Pharmaceutical Patents and Right to Health in Medical Emergency

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Abstract: *A person's health is essential for their holistic growth and for leading a happy life. It is acknowledged as a fundamental human right by international human rights Law. Article 21 of the Indian Constitution guarantees the right to health. Access to medicine is crucial to protecting the right to health since medicines significantly contribute to health. Patents are crucial for the development of new medicines because they safeguard inventors' rights. With the passage of the Patent Amendment Act in 2005, product patents were also granted in India in addition to process patents. Developing medications for contagious diseases requires risky and expensive biomedical research. We are motivated to conduct biomedical research because of patents because there is a prospect of exclusivity and significant financial gain. However, pharmaceutical patents stop the production of generics, which has an impact on the cost and accessibility of medications and the right to health. Additionally, there is a tremendous loss if a pharmacological discovery is kept a secret for a protracted period of time, particularly in times of medical crisis like pandemics. Thus, the right to health and pharmaceutical patent rights are incompatible. Both the interests of pharmaceutical firms and the general public should be safeguarded, and a balance between the two should be established. The right to health must always take precedence over pharmaceutical corporations' rights in cases of medical emergencies like pandemics. The significance of patent exclusions in protecting the right to health during medical emergencies is examined in this paper. In this study, an analysis of the TRIPS agreement's flexibilities as well as patent exclusions including compulsory licencing, patent pooling, and regulatory exceptions like the bolar exemption and how they can be used to safeguard the right to health during pandemics was attempted.*

Key words: Health, Patents, generics, TRIPS, Emergency

1. INTRODUCTION

The right to health is guaranteed internationally by numerous constitutions and covenants. [1] . This right's accessibility is constrained by the current global patent rights framework. Patent rights have a direct impact on health-related rights, especially in underdeveloped countries where medications are expensive and are not affordable to the poor.

One of the international agreements that protects the right to health is the international covenant on economic, social, and cultural rights (ICESCR). Article 12(1) of the ICESCR requires the parties to the covenant to acknowledge that everyone has the right to the best physical and mental health. According to General Comment No. 14, availability is one of the core components of the right to health. It states that everyone should have access to affordable health services and essential medications. “As a result right to health now includes access to essential medicines as a fundamental element”[2]

States shouldn't interfere with people's right to health by limiting or prohibiting access to medical care that is necessary for disease prevention and treatment. The provision of "essential drugs" is one of the core responsibilities of States. Controlling the marketing of medications by third parties falls under the purview of the states. The states ought to

[1] Jonathan Wolff, “The Human Right to Health”, 2012

[2] Ida Madieha Azmi and RokiahAlavi, TRIPS, “Patents, Technology Transfer, Foreign Direct Investment and the Pharmaceutical Industry in Malaysia, 2001

pass a law implementing health-related rights. The creation, application, interpretation, and enforcement of a state's national patent laws are all impacted by its responsibility to preserve this right. When enacting their national patent laws, states must take into account how future legislative changes can impact the right to health.

Pharmaceutical companies' patent rights must not be upheld in a way that makes it harder for less fortunate people to access generic pharmaceuticals that are reasonably priced. By abstaining from implementing or interpreting patent laws in a way that either directly or indirectly prohibits persons from enjoying that right, the courts must protect the right to health.

According to the World Health Organisation Constitution 1946, everyone has the right to good health. States are required by law to offer timely, accessible, and affordable medical treatment because they have recognised health as a human right. By incorporating the right to health into international law and international development procedures, WHO has actively increased its leadership on the right to health in the technical, intellectual, and political spheres. Along with other rights pertaining to health, people are fighting for the right to health. It strengthens the capacities of WHO and its Member States.

2. RIGHT TO HEALTH IN INDIA

In the Directive Principles of State Policy section of Articles 39(e), 41, and 47 of the Indian Constitution, there are provisions relating to the right to health. The State is required by Article 39(e) to establish regulations for employee health protection. In accordance with the limitations of its economic capacity and growth, Article 41 mandates that the state protect citizens' rights in situations like disease or incapacity by enacting provisions. Improved nutrition and living conditions for people are one of the core responsibilities of government, as stated in Article 47.

