INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed

www.ijlra.com

 ISSN: 2582-6433

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 ISSN: 2582-6433

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 ISSN: 2582-6433

PHARMACEUTICAL PATENTING IN INDIA- PROBLEM OF PUBLIC ACCESS TO HEALTH

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ABSTRACT: -

Laws pertaining to intellectual property rights (IPRs) have been more well-known in recent years, providing confidence to inventors that their creations, concepts, or discoveries would be safeguarded. One of the most important parts of intellectual property rights is patent law. Nonetheless, patent limits might make it more difficult for everyone to get necessities like medication.

This research paper explores the importance of pharmaceutical drugs, their patenting in India, and the challenges they pose in terms of public health access.

India has long been commended for modifying its pharmaceutical regulations to meet local health demands, putting the welfare of its people first and coordinating them with the country's economic progress. With a high proportion of the population living in poverty and the majority of medical costs being paid for out of pocket, India is experiencing a serious health crisis with issues with medicine supply, affordability, and healthcare access.

In order to reconcile India's commitment to ensuring that the impoverished have access to medications with its responsibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Section 3(d) of Indian patent law grants exclusivity. This is a significant change from the TRIPS implementation. Currently, one of the main concerns is India's system for pharmaceutical patents. The Indian pharmaceutical industry and the Indian market are vital sources of reasonably priced generic medications, which are critical for maintaining public health. The Doha Declaration on TRIPS and Public Health (2001), to which India was a signatory, has had a major impact on drug access globally. India's prosperity depends on having a pharmaceutical sector that is export-oriented and actively involved in civil society. The nation has led the area in worldwide access The country has been a regional leader in the global access to medicines campaign, showcasing the potential for an alternative

 ISSN: 2582-6433

pharmaceutical industry.

The Supreme Court's judgement in the Novartis case, like other recent rulings under Indian patent law, demonstrates India's ongoing dedication to public health. The patent system for pharmaceuticals does, however, impede generic competition, which drives up costs and restricts access to medications in underdeveloped nations.

KEYWORDS: - Intellectual Property Rights, Pharmaceutical Drugs, Patenting, TRIPS, Public Health.

Introduction: -

Background on pharmaceutical patenting in India

Since 1970, the question of whether pharmaceutical innovations in India can be patentable has been hotly contested. Sections 2(1)(j), 2(1)(a), and Section 3 of the Patents Act 1970 (hereinafter referred to as the Act), in particular Sections 3(d), 3(e), and 3(i), provide guidance for the understanding and interpretation of patentability for certain innovations in India. Examiners of pharmaceutical innovations might also refer to the 'Guidelines for Examination of Patent Application in the area of Pharmaceuticals' published by the Office of the Controller General of Patents, Designs, and Trademarks. In the 1970s, India became a major supplier of reasonably priced pharmaceuticals to several emerging and impoverished countries. The Indian pharmaceutical industry became almost self-sufficient between 1970 and 1994, and it was one of the top exporters of generic drugs. India was a major supplier of reasonably priced generic pharmaceuticals to many developing nations. However, there was no incentive for innovation in the business because of India's patent regulations at the time, which did not permit patenting pharmaceutical items.

India reached an agreement with the World Trade Organisation (WTO), and it became operative on January 1, 1995. Article 27 of the TRIPS agreement (Trade-Related Aspects of Intellectual Property Rights) mandates the adoption of both process and product patenting in all technical domains, including food, medicine, chemicals, and microorganisms. The TRIPS agreement is located in Annex 1C of the WTO agreement. India has to change its patent rules to provide for the protection of pharmaceutical product patents in order to comply with TRIPS. The Supreme Court of India cited a letter dated December 17, 2004, from the WHO's

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HIV/AIDS Director to the then-Minister of Health and Family Welfare, Government of India, during the legislative process pertaining to pharmaceuticals. The letter emphasised India's position as a major global supplier of reasonably priced antiretroviral medications and essential pharmaceuticals, and it urged India to continue providing these drugs to the world's poorest countries without enacting needless restrictions that aren't required by the TRIPS Agreement and could impede their access. Consequently, in 2005, the Indian Parliament amended Section 3(d) of the Patents Act to ensure that India's patent laws complied with TRIPS while also safeguarding public health and interests. This amendment is reflected in the data provided in the Annual Reports of the Indian Patent Office, showing a significant 60.17% increase in the grant rate of pharmaceutical inventions from 2012 to 2017.[1]

Importance of public access to medicines

i) **Health and Well-being:** It is necessary to preserve health and well-being to have access to critical medications, which is a fundamental human right. Drugs are necessary for the diagnosis, treatment, and management of illnesses as well as the reduction of pain and suffering.

