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TRIPS, PATENTS, AND THE RIGHT TO HEALTH: LEGAL BARRIERS TO EQUITABLE ACCESS TO BIOTECH INNOVATIONS

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The research paper analyses the conflict between Right to Health and Intellectual Property Rights under TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement. The paper will discuss the accessibility to biotechnological innovations like vaccines, medicines etc with special reference to low , middle income countries which get affected due to the legal restrictions laid by TRIPS. The agreement has limited their ability to access and develop life-saving biomedical innovations, despite the fact that the agreement was intended to promote innovation and standardize global patent protections. These differences were brought to light by the COVID-19 pandemic, as supply shortages and patent restrictions hindered the equal distribution of vaccines in the face of international health crises. The paper will examine if International Human Rights Law (e.g., the right to health under ICESCR) be reconciled with IP protection

The study investigates the practical applications of TRIPS flexibilities, including parallel imports and compulsory licensing, and whether they provide useful avenues for enhancing access. In order to determine how states' health responsibilities can be balanced with intellectual property rights, it also examines the legal and normative frameworks of the right to health under international human rights law, particularly Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR). This paper examines important national and regional reactions to patent limits using a doctrinal and comparative legal methodology, incorporating case studies from the European Union, South Africa, and India. The research would be carried out using doctrinal method analysing the existing legal frame works related to access to medicines, right to health and protection of innovation. The outcome of the research paper would suggest what legal reforms or international mechanisms could better balance innovation incentives with public health needs.

Key words – TRIPS, Right to Health, Innovation, ICESCR , Public Health.

INTRODUCTION

The paper deals with the various provisions international instruments like TRIPS, patent laws relating the conflict between Right to Health and the protection of patents for medicines. Right to Health has been discussed in various international instruments like Universal declaration of Human Rights, International Covenant on Economic, Social and Cultural Rights, International Convention on the Elimination of All Forms of Racial Discrimination etc. The paper analyses the inter section of the patents given to medicines and the accessibility of medicines.

RIGHT TO HEALTH

Everyone has the fundamental human right to the best possible level of bodily and mental well-being, which is known as the right to health. It includes the fundamental determinants of health, such as clean water, safe food, hygienic conditions, and healthy

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surroundings, in addition to access to healthcare. Regardless of ethnicity, creed, or social status, the World Health Organization (WHO) declares that everyone has the fundamental right to the best possible level of health. Right to Health is an essential right which must be ensured for every citizen in a country.

INTERNATIONAL INSTRUMENTS RECOGNISING RIGHT TO HEALTH

Article 25 (1) – Universal declaration of Human Rights (1948)

Article 12 - International Covenant on Economic, Social and Cultural Rights, (1966)

Article 5 - International Convention on the Elimination of All Forms of Racial Discrimination (1965)

Article 12 – Convention on Elimination of all forms of discrimination against Women (1979)

Article 24 – Convention on rights of the Child

Article 28 – International Convention on the Protection of he Rights of All Migrant workers & Members of their family.

BIOTECH INNOVATIONS

The creation and application of novel goods and technology that make use of biological systems and living things is referred to as biotech innovation. These developments cover a broad spectrum of fields, such as industry, environmental management, agriculture, and medicine. Through the development of diagnostic instruments, disease prevention, and novel treatments including vaccines and medicines, biotechnology plays a critical role in modern medicine.

INTELLECTUAL PROPERTY AND BIOTECH INNOVATIONS

A patent is an exclusive right awarded for an idea, a product, or a method that offers a unique solution to a problem, according to the World Intellectual Property Organization ("WIPO"). From innovative medicine formulations to ground-breaking gene therapies, patents are essential for safeguarding intellectual property and encouraging R&D. For a set amount of time, usually twenty (20) years from the date of filing, a patent gives investors the sole right to use their inventions; after that, the invention is made public.

Following are the essential criteria to get Patents protection -

A) Novelty – New invention
B) Non – Obvious to the person skilled in art
C) Capable of Industrial Application – utility

Types of Patents

1. Product Patent

A product patent is an exclusive right for the original inventor(s) for a tangible product that he/she has created. With these rights in place, no other manufacturer can create/manufacture/develop/provide the same product through the same or any other process.

2. Product-by-process Patent

A product-by-process patent/claim describes a product in terms of the method used to manufacture it. This patent is commonly granted when the product cannot be defined or distinguished from the prior art except by reference to the process by which the product is made.

3. Process Patent

Process patent is a kind of protection for the inventors for a certain process of creating or manufacturing a product.

4. Formulation Patent

Formulation protection claims the pharmaceutical dosage form of the drug, commonly known as composition.

In the case of Dimminaco Vs. Controller of Patents design, a vaccine was invented and the inventor applied for patent. The court held that since the process was new, it is patentable.

THE TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AGREEMENT

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According to some, TRIPS is a constitution-like agreement that mandates member countries to abide by a set of baseline norms and values. By encouraging innovation through IP protection, allowing technology transfer, and striking a balance between rights and obligations to promote social and economic benefit, the goals and tenets of the TRIPS Agreement have an impact on biotechnology and pharmaceutical industries. In order to guarantee greater access to necessary medications, Article 27 of TRIPS permits actions to safeguard public health and nutrition, possibly restricting exclusive rights.

