also help to promote partnerships and licencing arrangements between various organisations. Pharmaceutical firms may get into cross-

[5] MANSFIELD, E. Patents and innovation: an empirical study, Management Sciences, 32, pp. 173-181, 1986
[6] MERRILL, S.A., R.C. LEVIN, M.B. MYERS (Eds.). A Patent System for the 21st Century, Committee on Intellectual Property Rights in the Knowledge-Based Economy, National Research Council, National Academies Press, National Academies of Science, Washington D.C., USA, 2004

licensing contracts whereby they exchange their proprietary technologies in order to obtain access to one another's breakthroughs. This cooperation can cut down on effort duplication and hasten the discovery of novel medicines.

Small biotech start-ups and academic institutions frequently lack the funding necessary to bring a medicine to market on their own. In certain situations, larger pharmaceutical firms that have the necessary resources, production capacity, and market reach to commercialise the idea may be granted patent licences. These licencing agreements allow for a more effective use of resources and guarantee that patients are more likely to receive cutting-edge treatments.[7]

1) *Intellectual property protection:* The intellectual property (IP) of inventors and businesses is crucially protected by the patent system. Without patents, this is a risk of competitors immediately duplicating and imitating novel medications, which would reduce the motivation for R&D spending. Patents establish a framework for equitable competition and compensation for innovators' labour by offering a legal barrier against unauthorised use of the innovation. IP protection promotes openness and dissemination of research findings. In order to spread scientific information and promote the medical industry, businesses must fully describe their ideas in the patent application. This sharing encourages learning and builds on prior research, which eventually encourages more invention.[8]
2) *Making Money to Support Future Innovation:* For pharmaceutical businesses, the money from patented medicines is a key source of income. To create new medicines or improve existing ones, these monies might be put back into research and development. In order to address new health concerns, developing diseases, and unmet medical requirements, innovation must continue.[9] Patented medicine revenues assist businesses in recouping the expenditures associated with failed R&D initiatives. The development of drugs is a dangerous activity, and many prospective treatments might not reach the market because of issues with safety or ineffectiveness. By allowing successful pharmaceuticals to recover expenses from failed endeavours, patents provide as a safety net and lessen the financial load on businesses.

[7] M. MAZZUCATO. 'The dynamics of knowledge accumulation, regulation and appropriability in the pharma-biotech sector,' in M. Mazzucato and G. Dosi (2006), Knowledge Accumulation and Industry Evolution, The Case of Pharma-Biotech. Cambridge University Press: Cambridge, 2006

[8] LALL, S. Indicators of the relative importance of IPRs in developing countries, Research Policy, 32, pp. 1657-1680, 2003

[9] MOWERY, D. and N. ROSENBERG. Paths of Innovation: Technological Change in 20th-Century America, Cambridge University Press, New York, 1998

3) *Regulatory approval processes can be improved*: The procedure for novel pharmaceuticals receiving regulatory approval can be streamlined with patents. Regulatory exclusivity is frequently granted to a corporation when it requests regulatory permission for a patented drug. This exclusivity prohibits generic competitors from entering the market for a set period of time. By allowing businesses to recover their investments without facing immediate competition, this exclusivity encourages them to seek regulatory clearance for novel treatments. Furthermore, patented pharmaceuticals can be seen by regulatory bodies as more valuable and innovative than already available treatments, which could speed up the approval procedure. This acceptance of innovation may provide quicker patient access to cutting-edge treatments, increasing patient outcomes.
4) *Enhancing Access for Patients*: Patents give inventors the right to exclusivity, but they are not indefinite rights. When a drug's patent runs out, it becomes publicly available, enabling generic producers to create and market cost-effective alternatives. As a result, costs decline and competition increases, greatly enhancing patient access to necessary pharmaceuticals. Several nations have laws allowing for compulsory licencing, which enables the government to sanction the manufacture of a patented drug by a third party in the event of a public health emergency or to solve affordability difficulties. This guarantees that essential medications are available to individuals who require them, even before the patent expires.
5) *Criticisms & Hurdles*: While promoting creativity in the pharmaceutical industry, patents are not without difficulties and detractors. Many patients, particularly in underdeveloped nations, cannot purchase patented medications because of their high cost. This raises moral concerns about vulnerable populations' access to life-saving drugs. Some pharmaceutical firms have been charged with patent evergreening, which involves extending the exclusivity of their products by making small changes without appreciable therapeutic advantages. By delaying generic competition, this practise can keep medicine costs high. Patents on traditional knowledge and therapeutic plants can cause some people to worry about biopiracy, which occurs when businesses profit from local knowledge and resources without paying fair compensation or sharing in the benefits.
6) *Global Health Inequities*: The patent system may cause to discrepancies in the availability of medications between high-income and low-income nations. By boosting R&D, fostering the discovery of new therapeutics, encouraging collaboration and