ii) **Reducing Mortality and Morbidity:** Death and morbidity rates can be considerably lowered by having access to medications. When illnesses are treated appropriately with necessary medications, health outcomes are improved and disease progression can be stopped.

iii) **Poverty Alleviation:** Because medical expenses are so high, illnesses and diseases have the potential to drive people and families farther into poverty. Having access to reasonably priced medications might lessen this cost and save families from becoming impoverished.

iv) **Enhancing Productivity:** Due to diminished capacity to work and absence, illnesses can lower production. Having access to medications can hasten recovery and allow individuals to return to their regular activities, which boosts the economy.

v) **Preventing Public Health Crises:** Pandemics and other public health emergencies must be prevented and controlled, and this requires access to medications. Access to medications in a timely manner can prevent the spread of infectious illnesses and perhaps save lives.

[1] Phillipe Cullet," Patent and medicines: The Relationship between the TRIPS and The Human Right to Health" (2003) 79 International Affairs.

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vi) **Promoting Social Justice:** Ensuring that all individuals, irrespective of their financial background, have access to the necessary medical treatment is a means of advancing social justice.

vii) **Fulfilling Sustainable Development Goals:** Achieving a number of Sustainable Development Goals (SDGs), such as eliminating poverty (SDG 1), promoting equality (SDG 10), and maintaining excellent health and well-being (SDG 3), depends on having access to medications. In addition to being a question of public health, public access to medications also affects social justice, human rights, and sustainable development. To guarantee that vital medications are accessible, inexpensive, and available to everyone in need, governments, pharmaceutical firms, civil society, and international organisations must work together.

"Pharmaceutical patenting in India, while fostering innovation and research, poses significant challenges to public access to medicines. This paper examines the impact of pharmaceutical patents on access to affordable healthcare in India, explores the effectiveness of existing mechanisms such as compulsory licensing, and proposes policy recommendations to strike a balance between intellectual property rights and public health needs."

Pharmaceutical Patenting in India: A Historical Perspective

- **Evolution of Patent Laws in India and Importance of TRIPS agreement on Indian Patent Regime**

The Patents Act, 1970 is the main piece of law that controls the patent system in India. This statute originally only permitted process patents, not product patents for inventions pertaining to medicines, foods, or chemicals. Nonetheless, India has allowed product patenting since 2005. India joined the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement in 1995 as a World Trade Organisation (WTO) member. TRIPS lays forth the minimal requirements for intellectual property legislation that each member nation must adhere to. India was required to modify the Patents Act in order to comply with the terms of TRIPS as a signatory.The Patents (Amendment) Act, passed in 1999, brought about the first modification to the Patents Act. This amendment introduced the issuance of Exclusive Marketing Rights (EMRs) on certain patents and allowed the filing of new applications for product patents in the fields of medicines and agrochemicals starting on January 1, 1995.

In order to meet its responsibilities under TRIPS, India modified the Patents Act once again in

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2002. A consistent term of 20 years for all kinds of innovations was adopted by this amendment. Along with adding a clause enabling inverting the burden of evidence in infringement lawsuits involving process patents, it also brought the concept of "invention" into compliance with the TRIPS agreement.

The Patents (Amendment) Act of 2005 brought about the third set of changes to the patent legislation. The Indian product patent system was established by this legislation. Under some restrictions, it permitted the patenting of novel characteristics, applications, or forms of well-known chemicals. It also modified provisions related to pre-grant and post-grant oppositions and introduced the grant of compulsory licenses for the export of patented pharmaceutical products under certain conditions.[2]

- **Criteria of Patentability:**

Inventions that satisfy certain requirements—referred to as the criteria of patentability—are awarded patents. The Indian Patent Act defines a patentable invention as "a new product or process involving an inventive step and capable of industrial application." Therefore, the basic requirements for an invention to be patentable are as follows:[3]

a) Novelty: An invention's subject matter must be unknown as of the date of patent filing in order for it to be eligible for patent protection. If an innovation hasn't been utilised globally or published in any document, it's deemed new.

b) Inventive Step: For an invention to be considered innovative, it must either represent a significant breakthrough in technology above what is already known, have practical applications, or both. A person with expertise in the relevant subject shouldn't be able to tell.

c) Industrial Applicability: The innovation needs to be able to be produced or used in a commercial setting. For instance, a novel and creative way to extract cancer cells from a patient's body could not have industrial application and hence be unpatentable.