According to Article 21 of our Constitution, the right to health is a part of the right to life. “According to the Judicial pronouncements of Indian courts, the right to life also includes the right to health and access to medicines" [3] . The government must take all necessary steps to ensure that residents have access to life-saving pharmaceuticals. The court concluded that Article 21 unambiguously calls for government action to ensure that everyone has access to medical care in order to protect their health. Everybody's fundamental rights must be upheld by the state in accordance with the constitution.

According to Article 21 of the Constitution, the State is obligated by law to make sure that patients have access to life-saving medications. In Mohd. Ahmed (Minor) v. Union of India and others, W.P. (C) 7279/2013, it was decided that appropriate and equal access to life-saving drugs is necessary for people to exercise their right to health.

The government must therefore, atleast, ensure that people have access to the essential medications, particularly for rare conditions. By claiming it cannot treat rare diseases, the government cannot get out of its fundamental duty to guarantee vulnerable people's access to healthcare facilities.

According to the Ayyangar Committee Report, the issuance of a patent confers monopoly powers, prohibiting a significant percentage of our population from having access to drugs because India is a developing nation.

3. PATENTS

A patent is a government-granted legal privilege that provides 20 years of temporary exclusivity in the production, marketing, and use of new inventions. In an effort to foster innovation and benefit all citizens, the government temporarily restricts specific activities from the pool of productive activity that is open to everybody. As a check on the evergreening of patents, Section 3(d) of the Patents Act of 1970 provides for inventions that are not patented**.**

[3] L.M. Singhvi and Jagadish Swarup ,“Constitution of India”, Vol. 1, 2nd Edition, Page No. 1100).

Patents in Pharmaceutical sector

The question of whether the pharmaceutical industry should exist to meet the health needs of the poor or be focused on maintaining intellectual property rights (IPR) is one that regularly involves it. The pharmaceutical industries spends a lot of money on the creation and research of new drugs, which are then sold at prices that allow for both a profit and a return on their investment.

As the pharmaceutical industry invests a lot of money in research and development, current sociopolitical and legal thinking in United States and western countries holds that it should be permitted to patent the drugs it develops in order to prevent rivals from copying or producing the same medications.[4]

Though scientific and technological knowledge has grown tremendously over the past century, there are worries that the rate of innovation is slowing down. Studies indicate a reduction in research output across many businesses, including the pharmaceutical industry.

4. DRUG DEVELOPMENT PROCESS

The process of developing drugs is complex and includes a number of processes. 1.Discovery and development: A product that is intended to prevent or reverse the consequences of a disease has undergone extensive testing, resulting in the identification of hundreds of potential molecules. Later in the development process, studies are done on how the medicine interacts with other drugs and therapies, how it works in the body, how much to take, how to take it, how it affects different populations of individuals, and other factors. 2. Preclinical research - Invitro and invivo investigations are carried out in preclinical research in the manner described below. Good laboratory procedures to determine the drug's toxicity before testing it on humans. 3. Clinical Research- Human testing of medications occurs after preclinical research. Clinical trials come before the investigational new medication process is completed. Clinical trials have four phases where research is carried on healthy volunteers and sick people to determine whether the medication is safe, the dosage that is necessary for the condition, the effectiveness of the medication, any side effects of the medication, and monitoring of adverse reactions. 4. Review by regulatory authorities - Regulatory bodies examine and approve new medication applications after receiving them. 5.Post Market regulatory Safety Monitoring - Only after a medicine is put on the market can the true picture of its safety be known. Regulatory agencies keep an eye on the medications' safety.[5]

The most brilliant minds in science and logic, state-of-the-art lab equipment, and thorough management of project are all essential for the efficient discovery of new drugs. It also needs perseverance and good fortune. [6]

Patents protect pharmaceutical companies' financial interests, which has historically served as moral cover, but this is really only a means to an end: more effective research and treatment of specific diseases.