licencing, safeguarding intellectual property, producing income for ongoing research, and improving regulatory approval processes, patents play a critical role in fostering innovation in the pharmaceutical industry. While patents have been crucial in advancing medicine, it is crucial to address the issues and concerns in order to guarantee that everyone has equal and affordable access to cutting-edge treatments. Collaboration between stakeholders, legislators, and the pharmaceutical business is necessary to achieve the complicated task of balancing the need for incentives with the objective of ensuring access to healthcare.[10]

**The Significance of Patents for Traditional Medicine**

Various civilizations have used traditional medicine for thousands of years, and it includes a wide range of ideas and methods that have been handed down through the generations. It entails the use of medicinal herbs, minerals, and products obtained from animals, together with certain therapeutic practises, to treat and prevent a variety of disorders and to advance general wellness. Due to its potential to offer alternative and complementary treatments for a range of medical ailments, traditional medicine has recently drawn more attention from researchers, pharmaceutical corporations, and governments. The significance of patents for conventional medicine becomes an important topic to investigate in this situation. This article explores the significance of patents for conventional medicine as well as its many ramifications.

The cultural legacy of indigenous and local cultures is profoundly ingrained in traditional medicine. They have been passing down their knowledge of medicinal plants, herbal cures, and methods for treatment orally for millennia. Patents can be very helpful in preventing biopiracy, which is the unauthorised commercial exploitation of traditional knowledge.

Indigenous groups can obtain judicial acknowledgment and protection for their ideas by patenting certain applications or formulas developed from traditional knowledge. This can stop big pharmaceutical corporations or researchers from using conventional treatments without crediting the communities who have developed them. In order to ensure that the owners of the knowledge are paid for their significant contributions, patents offer a way to establish ownership and make fair benefit-sharing agreements possible.[11]

[10] K.I. Menon. (1999) Clinical Champions and Critical Determinants of Drug Development, in R. Landau, Achilladelis, B.and Scriabine, A. (Eds.). Pharmaceutical Innovation: Revolutionizing Human Health, Chemical Heritage Press, Philadelphia, pp. 331-372, 1995

[11] J. Tarunika, and J. Tamilselvi, "Traditional knowledge and patent issues in India", International Journal of Pure and Applied Mathematics, Vol. 119(17), (2018), pp 1249 -1264.

Researchers and pharmaceutical businesses may be encouraged to invest in additional research and development of traditional medicines by the granting of patents for certain treatments. Patents can provide exclusivity and financial incentives to investigate the potential of traditional medicine to offer unique and effective treatments for different medical conditions. It is possible to better understand the safety, effectiveness, and mechanism of action of traditional treatments when they are exposed to scientific evaluation and validation. This procedure may result in the creation of fresh medications, therapeutic substances, or cutting-edge treatment regimens. In the long run, patents can help both conventional medicine practitioners and the larger healthcare community by stimulating more investment in clinical trials, safety studies, and product development.[12]

Natural resources, such as herbal remedies and other organic materials, are frequently used in traditional medicine. Traditional medicine's commercial appeal may result in overharvesting and resource depletion, endangering biodiversity and the ecosystems that sustain it. By supporting the cultivation and ethical harvesting of medicinal plants, patents can help advance sustainable practises. Patenting traditional medicines may also encourage the documenting and preservation of particular plant species that could otherwise go unnoticed or be in danger of extinction. Patents can help to preserve biodiversity and the ecological balance by protecting the intellectual property linked to these resources.