The Process of Pharmaceutical Patenting in India

The pharmaceutical sector is heavily dependent on information, yet research is expensive and uncertain. New, creative, and practical items or procedures are frequently the results of research projects. Pharmaceutical businesses must seek patent rights over their created goods or methods

[2] Nilesh Zakharias, 'Patents and The Indian Pharmaceutical Industry – Intellectual Property – India' (Mondaq.com, 2019) available at: https;//www. Mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical-industry (assessed on October 16, 2021)
[3] The Patents Act, 1970 (act no.30 of 1970)

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to safeguard their ideas from unapproved commercial usage in this fiercely competitive sector. Pharmaceutical patents in India can be categorized as follows, based on the list provided by the Indian patent office on its website:

1) **Drug compound patents**: These patents assert the medicinal compound's structure. These patents frequently make use of Markush type claims, which permit the presence of many "functionally equivalent" chemical entities in one or more medicinal compound components. Patents on drug compounds provide the most protection for a company's product since, until the patent expires, other firms are not allowed to produce or sell any formulation containing the medicine or prepare it using any synthesis method.
2) **Formulation/composition patents**: These patents address certain technology for formula preparation and ingredient quantification. For instance, an ayurvedic anti-retroviral substance for the treatment of acquired immunodeficiency syndrome was claimed in Indian Patent No. 203986.This composition included:
   - Guduchi or Giloe (cordifolium): 5 mg-2 gm
   - Panash or Kathal (jack fruit): 2 mg-5 gm
   - Tulsi or Krishna Tulsi (Holy Basil): 5 mg-5 gm
   - Kuda or Kutaja (Kurchi): 2 mg-2 gm
   - Bhui Amla or Bahu Patra (Gooseberry): 5 mg-2 gm These ingredients were combined with pharmaceutical acceptable excipients.
3) **Synergistic combination patents**: It involves the interaction of two or more medicines, amplifying or intensifying their effects. These patents describe novel medication combinations that demonstrate synergy. For example, roflumilast and salmeterol were claimed to work synergistically in Indian Patent No. 206328. A medication including a β2 adrenoceptor agonist (like salmeterol) and a PDE inhibitor (like roflumilast) from the PDE4 inhibitors group was detailed in the patent, either in a fixed or free combination.
4) **Technology Patent**: A pharmaceutical formulation with a masked taste, the masking of which persists during administration of the formulation, in particular in the form of a suspension in an aqueous vehicle, characterised in that it comprises at least the following elements: "These patents are based on the techniques used to solve specific technology-related problems, like taste masking, increase in the solubility, etc." a methacrylic polymer that is soluble in acidic media and practically insoluble at neutral or alkaline pH; a cellulosic polymer that is soluble in organic solvents but practically insoluble in water, regardless of pH; an active ingredient that is dispersed evenly and in the molecular state throughout the mixture, which takes the form of an atomized matrix.

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5) **Polymorph patents:** It includes altering a known compound's crystal structure or physical form; this is frequently done to improve stability or lower impurities. For example, the crystalline form B4 of atorvastatin magnesium was claimed in Indian Patent No. 237261. This form was identified by a certain X-ray powder diffraction pattern and purity of more than 98%. Section 3(d) of the Patents Act, 1970, as revised in 2005, is the primary statute that governs the granting of polymorph patents in India. According to this provision, a substance's new form cannot be patented if its existing effectiveness is not improved or if a new property or application is not discovered. This section's goal is to stop "evergreening of patents" and make sure that new forms are only patented when they are genuinely worthy.
6) **Biotechnology Patents:** In order to create pharmaceutical goods, live things or biological components are used. A vast variety of medicinal, immunological, and diagnostic items are covered by these patents. An aqueous, human serum albumin-free interferon solution, for example, was claimed in Indian Patent No. 234072. It contained interferon-alpha, a non-ionic detergent, a buffer for pH adjustment to 4.5–5.5, benzyl alcohol, and optionally an isochronizing agent. It's interesting to note that, following the establishment of the product patent system in 2005, Indian Patent Office issued this invention, number 234072, as its first product patent. Switzerland's F. Hoffmann-La Roche Ltd. is the owner of it.

On the other hand, process patents do not claim the product itself but rather cover a new and inventive process for producing a specific product.[4]

- **Patent Application Process**

The patent application process for pharmaceuticals in India involves several key steps. Here's an overview:

i) **Preparation of the Patent Application:** The first stage is to draft a patent application that contains the invention's complete description, any relevant illustrations, and claims that specify the invention's parameters.

ii) **Filing the Application:** The Indian Patent Office (IPO) accepts online or in-person filings for the application. The patent specification, a request for inspection, and the required payment must all be included in the application.

