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RESEARCH ARTICLE

INTELLECTUAL PROPERTY RIGHTS AND PUBLIC HEALTH : A CRITICAL ANALYSIS

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Abstract

Intellectual Property plays a vital role in making sure that essential medicines and medical products are safe, affordable, easy to get, and widely available. IPR has supported the healthcare sector by improving patient treatment, by discover new cures for old diseases, boosting the economy, addressing global health problems, and ensuring long-term progress in medical care.This research paper looks at how Intellectual Property Rights (IPR), especially patentsaffect public health. IPR laws help companies by giving them the right to control their inventions, which encourages them to develop new medicines. However, these rights can also lead to high medicine prices, making it hard for poor people to afford life-saving treatments. The paper studies international rules like the TRIPS Agreement and shows how some countries, like India, use special options such as compulsory licenses to make medicines more affordable. Real-life examples are discussed to show how laws can protect both innovation and people's health. The paper also talks about how IPR affected access to medicines during the COVID-19 crisis. In the end, it suggests that the IPR system should be fair—supporting both medical research and everyone's right to get the treatment they need. Compulsory license is a legal process which allows a government to authorize the use of a patentedprocess and product invention without the consent of patent holder under certain conditions. In the context of public health, especially Compulsory License in developing countries like India, compulsory licensing serves as a critical tool to ensure access to affordable medicines. This paper explores the significance, legal framework, case studies, and public benefits of compulsory licensing, with a focus on its role in promoting public health, controlling monopolistic pricing, and addressing national emergencies.

Introduction:-

Intellectual Property Rights (IPR) are legal protections given to people who create new inventions, artworks, or designs. In medicine, these rights help to encourage innovation by giving companies the right to sell their new drugs exclusively for a certain period. But this can also cause problems for public health, especially in poorer countries, because it can make important medicines too expensive or hard to get.

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Public health is focused on making sure that everyone can access affordable and good-quality healthcare and medicines. When drug patents stop cheaper, generic versions from being made or sold, it creates a conflict between supporting new medical discoveries and making sure people can get the medicines they need.

Non Accessibility to life saving medicines, especially in low- and middle-income countries is always challenging. While patents grant pharmaceutical companies the exclusive right to manufacture and sell a drug, they often result in high prices that make life-saving medicines unaffordable to the public. Compulsory licensing plays a very important role in balancing the patent rights and public health needs. Compulsory license based on the utilitarian theory of Jeremy Bentham "greatest number of happiness to the greater number of people". It means in Compulsory license Law should provide maximum number of benefits to maximum number of people in the society. Compulsory license not only help in accessing medicines at a very cheaper price in one Country but it is helpful for many Countries during national emergency or national pandemic, or in great urgency. Everyone can be benefited by the Compulsory License who is in urgent need of life saving medicines whether he is rich or poor. In Compulsory License patentee is also get benefitted by getting reasonable royalty of his invention by applying the labour theory of John locke that the invertor has a natural right of the fruit of their efforts..

Intersection of intellectual property rights (IPR) and public health is a complex and contentious area, particularly regarding access to essential medicines. The literature reveals significant challenges posed by IPR, especially in developing countries, where high drug prices due to patent protections limit access to healthcare. This review synthesizes key findings from recent studies on the topic.

Invention-
Under 2(1)(j) of Patent Act ,1970 A New Product or Process involving an inventive step and capable of industrial application

Barriers to Access
High Costs of Patented Drugs: Patents create monopolies that lead to inflated prices, making essential medicines unaffordable for low-income populations(Li, 2011).

Impact of TRIPS Agreement: The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, while intended to promote innovation, often exacerbates health disparities by restricting access to generics(Oliveira & Santos, 2017)(Lelisa, 2024).

Recommendations for Reform:-

Compulsory Licensing: Advocates suggest implementing compulsory licensing to allow generic production of essential medicines, thereby improving access(Li, 2011)(Lelisa, 2024).