The fusion of mainstream medicine and traditional medicine can be facilitated by patents. Integrative medicine, which mixes traditional practises with mainstream therapies that are supported by science, is becoming more and more popular as a holistic method of providing healthcare. Traditional treatments may be more readily accepted and incorporated into established healthcare systems if they are given legal protection and legitimacy through patents. Patenting conventional treatments can occasionally result in partnerships between conventional healers and contemporary scientists or pharmaceutical companies. The best aspects of conventional and contemporary medical practises can be combined in novel therapeutic strategies as a result of this knowledge convergence.

When properly applied, patents can also improve access to conventional medicine. Patents can entice funding as well as advocate for development of products and research by offering legal

[12] "Health Innovations in India: Demand In-stitutions and Limits on Market Size", in K.J. Joseph and S. Ramani (Eds.) Technological change, Innovation and Inclusive Development in India

protection to particular traditional treatments. As a result, more people may have access to conventional medicines because they may be produced in a standardised, high-quality manner. Further promoting and conserving conventional medical practises is possible by reinvesting the profits from patented traditional treatments in community healthcare programmes. Traditional medical practises may develop and endure as a result of this cycle of reinvestment, thereby continuing to meet the community's health requirements.

While patents provide many benefits for conventional medicine, there are a number of issues that need to be taken into account. The indigenous and local people that own the traditional knowledge should be consulted prior to and informed of any patents being granted. To guarantee that these communities obtain just recompense and real benefits from the commercial use of their expertise, benefit-sharing mechanisms should be put in place.

When traditional treatments are patented, the possibility of biopiracy is still a worry. The cultural history of certain communities must be protected in order to prevent patents from unintentionally granting complete rights to information that has long been in the public domain.[13]

The ethical use of traditional treatments should not be jeopardised by their commercialization. The preservation of traditional understanding and reverence for the spiritual and cultural value of particular procedures and treatments are two things that patent holders must keep in mind. Various nations may have various traditional medicine regulatory frameworks. To safeguard customers and preserve public trust, it is crucial that patented traditional treatments adhere to security, efficacy, and quality criteria.

The importance of patents for traditional medicine is found in their potential to safeguard traditional knowledge, encourage research and development, maintain biodiversity, make it easier to integrate traditional treatments with modern medicine, and improve public access to traditional treatments. Patents can promote a productive partnership between conventional medical practises and the larger healthcare ecosystem by carefully balancing financial interests, cultural propriety, and ethical considerations. Patents can be an essential tool in maximising the possibilities of traditional medicine for the advancement of global health by recognising and safeguarding the contributions made by indigenous and local populations. The groups that

[13] Biopiracy and Traditional Knowledge-R.V Anuradha (Lawyer and Legal Consultant-www.hinduonnet.com)last visited the website on 13th July 2009 )

have protected traditional medicines for generations must manage the difficulties and guarantee that patents are given and used responsibly while honouring their cultural legacy and knowledge.

**Legal Framework for Pharmaceutical Sector**

Incentives for research and development, access to necessary medications, and innovation are all strongly influenced by the regulatory structure for pharmaceutical patents. Pharmaceutical patents give innovators exclusive ownership of their ideas, allowing them to recoup their R&D costs and gain a commercial edge. The legal framework for patenting drugs is described in this article in general terms, stressing its salient features and difficulties.