[4] Vipin Mathur, "Patenting of Pharmaceuticals: An Indian Perspective"30 IJDDR (2012)

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iii) **Publication:** After 18 months from the priority date, if sooner, or the filing date, the application is published in the Indian Patent Journal. If requested, an applicant may, nonetheless, ask for early publication.

iv) **Examination:** A patent examiner reviews the application to assess its industrial usefulness, inventive step, and originality. Within the allotted time, the applicant must address any concerns made by the examiner.

v) **Grant or Refusal:** The patent is awarded if the examiner finds the application satisfactory and all objections are resolved. The application could be rejected if it isn't. The applicant receives written notice of the judgement.

vi) **Opposition:** Pre-grant objection may be filed against the patent within six months of the date of publication after the patent's issuance. Anyone may submit an objection on the basis of predetermined reasons.

vii) **Sealing of the Patent:** The patent is sealed and the applicant receives a patent certificate once all conditions are satisfied and any objection is addressed.

viii) **Maintenance of the Patent:** The patentee must pay renewal fees periodically to maintain the patent in force for the entire term of 20 years from the filing date

- **Post-grant Opposition:** From grant, the patent is subject to post-grant objection for a year from the day the award was published in the official patent publication.

Role of Indian Patent Office:

As a branch of the Controller General of Patents, Designs and Trademarks (CGPDTM) agency under the Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, Government of India, the Indian Patent Agency (IPO) is responsible for managing the country's patent award procedure. Over the course of its 150-year history, the Patent Office has undergone a number of significant changes.

The Patents Act of 1970 was amended to conform to the terms of international agreements and treaties to which India became a party. With large expenditures in human and physical infrastructure over the last 10 years, the Indian government has created a strong foundation for intellectual property rights in the country. Following its designation by the PCT as an International Searching Authority and International Preliminary Examining Authority, the Indian Patent Office commenced its functions on October 15, 2013. We have access to a large corpus of patent and non-patent material that addresses the PCT minimum documentation. Our skilled and highly educated Examiners are our greatest advantage. IPO

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has developed a quality management system that encompasses both technical and administrative office tasks. A fully computerised processing system guarantees prompt information distribution and disposal on real time basis.[5]

Impact of Pharmaceuticals Patents on Access to Medicines:

Since the establishment of Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, there has been growing concern over the relationship between stronger intellectual property rights (IPR) and pharmaceutical market monopolies as well as the delayed entrance of less priced generic medications. In poor nations, inadequate access to necessary medications is already an issue that has become worse. Despite a considerable quantity of research and debate on the topic, there aren't many empirical studies on the issue. In this study, we examined the effect of IPR on pharmaceutical availability and catastrophic medical cost using data from the World Health Surveys conducted in 2002 and 2003. The Ginarte and Park (1997) index of patent rights was used to determine the level of IPR protection in each country. Estimates were changed to take into consideration national and individual factors. In the results of Despite a considerable quantity of research and debate on the topic, there aren't many empirical studies on the issue. In this study, we examined the effect of IPR on pharmaceutical availability and catastrophic medical cost using data from the World Health Surveys conducted in 2002 and 2003. Ginarte and Park's (1997) patent rights index was used to evaluate each country's level of intellectual property rights protection. Estimates were adjusted to take both personal and societal aspects into consideration. Multilevel logistic regression analysis revealed that higher levels of IPR significantly increased the likelihood of not having access to prescription pharmaceuticals, even after controlling for national and individual socioeconomic status indicators connected to medication availability. The study's findings, which demonstrate that intellectual property rights (IPRs) negatively impact pharmaceutical access, call for more proactive supranational policymaking to improve access for low- and middle-income countries.

High Drug Prices and affordability issues:

International human rights concepts are based on the fundamental right to health. Ensuring equal access to pharmaceuticals has been a recurring concern, since it continues to be essential for further advancement in healthcare. The Sustainable Development Goals 2030 (SDG 2030) have been announced by the UN, and one of the main goals under the "Good Health and Well-

[5] https://ipindia.gov.in/about-us.html

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Being" aim is Universal Health Coverage (UHC). Diverse legitimate interests are sought to be balanced in the administration, enforcement, and regulation of intellectual property in order to advance equitable access to drugs and improve overall well-being.

Both wealthy and developing nations are deeply concerned about the rising costs of medical care and prescription drugs. Healthcare expenses can be significantly impacted by pharmaceutical prices, which frequently make up a sizable amount of the entire cost of treatment. Public healthcare spending is often low in developing nations, and health insurance coverage is scarce, especially for the unorganised and informal sector's members who do not have social security.