HEALTH INNOVATION CYCLE IN DEVELOPED AND DEVELOPING

NATIONS

The process of innovation is typically linear. Health innovation, however, is a circular process with numerous steps. The present market-driven innovation cycle works well in industrialised countries with high demand for health products and adequate financial resources. The availability of incentives that promote the conventional innovation cycle, however, is severely lacking for diseases that primarily affect people in developing countries. There is an urgent need for new pharmaceuticals to treat diseases that mostly affect developing countries, yet the market for those

[4] Robertso D,"Pharma Strategies extend drug lives. NatureBiotechnology", 1999

[5] Dr.S.Madhuri Paradesi , S.Kirankumari "Patents and Regulatory Exceptions in Protecting Right to Health", Proceedings of International Conference on "Intellectual Property Rights & Emerging Trends in the Healthcare Sector, ICFAI Law School, 2023

[6] DiMasi JA, Hansen RW, Grabowski HG, "The price of innovation, New Estimates of drug development costs", Journal of Medical Ethics, Vol 35, 2008.

drugs is restricted in many countries due to poor purchasing power and a lack of health insurance.

Since the majority of their inhabitants are poor and are in desperate need of affordable, life-saving pharmaceuticals, developing nations that are submerged in poverty cannot pay the high drug prices. The Western Pharma corporations have argued against this position since it would mean losing their exclusive rights to their patented medicines, in which they have invested a lot of money.

5. THE TRIPS AGREEMENT AND PHARMACEUTICAL PATENTS

Articles 7, 8, 27, 30, and 31 TRIPS Agreement, encourage developing nations. (i) Article 7: In all respects, there should be a balance between scientific progress and the welfare of society's citizens. (ii) The States are granted sovereignty under Article 8 so they can take the required actions to protect the public's health. (iii) Under Article 27(2), a State may restrict the patentability of an invention for a variety of reasons, including a threat to the safety or health of others. (iv) Article 30 of Trips states that the power of WTO members to grant particular exceptions to the rights obtained via patents has no bearing on the rights of patent holders. (v) When a WTO Member Country's law permits the use of the patent's subject matter without the patent owner's approval, Article 31 specifies standards that must always be followed.

The Doha Declaration on the TRIPS Agreement and Public Health, the 2003 Waiver decision, and the 2005 Amendment decision have since reinforced the TRIPS' flexibility provisions to make it easier for states that need to import medications to obtain compulsory licences to do so..

6. THE RIGHT TO HEALTH AND PATENT EXCEPTIONS DURING PUBLIC HEALTH EMERGENCY

A balance between inventors and the general public's entitlement to cheap healthcare is represented by the COVID-19 outbreak. Numerous vaccinations have been created by numerous parties in the less than two years since the corona outbreak. By creating COVID-19 Vaccines Global Access (COVAX) for fair vaccination distribution, WHO also played a crucial role.

With the COVID-19 epidemic, innovative solutions are needed to address IP's difficulties. This includes the COVID-19 technology access pool (C- TAP) and the Medical Patent pool. They both failed to offset the effect of the much more potent pharmaceutical lobby. As a result, several companies, including the Serum Institute of India, obtained an AstraZeneca licence to produce Covishield..

A waiver from Part II's Sections 1, 4, 5, and 7 of TRIPS agreement were requested by India and South Africa formedicines and equipment related to COVID-19 treatment. Several developing nations, including those in Africa and the least developed nations, have endorsed the waiver idea. Although the US has not backed the WTO's present proposal, it has made a statement in favour of a waiver that would apply just to COVID-19 vaccinations. strong advocates for IP regulation Canada, France, and Germany have established emergency laws enabling their governments to impose compulsory licencing during COVID-19.Patent pooling, compulsory licencing, voluntary licencing, and waiver of patent rights all helped increase access to essential medications during the COVID-19 pandemic.