International Collaboration: A call for global partnerships among governments, organizations, and pharmaceutical companies is emphasized to balance IPR with public health needs(Lelisa, 2024).

The Need for a Balanced Approach
While IPR is essential for incentivizing pharmaceutical innovation, it must be balanced with public health objectives to ensure equitable access to medicines. The ongoing debate highlights the necessity for flexible IP frameworks that prioritize health equity alongside innovation(Babyar, 2022)(Abbott, 2013).

Conversely, some argue that strong IPR is crucial for fostering innovation in drug development, suggesting that without adequate protections, pharmaceutical companies may lack the incentive to invest in new treatments. This perspective underscores the ongoing tension between protecting intellectual property and ensuring public health access.

Legal Framework of Compulsory Licensing
The TRIPS Agreement, part of WTO rules since 1986-1994, made basic rules for protecting intellectual property in all member countries. It requires countries to respect each other's intellectual property, including patents. For medical innovations, it gives companies and research organizations exclusive rights to profit from their inventions, which encourages them to invest in research and create new medicines. Compulsory licensing is permitted under the TRIPS Agreement (Article 31) of the World Trade Organization (WTO), and incorporated into national legislations

like Section 84 of the Indian Patents Act, 1970. According to these provisions, a compulsory license can be issued on grounds such as:
-When Reasonable requirements of the public are not fulfilled;
-When the patented invention are not available at a reasonably affordable price;
-When of the patent is not working in the territory of the country.

How It Helps the Public
The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), created by the World Trade Organization (WTO), requires all member countries to give patent protection for medicines for at least 20 years. This rule is meant to support innovation by rewarding inventors. However, it can also make it harder for people to get the medicines they need, especially in poorer countries.

How TRIPS affects public health:
It raises the cost of medicines by stopping cheaper, generic versions from entering the market.

It makes it harder to get affordable treatments for serious diseases like HIV/AIDS, cancer, and tuberculosis.

It delays access to low-cost, life-saving drugs.

Solutions within TRIPS:
To deal with these problems, the TRIPS Agreement includes some flexible options, such as:
Compulsory licensing (under Article 31):
This lets governments allow someone else to make and sell a patented medicine without the patent holder's permission, but under certain rules.

Parallel importation:
This allows a country to buy a patented drug from another country where it is sold at a lower price.

The Doha Declaration of 2001 confirmed that countries can use these flexible options to protect public health and make sure people can access medicines.

Improves Access to Medicines
Patents help pharmaceutical companies recover the money they spend on research and development (R&D) by giving them exclusive rights to make and sell their drugs. But in reality, patents often:

Allow companies to charge very high prices without competition.

Stop others from making cheaper, generic versions of the medicine.

Delay the availability of other treatment options in the market.

Compulsory licenses allow for the production of cheaper generic versions of patented drugs, making treatment more affordable for the general population.

Checks Monopolistic Practices
It acts as a deterrent against abuse of patent rights by ensuring that companies do not set exorbitant prices.

Ensures Availability During Emergencies
During health crises such as pandemics or epidemics, compulsory licensing can be invoked to ensure an uninterrupted supply of critical medications.

Promotes Public Health
By increasing access to treatment for diseases like cancer, HIV/AIDS, and tuberculosis, compulsory licensing directly contributes to better health outcomes and reduced mortality.

Case Study: India – Bayer v. Natco (Nexavar Case, 2012)
In 2012, India granted its first compulsory license to Natco Pharma to produce a generic version of Bayer's cancer drug Nexavar. The drug originally cost ₹2.8 lakhs per month, while Natco's version brought the price down to ₹8,800—a 97% reduction. This case is a landmark example of how compulsory licensing can ensure affordable access to life-saving treatments.

Compulsory Licensing as a Public Health Tool
Compulsory licensing is a legal method that allows governments to bypass patent rights in order to protect public health.