The majority of the public lacks knowledge and there are economic concerns, which contribute significantly to the limited coverage of private health insurance. People now face greater healthcare expenses as a result of the shift from communicable to chronic, non-communicable diseases, as public health systems are ill-equipped to handle these emerging health issues.
Because of this, households in developing nations frequently rely significantly on out-of-pocket (OOP) healthcare expenses, which have the potential to drive many families into poverty. Two of the main causes of this phenomena are the high cost of vital medications that can save lives and the high cost of healthcare.

Healthcare costs are greatly impacted by the expansion, structure, and associated laws, regulations, and pricing tactics of the pharmaceutical business. Nonetheless, the pharmaceutical industry's economic viewpoint frequently minimises these negative consequences, highlighting the sector's innovation-heavy structure and the life-saving qualities of its goods as grounds for unrestricted pricing policies.[6]

- **Availability of Generic medicines**

Access to cheap healthcare is greatly facilitated by the availability of generic medications, particularly in underdeveloped nations where household costs associated with healthcare are frequently high. Despite being bioequivalent to their branded counterparts, generic medications are sometimes offered for a much cheaper price because of reduced marketing and R&D expenditures.

[6] Marion Motari, "The Role of Intellectual Property Rights on access to Medicine" BMC Public Health 490 (2021)

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Several factors influence the availability of generic medicines:

i) **Regulatory Environment:** The supply of generic medications may be impacted by the regulatory environment around pharmaceuticals. Access to these medications is often greater in nations with well-established legislation governing generic drugs.

ii) **Intellectual Property Rights:** Generic medication availability may be restricted by patent protection. Generic versions of copyrighted medications may take longer to become available in nations with strict patent laws.

iii) **Market Competition:** Generic medication availability is encouraged by a competitive market environment. Prices typically drop when numerous producers create generic copies of the same medication, increasing accessibility to the medications.

iv) **Procurement and Distribution Systems:** Having effective mechanisms for distribution and procurement is crucial to guaranteeing the supply of generic medications. Shortages and restricted availability can result from poorly managed supply chains.

v) **Public Health Policies:** Generic medications may be more widely available if government policies support their usage. This covers actions like rules for generic prescription and generic replacement.

vi) **Quality Assurance:** The availability of generic medications depends on their quality being guaranteed. Enforcing quality standards is crucial for regulatory bodies to uphold customer confidence in generic products.

vii) **Awareness and Education:** Increased knowledge regarding the efficacy and safety of generic medications among patients and healthcare professionals may also help to increase their accessibility.

The availability of generic medications is often influenced by a confluence of commercial, policy, and regulatory variables. In order to increase the availability of and encourage the use of generic medications as a cheap substitute for branded ones, efforts are frequently made to increase access to affordable healthcare.

- **Case studies or examples illustrating the impact: -**

Here are some case studies and examples illustrating the impact of generic medicines on healthcare access and affordability:

i) **India's Generic Drug Industry:** Several commercial, policy, and regulatory factors typically interact to affect the accessibility of generic drugs. Efforts to

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improve access to inexpensive healthcare are sometimes undertaken in an attempt to promote the use of generic pharmaceuticals as a less expensive alternative to branded ones and to enhance their availability.

ii) **The Impact of Generic Competition on Drug Prices:** Price reductions for branded medications can be substantial when generic competition enters the market. For instance, the entry of generic versions of cholesterol-lowering statin medications resulted in a significant drop in cost, making these medications more accessible to patients.

iii) **Generic Drug Use in the United States:** The adoption of generic medications has contributed significantly to lower healthcare expenditures in the US. The FDA claims that between 2008 and 2018, generic medications helped the American healthcare system save $1.68 trillion.

iv) **Generic Drug Access in Low- and Middle-Income Countries:** Low- and middle-income nations now have easier access to reasonably priced generic copies of copyrighted medications because to initiatives like the Medicines Patent Pool (MPP). For instance, the MPP's contracts with pharmaceutical firms have made it possible to produce and market generic versions of medications for hepatitis C, TB, and HIV/AIDS.

v) **Generic Drug Shortages:** Although generic medications are often less expensive, shortages can happen for a number of reasons, such as problems with production or legal obstacles. Access to and the cost of healthcare may be impacted by these shortages, especially for necessary medications.

vi) **Government Policies Promoting Generic Drug Use:** Generic substitution and generic prescription rules are among the measures that some nations have put in place to encourage the use of generic medications. These regulations have improved patient access to medications and assisted in lowering healthcare expenditures. These illustrations show how important it is to ensure the availability of and encourage the use of generic medications by highlighting the substantial influence they may have on healthcare affordability and access.

