Commission: World Health Organisation
Topic 1: Assessing the Threat of Pharmaceutical Patents on Affordable Access to Medicines Worldwide.
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1. Overview

Gaining access to medicines globally has posed a formidable challenge with two billion people lacking access to medicines worldwide, with pharmaceutical patents contributing significantly to the problem. Pharmaceutical patents are a form of intellectual property and come in many types which include: product, usage, composition, formulation, and combination patents. Each type of patent provides protection to the invention while also allowing the patentee temporary legal monopoly which permits them to establish costs much higher than the cost of production.

This creates a crisis where barriers are created as a result of expensive medicines, meaning patient and healthcare systems in lower income countries do not receive equal access to medicines essential for living.

2. General Background

During the 19th century, countries began initiating patent laws to protect medicinal inventions and their mechanics of production. Following this, the key development through the years was the enactment of the treaty on Trade-Related Aspects of Intellectual Property Rights (TRIPS) by the World Trade Organisation (WTO) in 1955. The TRIPS Agreement was created to implement strict patent protections, requiring Member Countries to grant patents to both medical inventions and their process of production - with each patent existing for a minimum of 20 years prior to their filing. This hereby granted the inventor the exclusive rights to sell, use, and import their patented products. Nevertheless, subsequent to the TRIPS Agreement was the further escalating HIV and AIDS crisis in the developing world. The gradual intensification of the crisis emphasised how patented medicines were now preventing equitable and affordable access to treatments with the potential to save lives. Regarding the situation, the 2001 Doha Declaration was made known. The Declaration published that global health should take priority over compulsory licensing of patents relating to the rigid patent laws established by the TRIPS agreement. This is on account of the fact that the TRIPS agreement only worsened

circumstances for developing nations alongside less developed countries (LDCs) by making patented medicines inaccessible and costly.

3. Present Circumstances

Today, the use of pharmaceutical patents still crucially affects affordable access to medicines internationally. Instead of patents expiring after the agreed upon 20 years (TRIPS Agreement) multinational pharmaceutical companies severely abuse and exploit patenting mechanisms which removed the ability allow for generic competition

Manufacturers are able to acquire multiple patents concerning one product such as its process of manufacturing, its formulation and its methods of use. When multiple patents have been accumulated for one product, it is then called a patent thicket - this then allows manufacturers to keep medicinal prices high.

Furthermore, due to the high failure rate and development of costs of new drugs, many pharmaceutical companies prefer “pseudo-innovation”, meaning there is only a change to the formula or combination of drugs that may provide equal effect as the original medication, all this being done in order to do secure more patents on a functioning drug. This process is hereby known as incremental patenting or evergreening because it attempts to extend or “evergreen” the exclusivity period of a drug.

Both patent thickets and evergreening distort the global pharmaceutical lifecycle as rather than using patents to reward innovators, they create a cycle of exclusivity that impacts healthcare systems worldwide.

- <u>How does this affect the World Health Organisation?</u>

While being the leading organisation designated for the responsibility of public health, WHO faces adversities regarding the promotion of equal and cost-effective healthcare while also acknowledging the importance of pharmaceutical innovations. Additionally, highly patented products directly contrast WHO’s core mission - the mission being to achieve Universal Health Coverage (UHC) and ensure essential medicines are available to all nations.

4. **Measures Taken**

The World Health Organisation (WHO) has taken multiple measures along with key strategies to address the impact of medicinal patents on the availability of medicines.

WHO works alongside Member States and partners in order to identify patent status of individual health products to achieve steady and reliable access to medicines. This has been executed via WHO's Global strategy and plan of action on public health, innovation, and intellectual property guides.