Article 8 of TRIPS agreement aims to balance the need to protect intellectual property rights, which incentivize innovation, with the need to ensure access to essential medicines, which is crucial for public health. These flexibilities provide mechanisms for governments to address public health challenges while respecting the rights of patent holders

MEASURES TO GIVE ACCESS TO MEDICINES

1. COMPULSORY LICENSING

Article 31 of TRIPS agreement allows for mandatory licensing. When the government permits someone else to manufacture a patented product or process without the owner's permission or plans to utilize the patent-protected invention themselves, this is known as compulsory licensing. It is among the patent protection flexibilities provided by the WTO's intellectual property accord.

In 2005, WTO members decided to formally alter the TRIPS Agreement, establishing a new type of mandatory license specifically designed for the export of pharmaceuticals to developing nations. After being formally approved by two-thirds of WTO members, this change went into effect in 2017. The "paragraph 6 system" is another name for this unique export licensing procedure, which has its roots in the Doha Declaration.

DOHA CONFERENCE ON PUBLIC HEALTH –

The Doha conference that was held in the year 2001 played a significant role in the implementing the concept of compulsory licensing. The conference allowed the member countries to decide the ground to grant compulsory licensing. The conference addressed the challenges faced by WTO member states with insufficient or no manufacturing capacities in pharmaceutical sector and the need for giving easy access of medicines to those countries. Para 6 of the Doha Conference emphasised on the measures that has to be taken by the member countries to support the countries with inadequate facilities.

2. PARALLEL IMPORTS

Article 6 of TRIPS agreement discusses about the concept of parallel imports. Parallel imports, as defined by TRIPS (Trade-Related Aspects of Intellectual Property Rights), are the importation of authentic goods from one nation to another without the owner's consent, provided that the goods were first marketed or sold in the first nation with the owner's consent. Importing goods that are lawfully manufactured and sold in one nation and then transported into another without the IP owner's consent is basically what it is all about. TRIPS also permits the importation of medicines from countries where the product was legitimately put on the market, even if the patent holder is not directly involved

SCENARIO IN INDIA

In India, the concept of Right to Health has not been explicitly mentioned in the Indian Constitution but there are various judicial interpretations in which it was held that Right to Health is implied under Article 21 which states about Right to Life.

CONSTITUTIONAL PROVISIONS

States are required to adhere to the Directive Principles of State Policy (DPSP), which is Part IV of the Indian Constitution. States are obligated under Article 38 to maintain a social order that promotes the welfare of the populace, but we cannot do so without public health. Article 39(e)

dealt with the protection of employees' health. The article calls on the state to ensure that workers' health and strength, as well as the young age of children, are not mistreated. The state was required by Article 41 to provide public aid, primarily for the elderly, the ill, and the disabled. According to Article 42, the state's main duty is to safeguard the mother's and child's health by providing maternity benefits.

According to Article 47, the state has an obligation to enhance public health, ensure justice, improve working conditions for people, and extend benefits for illnesses, old age, disability, and maternity. Additionally, it is the responsibility of the state to forbid the use of drugs and alcohol that are harmful to one's health. According to Article 48A, the state must make every effort to safeguard and enforce a pollution-free environment for public health. Other health-related measures are included in the DPSP.

Article 21: Defence of Individual Liberty and Life addresses the principle that "no one shall be deprived of his life or personal liberty except in accordance with procedure established by law." The right to life encompasses the right to live in accordance with human dignity and decency and goes beyond simple animal existence. The Supreme Court has ruled in a number of judgments that the right to health and medical care is a fundamental right protected by Article 21 since workers' health is necessary to give their lives meaning, purpose, and compatibility with their personal dignity.

CASE LAWS SUPPORTING RIGHT TO HEALTH

1. In the case of Indian Medical Association Vs. Union of India, it was held that it is the government's responsibility to ensure the availability of essential drugs, and it was held that the Right to Health includes the availability and accessibility of essential medicines.
2. In the case of State of Punjab Vs. Mohinder Singh Chawla, the court observed that the state has an obligation to ensure the availability of essential drugs, which are critical for the right to health.

Indian Patents Act, 1970

Sections 84 to 90 of Indian Patents Act, 1970 deals with Compulsory Licensing. The section provides for the following conditions that must be fulfilled in order to get compulsory licensing -

1. 3 years from the grant of patents.
2. The reasonable requirements of the public with respect to the patented invention have not been satisfied; or
3. The patented invention is not available to the public at a reasonably affordable price; or
4. Patented invention is not worked in the territory of India.

Section 92 A

Section 92A of the Indian Patents Act has provisions requiring patented pharmaceutical items to be developed and sold to nations with lack of manufacturing capability in order to address public health issues. According to the official website of Intellectual Property India, this clause only permits the granting of obligatory licenses for export to nations that have either already awarded a compulsory license for the same product or have permitted the importation of the same from India.

NOTABLE CASE LAW

1. Bayer Corporation and NATCO Pharma Ltd
   The case is the only case till date in India wherein compulsory license for a medicine. The case deals with the compulsory license of the medicine namely Sorafenib Toyslate" which is used to cure cancer.
2. Lee Pharma Vs. Astrazeneca
   The Indian pharmaceutical company Lee Pharma requested a mandatory license for AstraZeneca's patented anti-diabetic medication Saxagliptin in the Lee Pharma v. AstraZeneca lawsuit.

Because Lee Pharma was unable to prove that the drug's reasonable standards were not met, that it was not being produced in India, or that it was not reasonably priced, the Indian Patent Office (IPO) denied this application. The controller also stated that Lee Pharma failed to demonstrate the exact number of patients that were unable to obtain the drug due to its non-availability. Hence, the Compulsory Licensing was not granted.

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