Key examples:
In 2012, India granted its first compulsory license for the cancer drug Nexavar, which was patented by Bayer. This allowed Natco Pharma to sell a much cheaper version—about 97% less expensive.

Brazil and Thailand also used compulsory licenses to make affordable HIV/AIDS medicines available to the public.

These steps helped increase access to vital treatments and saved many lives.

Case Studies: Global and Indian Perspective
India
India has a strong generic medicine industry and has applied legal options under the TRIPS Agreement to protect public health.

The Nexavar case (2012) was a major example, where India allowed a cheaper version of a patented cancer drug.

India's Patent Act (Section 3(d)) stops companies from getting patents for small changes to old drugs—a practice known as "evergreening"—so that cheaper generic drugs can be made more easily.

South Africa
During a major HIV/AIDS crisis, South Africa changed its law to allow the use of cheaper imported and generic medicines. Although 39 pharmaceutical companies challenged this, international pressure forced them to drop the case, helping the country put public health first.

Thailand
In the 2000s, Thailand issued compulsory licenses for HIV and cancer drugs. This helped lower the cost of treatment and made these medicines available to more people.

The Role of Generic Medicines
Generic medicines are very important for public health because they:
- Work just as well as branded drugs but cost much less.
- Help lower medical costs for both people and governments.
- Make essential medicines more accessible, especially in poor or rural areas.

In India, over 80% of prescriptions are for generic drugs. This has made India known as the "pharmacy of the Global South" because it supplies affordable medicines to many countries.

Ethical and Economic Dilemma
The clash between patent rights and public health raises both moral and financial questions:
Moral question: Should making money be more important than saving lives? The United Nations says health is a basic human right.

Economic point: Patents help companies invest in research, but public health must still be protected—especially during crises like pandemics.

Finding the right balance is essential, so that new drug development continues without making life-saving treatments too costly or unavaila

COVID-19 and IPR Challenges

The COVID-19 pandemic brought back global discussions about how intellectual property rights (IPR) affect public health. In 2020, India and South Africa asked the WTO to temporarily remove certain patent rules for COVID-related products, like vaccines and treatments.

Although part of this TRIPS Waiver was accepted in 2022, it took a long time and faced strong opposition from richer countries. This showed that there is still an unfair gap in the global system for sharing medical technologies.

Policy Recommendations:-

To better match IPR rules with public health needs, the following steps should be taken:

1. Make better use of TRIPS options like compulsory licensing and challenging weak patents.
2. Build and support local medicine production in developing countries.
3. Encourage research through new methods, such as public-private partnerships and open-source drug development.
4. Improve global cooperation to make sure all countries get fair access to vaccines and treatments.
5. Make drug prices and R&D costs more transparent, so people understand why medicines cost what they do.

International Examples

Thailand: Issued CLs for HIV and cancer drugs, saving millions in healthcare costs.
Brazil: Used CL for antiretroviral drugs, helping curb the AIDS epidemic.

Challenges and Criticism

While useful, the use of compulsory licensing faces:

1. Pressure from developed countries and pharmaceutical lobbies.
2. Limited use due to diplomatic and trade consequences.
3. Legal hurdles, including litigation by patent holders.

Conclusion:-

Compulsory licensing is a powerful tool that, when used judiciously, can bridge the gap between intellectual property protection and public welfare. It is particularly important for countries struggling with high disease burdens and limited public healthcare budgets. The future lies in a balanced approach that respects innovation while prioritizing the right to health.

Recommendations:-

Governments should strengthen the legal and administrative mechanisms for issuing compulsory licenses.
Public awareness and international cooperation must be promoted to legitimize the practice.
Transparent criteria should guide the issuance of licenses to prevent misuse and ensure fairness.
Awareness of generic medicines and stores to children at school level.
Awareness of authenticity of generic medicines and stores to general public by advertisement and camps etc. in localities of rules and urban areas.
Government should make medicines Contingency fund for generic medicines.

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