1) *Norms and Laws Regarding Patents*: National patent laws and international agreements, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organisation (WTO), regulate pharmaceutical patents. Uniqueness, non-obviousness, and industrial application are three requirements that an invention must meet in order to be given a patent.[14] In the realm of medication, the invention often comprises a brand-new, unusual, and therapeutically useful chemical component or composition. The innovation must be sufficiently described in the patent application for those who are knowledgeable in the field to be able to duplicate it. The exclusivity granted to inventors by patents is time-limited and is typically 20 years from the filing date.
2) *Exclusive Market Access and Data*: Pharmacies frequently profit from exclusivity of data and exclusivity in markets in addition to patents. Data submitted to regulatory agencies (such as the European Medicines Agency or the U.S. Food and Drug Administration) for marketing clearance are protected by data exclusivity. Generic producers are not permitted to submit applications for approval of their products' generic counterparts while the data exclusivity period is in effect. On the other hand, once a drug is authorised, a policy known as market exclusivity offers further protection from rivalry for a specific time. These time frames, which change from nation to nation, are meant to compensate pharmaceutical companies for spending a lot of money on clinical trials and ensuring a profit.

[14] CORIAT, B., F. ORSI, and C. D'ALMEIDA. TRIPS and the international public health controversies: issues and challenges, Industrial and Corporate Change, Volume 15, Number 6, pp. 1033–1062, 2006

3) *Linkages between patents and regulatory exclusivity*: To deal with potential patent violations during the medicinal product approval process, many nations have put in place procedures including regulatory exclusivity and patent linkage. Because of patent linkage, regulatory agencies must determine if a generic drug that is applying for clearance violates on any existent patents. If a patent is discovered to be legitimate, the approval of generic drugs may be postponed until that patent lapses or is destroyed. The approval of generic copies of a drug for a set amount of time following the originator's approval is not permitted under regulatory exclusivity, however. This time frame is usually associated with medicines that have been authorised via an application for a new drug (NDA) or a biologics licence application (BLA), and it was created to compensate the inventor for their research and development work.
4) *Challenges to Patents and Generics*: Due to worries about the expensive nature of copyrighted medications and access restrictions, the medical device patent system has come under fire. When generic producers think that a patent is invalid or not being violated, they may file patent oppositions or dismissal actions. These difficulties may result in disagreements and legal action between original manufacturers and generic producers, delaying the introduction of reasonably priced generic substitutes.[15]
5) *Compulsory Licencing and Access to Medicines*: Some nations have laws requiring compulsory licencing to solve difficulties with access to medications. As a result, without the patent holder's permission, the government may award licences to other parties to make and market protected medicines. When there is a public health emergency or when the cost of necessary medications makes them inaccessible or unaffordable, compulsory licencing is frequently implemented. Compulsory licencing has the potential to improve access to medications but also raise tensions between governments and pharmaceutical firms. Global health policy continues to face substantial difficulties in balancing public health concerns with the protection of intellectual property.
6) *Biotechnology and patents*: Complex molecules known as biologics, which are generated from living things, create special difficulties for the patent system. Contrary to conventional small-molecule medications, the production of biologics is frequently intricate and challenging to duplicate. Because of this, the approval process for biological substitute is different from the one for generic medications. Biologics' patent protection is a controversial topic as well because many patients may not be able to

[15] LÉA G. et P. Hall. Standards and intellectual property rights: an economic and legal perspective, Information Economics and Policy, 16, 2004, pages 67-89, 2004

afford their expensive medicines. Countries struggle to strike a balance between providing inexpensive access to biologic treatments and the need for innovation.

**WHAT ARE THE CHALLENGES FACED WHILE PATENTING**

The complexity of ideas, strict regulatory constraints, and ethical issues make licencing in the medical industry particularly difficult. The capacity of inventors to secure their ideas and the patenting procedure both may be severely impacted by these difficulties. The following are some of the main difficulties encountered when obtaining a medical patent:

Complexity of Inventions: Complex technologies, such as pharmaceutical substances, medical devices, or biotechnological processes, are frequently used in medical inventions. These inventions must be described in patent applications with great technical correctness and detail. The patent examination procedure is more difficult than in other industries because patent examiners must comprehend the scientific principles underlying the invention in order to evaluate its novelty and non-obviousness.[16]

Strict Patent Requirements: In order to be granted, a patent must satisfy a number of conditions, including innovation, non-obviousness, and industrial usefulness. Since there may be a great deal of prior art and current knowledge in the medical field, proving innovation can be particularly challenging. Furthermore, because of the abundance of scientific literature and the quick speed of research in this area, it could be difficult to demonstrate non-obviousness.