Measures to improve Access to Medicines

Increasing drug availability, with particular emphasis on countries of the developing world, is a complex problem that is to be solved by disseminating the proper policy, regulations, and

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market-based solutions.

Here are some measures that can help improve access to medicines:

i) **Generic Drug Promotion:** Lowering drug costs and enhancing access to reasonably priced medications can be achieved by encouraging the use of generic medications through programmes like generic substitution and generic prescribing.

ii) **Price Regulation:** Ensuring that medications are accessible and affordable for all demographic groups can be achieved through the implementation of price regulation mechanisms, such as reference pricing or price controls.

iii) **Compulsory Licensing:** Compulsory licences for essential medications can enable generic producers to manufacture and market patented drugs at reduced costs, thereby expanding the availability of these medications.

iv) **Health Technology Assessment (HTA):** By determining the value of medications and providing information for pricing and reimbursement decisions, HTA can help make sure that resources are distributed effectively to increase access to affordable treatments.

v) **Public Procurement and Supply Chain Management:** Enhancing supply chain management and public procurement procedures can help guarantee a consistent supply of medications, lower stockouts, and increase accessibility to necessary medications.

vi) **Intellectual Property Flexibilities:** Access to reasonably priced generic medications can be facilitated by making use of intellectual property law flexibilities, such as those permitted under the TRIPS Agreement, particularly during emergencies or public health crises.

vii) **Health Insurance Coverage:** Increasing the number of people covered by health insurance, especially the most disadvantaged groups, can lower prescription drug costs out of pocket and increase access to medical care.

viii) **Capacity Building and Technology Transfer:** Enhancing local manufacturing capabilities and promoting technology transfer can contribute to a rise in domestic medicine production, lowering reliance on imports and enhancing accessibility.

ix) **Public-Private Partnerships (PPPs):** Participating in PPPs can assist in utilising the resources and knowledge of the public and private sectors to enhance access to medications, particularly in underprivileged areas.

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x) **Patient Education and Awareness:** Improving patient knowledge about medication availability and usage can enhance treatment compliance and enhance overall health results.

By implementing these measures, policymakers can enhance global population health outcomes and enhance access to necessary medications by putting these recommendations into practice

Compulsory Licensing and its Implications

There is no definition for "compulsory licencing" in the Indian Patents Act. It is generally understood to refer to a scenario in which a government allows another party to manufacture a patented good or method without the patent owner's permission or with the intention of using the patented invention itself. Crucially, the patent holder retains all rights related to the patent, including the right to payment for any products copied using the compulsory licence.

Sections 84 and 92 of the Act specify the requirements for issuing a compulsory licence, and Chapter XVI of the Act contains the provisions pertaining to compulsory licencing in India. Under Section 84, any person, regardless of whether they hold a license for the patent, can request a compulsory license from the Controller after three years from the grant of the patent if:

i) The reasonable requirements of the public regarding the patented invention are not being met.
ii) The patented invention is not available to the public at a reasonably affordable price.
iii) The patented invention is not being worked in the territory of India.

Furthermore, under Section 92(1) of the Act, the IPO suo motu may grant compulsory licences in response to a notification from the Central Government in situations involving extreme urgency, national emergency, or public non-commercial use.

The objectives of the section 84 are to make it harder for patents to be abused as monopolies and to make it easier for interested parties to commercialise inventions. The nature of the invention, the efforts made by the patentee to use the invention, the applicant's capacity to use the invention for the benefit of the public, and the applicant's attempts to secure a reasonable licence from the patentee are among the factors listed in Section 84(6) that the IPO considers when awarding a compulsory licence. These provisions reflect the Indian Parliament's effort to strike a balance between the interests of innovators and the wider public interest to create an

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environment conducive to creativity and innovation.[7]

In addition to granting patentees the ability to enjoy a monopoly, Section 83 of the Act makes clear that patent rights are not misused in order to unjustly restrict trade or negatively impact the transfer of technology.

The IPO pointed out that patent rights entail obligations to the public and that it is essential to strike a balance between these rights and obligations when evaluating applications for compulsory licencing.