COMPULSORY LICENSING

Compulsory licencing is frequently utilised in the pharmaceutical sector to ensure inexpensive access to life-saving medications, particularly in low-income nations where prescription costs are unaffordable. Article 31 bis of TRIPS, which states that countries without or with insufficient pharmaceutical manufacturing capacity may also import pharmaceuticals from a country that exports them if that nation also issues a compulsory licence for that purpose, makes reference to the provision for compulsory licencing..

Compulsory licencing is governed by Indian legislation, which complies fully with TRIPS. Instead of requesting a patent waiver from other countries, India has its own locally produced vaccines. Indian businesses produced the Covexin and Covishield vaccines. Due of the complicated manufacturing process required to create vaccinations, the government has judged that compulsory licencing is a less preferable choice. The COVID-19 vaccination COVAXINTM, developed by Bharat Biotech in collaboration with

government agencies, is the first of its kind in India. Consequently, the government and pharmaceutical industry collaborated to produce a corona vaccine.

Administration processes must be followed when granting compulsory licences. Some nations altered the covid-19-related procedural procedures for granting compulsory licences prior to the filing of patents. In order to facilitate the quick issuance of compulsory licences during pandemics, Germany and Canada have changed their intellectual property laws. The "Act for Protecting the People in the Event of an Epidemic Crisis of National Importance" is one such law that Germany has approved.Canada approved the "COVID-19 Emergency Response Act" in a manner similar to this.Some countries, including Ecuador, have put laws into place that empower their health ministers to mandate that permits be issued for all COVID-19 patients.

PATENT FREE VACCINES

Texas Children's Hospital created the patent-free COBREVAX vaccine. A patent-free licence for COBREVAX is presently held by Biological E. Ltd. (BioE), the largest vaccine producer in India. Because of this vaccine's lack of a patent, countries with limited resources can produce affordable, dependable vaccines at home.

BOLAR EXEMPTION

The Bolar exemption makes it possible for manufacturers of generic medications to launch their products as soon as the patent on the original medication expires, which promotes more competition in the pharmaceutical industry. The Bolar exemption was acknowledged by many countries. Despite these disagreements, the Bolar exemption is nevertheless an important legal provision in the pharmaceutical industry and is widely regarded as an essential tool for promoting competition and innovation.

Several well-known Indian pharmaceutical firms, including Cipla, Glenmark, and Dr.Reddy's, did research on the medication Remdesivir by taking use of the Bolar exception in patent law. Due to the drug's patent status, they do not, however, currently have any intentions to introduce it to the market. Even while a patent is active, the bolar exemption (under Section 107A of the Patents Act) permits generic enterprises to research patented pharmaceuticals for the generation of data and obtaining regulatory approvals. This ensures that the availability of generic drugs beyond the patent's expiration date won't be postponed. Remdesivir's (IN 332280) patent was only recently granted on February 18, 2020, and it is valid until the year 2035. As a result, if this medication proves to be the cure-all for COVID-19, this exemption may not be of much use.

7. CONCLUSION

No one should be denied the opportunity to enjoy good health. Access to life-saving medicines and patent protection have long been contentious issues with contrasting points of view. To safeguard the interests of both pharmaceutical corporations and people, a delicate balance should be struck. Only 5% of patents have been found to be commercially viable, and the success rate of patent applications is extremely low. There are other issues as well, such as the fact that pharmaceutical corporations cannot profit from those who are in need when there is a health emergency. The TRIPS Agreement strongly emphasises the need for a fair balance between the interests of people and owners of intellectual property rights

In the midst of the Corona pandemic, patent-free vaccinations were created. By altering their patent regimes and granting compulsory licences, Germany and Canada provided flexibility in the issuance of compulsory licences. The creation of generic versions of medicines during the pandemic was further aided by the regulatory exception, or bolar exception. In order to protect the right to health, medical patent pools also assisted in removing the intellectual property barrier. By utilising patent exclusions, we were able to effectively manage the covid-19 pandemic's health crisis. The development of covid-19 vaccinations was supported by funding from numerous nations. During the COVID-19 Emergency, governments and pharmaceutical corporations collaborated to safeguard the right to health.

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