Medical inventions frequently generate ethical and moral questions regarding patient safety, human health, and the possible effects on vulnerable communities. Certain medical innovations, such as the use of genetics or stem cell therapies, may have their patent applications scrutinised by ethical review boards and society at large, resulting in delays or rejections.

Clinical Trial Data and Data Exclusivity: When it comes to pharmaceutical discoveries, regulatory approval is often based on clinical trial data, which might provide problems for data exclusivity. Even after the patent expires, the protection of data provided to regulatory agencies in many nations can prevent inexpensive or biosimilar competitors from entering the market.

Litigation and Patent Thickets: Patent thickets, in which several patents cover different facets

[16] SRINIVAS, S. Technological learning and the evolution of the Indian pharmaceutical and biopharmaceutical sectors, Ph.D. thesis, Massachu-setts Institute of Technology, Cambridge, MA, USA, 2004

of a single invention, are a problem for the medical industry. The commercialization of novel medical technology may be hampered by uncertainty caused by patent issues and litigation between various firms or inventors.

Timelines for Regulatory Approval: The drawn-out and demanding process of acquiring regulatory approval for medical discoveries, particularly medicines and devices for medical use, can greatly affect the actual duration of the patent's protection. The patent period may have already passed by the time a product is approved and released onto the market.

Patenting in Multiple Jurisdictions: Because medical ideas frequently find a global market, patent protection must be sought in several different jurisdictions. It can be challenging and expensive to navigate the numerous patent laws, rules, and procedures in different nations.

Patent Eligibility: Due to particular legal interpretations of the patent eligibility requirements, the patentability of some medical inventions, such as diagnostic techniques or natural biological materials, may be restricted in various jurisdictions.

Emerging Technologies: New issues in patenting are brought on by the quick development of medical technology, such as the use of artificially intelligent systems in healthcare or gene editing methods. For both inventors and patent examiners, determining the proper level of patent protection for developing technology can be difficult. The process of obtaining a patent in the medical industry is intricate and diverse, requiring careful evaluation of all relevant technological, moral, and legal considerations. Inventors and businesses have to deal with strict guidelines, ethical dilemmas, and the ever-changing environment of healthcare development and research. Despite the difficulties, obtaining a patent for a medical invention can be extremely important for promoting innovation, encouraging research funding, and ultimately enhancing patient care and wellbeing.

**CASE STUDIES**

1. **Turmeric Patent:** The Indian Gathering for Logical and Modern Exploration (CSIR) had protested the patent allowed and given reported confirmations of the earlier workmanship to USPTO. However it was undeniably true that the utilization of turmeric was known in each family since ages in India, it was a considerable errand to find distributed data on the utilization of turmeric powder through oral as well as effective course for wound mending. Due to broad explores, 32 references were situated in various dialects in particular Sanskrit, Urdu and Hindi. Thusly, the USPTO disavowed the patent, expressing that the cases made in the patent were self-evident

and expected, and concurring that the utilization of turmeric was an old specialty of mending wounds. In this way, the conventional information (TK) that had a place with India was defended in Turmeric case.

The turmeric patent retraction is the earliest illustration of a fruitful test to a patent over customary information. It was the initial occasion when a patent in view of customary information on a non-industrial nation had been effectively tested. It exhibited both that 'outlandish patent can be tested' and the trouble of actually taking a look at in one nation (for this situation the US) whether public information about a thought as of now exists in another nation (for this situation India). The legitimate expense caused by India was assessed to be about at US $10,000 however the immaterial worth to the Indian clients is tremendous.