- **Price control Mechanism**

Governments impose price control mechanisms as regulatory measures to manage the costs of necessities, such as prescription drugs, in order to guarantee accessibility and affordability. These are a few typical pharmaceutical industry price control techniques:

i) **Price Ceilings:** The highest prices that pharmaceutical companies may charge for their goods may be set by governments. This can guard against price gouging and guarantee the continued affordability of necessary medications.

ii) **Cost-Plus Pricing:** A fair markup is added to the cost of production to determine the price of a pharmaceutical product under this mechanism. This keeps prices from being too high while guaranteeing that businesses can pay their expenses.

iii) **Reference Pricing:** The process of reference pricing entails determining the cost of a pharmaceutical product by comparing it to similar products in other nations or areas. This can guarantee that prices are fair and competitive and help avoid price disparities.

iv) **Price Monitoring and Reporting:** To make sure that drug prices stay fair and reasonable, governments may set up systems to track and report on drug prices. Price gouging and other pricing abuses may be easier to spot as a result.

v) **Price Regulation Authorities:** Certain nations have instituted autonomous regulatory bodies tasked with overseeing the prices of pharmaceuticals. These authorities have the power to impose rules, keep an eye on compliance, and set prices.

[7]The Patent Act,1970, India, available at: https://www.candcip.com/pharmaceutical-patenting-in-india

 ISSN: 2582-6433

vi) **Subsidies and Price Caps:** Governments can guarantee that necessary medications are within the financial means of low-income groups by imposing price caps or offering subsidies. For vulnerable populations, this can help increase access to medications.

All things considered, price control measures are vital to maintaining the affordability and accessibility of necessary medications for every member of the public. To prevent unforeseen consequences like limiting innovation or decreasing the availability of medications, they must be implemented cautiously.

- **How Patent hinders Right to Health**

In developing nations, access to branded and patented medications is frequently hampered by their high costs. New drug patents enable the inventor to gradually recover their R&D expenses. Sponsors can, however, exploit several legal snags to increase the scope of their patent protection, such as charging more for novel ideas.

Bilateral trade agreements, for instance, could be used by businesses to set the price of new medications according to their economic worth, which considers aspects like cost-effectiveness, safety, and efficacy in comparison to current treatments. These strategies may result in patented medications being out of reach for citizens of low-income nations. As a result, access to necessary medications and healthcare services is now significantly impacted by international trade agreements.

Furthermore, the World Health Organisation (WHO) only has non-voting observer status in the main political bodies of the WTO because of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. As a result, WHO has less influence over significant WTO decisions pertaining to social, economic, and health rights.

- **Balancing intellectual property rights with access to medicines**

First and foremost, creating new medications necessitates large financial outlays, highly developed methods, and information availability. Second, the global pharmaceutical industry depends on Intellectual Property Rights (IPRs) like patents to safeguard their investment. By passing these costs on to end consumers, they reap significant profits. Thirdly, under the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), nations having the capacity to manufacture vaccines are required by international trade agreements to offer patent protection.

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- IP laws are therefore required to encourage innovation in the R&D of novel medications or vaccines. However, the worldwide pharmaceutical industry creates a monopoly over life-saving drugs because of these intellectual property rights laws. Investors profit billions of dollars because of this. But it also makes it more difficult for new producers to enter the pharmaceutical research market.

- **TRIPS covering Public Health**

The necessity to strike a balance between patent rights and other significant interests, like public health, is acknowledged by the TRIPS agreement. Governments are permitted to enact laws that conform to TRIPS standards while also taking the necessary steps to safeguard public health. These guidelines might not always be appropriate for developing nations with underdeveloped infrastructure for healthcare and unfulfilled development needs. Developing nations may, nevertheless, make use of some TRIPS provisions to safeguard public health, especially about obtaining necessary medications. These alternatives include the promotion of generic medications, parallel importation, compulsory licencing, exclusions from patentability, and exceptions to patent rights.

Despite these clauses, there have been worries about how TRIPS will affect the availability of necessary medications, particularly in developing nations. These issues were brought up during the June 2001 WTO Ministerial Conference in Doha, Qatar. The TRIPS Agreement will be interpreted and implemented in a way that promotes public health and medical access, as agreed upon by WTO Ministers. The Doha Declaration on TRIPS and Public Health, which reiterates nations' sovereign rights to enact laws pertaining to compulsory licencing and parallel imports to safeguard public health and give precedence to intellectual property, reflects this commitment.

Interpreting Article 31(f) of the TRIPS Agreement—which stipulates that compulsory licences should be used "predominantly for the supply of the domestic market"—is particularly interesting. While paying fair royalties to patent holders, governments can grant licences to regional producers. Due to increased competition in the market for patented goods, this may result in lower consumer prices. The WTO has also decided to modify the TRIPS clause regarding mandatory licences, acknowledging that many developing nations lack the internal resources necessary to produce patented medications.