In a distribution in Nature K. CSIR's Overseer of Board for Logical and Modern Exploration (CSIR) during 1995 - 2006, R. A. Mashelkar, said the outcome of the case had sweeping ramifications for the security of the customary information base, "in India as well as in other Underdeveloped nations" [8]. In the paper the creator proceeds to express that the CSIR then Chief R. Mashelkar had said 'the case likewise features the significance of archiving conventional information, to give proof of earlier information' To keep away from/forestall patent awards to TK in India, a drive has been taken to report and distribute all the T.K. by an e-library and such library is called as Customary Information Computerized Library (TKDL). TKDL gives subtleties of logical and conventional information organized in a way as per the grouping of worldwide licenses. This kind of licensed innovation assurance intends to keep individuals outside the local area from getting protected innovation Freedoms over Conventional Information. The Conventional Information Computerized Library (TKDL) is an accessible data set of customary medication ordered by India. This provisions for proof that help earlier craftsmanship by patent analysts while evaluating plant application.[17]

In 2017 World Protected innovation Association (WIPO) distributed a Tool stash to report conventional information. In the Tool stash it the meaning of Conventional information (TK) documentation is 'TK documentation is fundamentally a cycle in which TK is recognized, gathered, coordinated, enlisted or kept here and there, as a way to progressively keep up with, make due, use, scatter or potentially safeguard TK as per explicit objectives'.

2. **Neem Patent:** W.R. Grace and the United States Department of Agriculture first submitted the patent for neem to the European Patent Office. According to the aforementioned patent, fungus on plants can be controlled by touching them with a

[17] S. Kumar, “India wins battle with USA over turmeric patent”, The Lancet, Vol. 350 (9079), (1997), pp 724. DOI: 10.1038/37838

formulation of Neem oil. India has launched a lawsuit to challenge the patent's granting. The Research Foundation for Science, Technology and Ecology (RFSTE), based in New Delhi, filed a lawsuit opposing this patent in collaboration with the International Federation of Organic Agriculture Movements (IFOAM) and Magda Aelvoet, a former green MEP.4. The Neem tree is a legendary tree in India. From its roots to its spreading top, the tree is full of powerful substances, most notably one contained in its seeds named azadirachtin. In so many different disciplines, it serves as an astringent. Leprosy, diabetes, skin conditions, and ulcers are just a few of the maladies that can be treated using the bark, leaves, blossoms, and seeds of the neem tree. Since ancient times, neem twigs have been utilized as antibacterial teeth brushes. the hydrophobic extracts of neem seeds were known and used for generations in India, both in the treatment of human dermatological illnesses and in the protection of agricultural plants from fungal infections, according to the opponents' provided evidence of old Indian ayurvedic writings. The patent was cancelled by the EPO because it lacked novelty, an innovative step, and potentially even relevant previous art. In addition, Neem-based emulsions and solutions recently lost a number of US patents.[18]

**Futuristic Approach and Conclusion**

The preservation of medicinal plants and issues relating to patents in the pharmaceutical industry present complicated problems that call for a careful balancing act between encouraging innovation and guaranteeing equal access to healthcare. Addressing global health inequities, avoiding biopiracy, promoting sustainable practises, and safeguarding traditional knowledge are all necessary to achieve this balance. We could move towards a more equitable and long-term sustainable approach to medicinal development and access to healthcare by encouraging collaboration and trust between pharmaceutical firms, researchers, and local communities.

In order to solve the difficulties associated with patenting medicinal plants, it is essential to create a thorough legal system that values and safeguards traditional knowledge. The rights of indigenous populations and the promotion of innovation in the medical field should be balanced within this framework. For the long-term preservation and advancement of traditional medicine, cooperation among diverse stakeholders is crucial, including indigenous people, researchers, legislators, and pharmaceutical companies.

[18] U., Hellerer and K. Jarayaman, “Greens persuade Europe to revoke patent on neem tree”, Nature, vol. 405, (2000), pp 266–267.

In conclusion, it is crucial for the pharmaceutical industry to protect traditional knowledge and therapeutic plants through patents. We can guarantee the continued existence, respect, and innovation of conventional healthcare for the benefit of everyone by putting in place strong legal frameworks, resolving issues, and encouraging collaboration.

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