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August 2003 saw the introduction of a temporary waiver that permitted nations possessing the means of manufacturing to grant mandatory licences and export pharmaceuticals to nations in which local production was not feasible.

If member states satisfy the minimal requirements outlined in the TRIPS Agreement, they are free to choose how best to incorporate the agreement's requirements into their own national legal frameworks.

Case Laws:

NOVARTIS AG VS. UNION OF INDIA (UOI) AND ORS[8]

In an appeal of the IPAB's denial of Novartis' patent application for a "Crystal Modification of an N- Phenyl-2-Pyrimidineamine derivative, processes for its manufacture and its use," the company filed a special leave petition before the Supreme Court of India, citing Section 3(d) of the Act as justification for the denial.

The IPAB's ruling was upheld by the Supreme Court, but pharmaceutical patent applicants should take note of its conclusions. The Court clarified a few important points, one of which is incremental inventions. It was declared that patent protection for all incremental inventions involving pharmaceutical substances should not be excluded by the interpretation of Section 3(d). The Court made clear in its decision that it did not mean to reverse the fundamental shift in the patent regime that the removal of Section 5 from the Patent Act. The Court further stated that the Applicant's materials and data, which did not support the claimed invention's therapeutic efficacy, served as the basis for its decision. The Court emphasised that such claims must be backed by research data but did not rule out the possibility that improved bioavailability could improve therapeutic efficacy. The Applicant failed to provide evidence to support its claim of 30% higher bioavailability in free base form when compared to imatinib; as a result, the Court determined that the claimed invention did not disclose enhanced therapeutic efficacy.

Therefore, it would be against the intended outcome to interpret the judgement as discouraging inventions related to pharmaceuticals. The IPO and Indian Courts have continuously preserved the innovators' interests while upholding the sanctity of Section 3(d) since the Given ruling in

[8] Novartis AG vs. Union of India (UOI) and Ors. 1 Apr. 2013

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2013.

RANBAXY LABORATORIES LTD. VS. PFIZER HEALTH AB[9]

Ranbaxy Laboratories Ltd.'s pre-grant opposition against Pfizer Health AB's patent application for a pharmaceutical formulation was denied by the Indian Patent Office in 2007. Despite the opposition, Pfizer was awarded the patent.

As for Ranbaxy's claims under Section 3(d) of the Act, the Controller concluded that Pfizer had proven therapeutic efficacy by showing a 71% decrease in weekly episodes of urge incontinence when compared to a placebo. Furthermore, the Controller responded to the opposition's claim made in accordance with Section 3(e) of the Act, asserting that the invention qualified for patent protection because of the specification's disclosure of the synergistic effect. As a result, the Controller gave Pfizer the patent.

The opposition had contended that the composition claimed in the patent application was not patentable under Section 3(d) because it was a mixture of well-known substances with no appreciable variation in efficacy. Additionally, they argued that Section 3 should not allow a patent to be granted for a composition that lacks a synergistic effect (e). The Controller, on the other hand, disagreed, claiming that the composition was creative, innovative, and applicable to industry, and that it had a synergistic effect as evidenced by the weekly decrease in urge incontinence episodes. As a result, the Controller awarded Pfizer the patent after finding that the modified claims complied with Sections 3(d) and 3(e) of the Patents Act.

Conclusion: -

The impact of pharmaceutical patenting in India on public health access is a complicated and multidimensional issue. Patents are necessary to encourage innovation and investment in the pharmaceutical sector, but they can also make it more difficult for people to obtain necessary medications, particularly in underdeveloped nations. India's Patents Act aims to achieve a balance between encouraging innovation and guaranteeing that everyone has access to medications through its provisions for mandatory licencing and other protections.

Considering Section 3(d) of the Patents Act, the case studies of Novartis and Pfizer underscore

[9] Ranbaxy Laboratories Ltd. VS. Pfizer Health AB (2007)

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the difficulties faced by pharmaceutical companies in obtaining and defending patents in India. These cases also highlight how crucial strong patent laws and regulatory frameworks are to maintaining public health and facilitating the availability of reasonably priced medications.

To address the issues raised by pharmaceutical patenting, legislators, pharmaceutical companies, and civil society must keep up their positive communication going forward. In addition to improving access to medications, policies like supporting generic drugs, bolstering regulatory frameworks, and improving healthcare infrastructure can also foster innovation in the pharmaceutical industry.

In conclusion, resolving the complex issues surrounding pharmaceutical patenting and guaranteeing universal access to necessary medications require a balanced strategy that considers the interests of innovators and the public.