- This initiative works on facilitating access to databases which contain information on health-related patents while also promoting further development of similar global databases
- WHO South East Asia Region and Western Pacific Region , while aiming for a complete, accessible source of patent information, have published guides on how to conduct patent searches for medicines to introduce non-experts to the science of patent searches and allow for the procurement of the most cost-effective quality medicines.
- WHO and The World Intellectual Property Organisation (WIPO) have jointly developed a patent landscape report including:
    1. What is being patented (in terms of disease targets)
    2. Who is doing the patenting
    3. Where patents are filed
    4. How patent policies change over time

Additionally, alternate mechanisms to compulsory licensing are needed to achieve an improvement in global drug access, this has been established by:

- Companies willingly share their patents and manufacturing methods so generic factories can recreate cheaper replicas for lower-income countries. This became a primary mechanism that was used during the COVID-19 pandemic.
- Governments provide tax breaks and market exclusivity to companies in the industry in order for them to conduct research and development (R&D) for more diseases that may be centered in developing countries while noting that these diseases are less lucrative.
    - Market Exclusivity Incentives: When developing a drug for a neglected or rare disease, the inventor is then granted a voucher by the government that allows them to either:
        1. Extend the Monopoly of their own drug in a wealthy market
        2. Sell to another individual/company.
    - Tax Breaks: The use of tax breaks allows companies to deduct tax credits on rare or undiscovered diseases.

5. Countries Affected

- India: In the early 1970s, the Indian Patents Act was passed under the Indira Gandhi government, as stated in the act, process patents rather than product patents were recognised. It follows that India would not reward patents to individual drugs, but to the process whereby the drug was produced. However, while being part of the World Trade Organisation in 1955, India required a new patent law to fulfill its obligations under the Trade-Related Aspects of Intellectual Property Rights (TRIPS). This led to a 40% decrease in generic competition which is indirectionally proportional to drug prices and market concentration. This has affected the oncology in India as it received a surge in high priced, unaffordable treatment in domestic areas.

- South Africa: South Africa is subject to a flawed system that permits pharmaceutical companies to prolong their monopoly periods for years, even decades after their patent protections have expired in different parts of the world. Additionally, medicinal patents that have been overturned in different countries are continually unchallenged by courts in South Africa. This results in the costs of patented medicines to be severely high and are only provided under limited circumstances - or not at all. Meaning there is a reduced quality of life and an increased chance of death among patients who find difficulty to cover treatment costs.

- Brazil: Brazil is noted as one of the countries in which fewer pharmaceutical patents are granted, compared to India where 2,347 patents were granted from 2005 to 2008, Brazil had only granted 278 patents between those years. This leads to medicines in Brazil to be bought exclusively from one producer at typically high prices. While increasing public spending on medicine may indicate a large number of individuals being treated - it rather reflects the high spending on drugs, where many of which are under monopolistic situations due to the patent system. This has hence resulted in Brazil becoming under the influence of the Patent Paradox.

6. Possible Solutions

➢ Strengthening international cooperation by encouraging the WHO and the WTO to enhance already existing policies or develop policies that harmonise intellectual property protection with equal access to medicines, especially in lower or middle income countries.

➢ Prompting countries with a high-income economy alongside with international organisations to provide monetary aid to lower income countries in an attempt to relieve the costs of obtaining medicines.

➢ Fostering enhanced patent examination systems with the conclusion of preventing prolonged extensions of improper patent monopoly and encouraging legitimate competition.

➢ Motivating Member States to encourage the production adjoining the distribution of low-cost entry generic medicines in order to achieve lower treatment costs in addition to improving access to essential medicines across countries.

7. Definitions

1. Essential Medicines: Pharmaceuticals that satisfy the priority health care needs of a population, selected based on public health relevance, clinical effectiveness and cost-effectiveness

2. Intellectual Property (IP): A system that allows companies that produce drugs to minimise or block competitors from copying their products (creating a temporary monopoly over new medications and medical technologies).

3. Patent: a special government granted document that gives the legal right to produce or sell a new medical invention/product that no other companies are allowed to copy by either making, using or selling.

4. Monopoly: A market structure of one single firm is the only seller/producer of a product that also has no close substitutes

5. World Trade Organisation (WTO): Global governing body that controls the international trade rules which heavily influences the affordability of drugs,

new medical ideas and intellectual property protection through its treaty for medicine (TRIPS Agreement).

6. World Intellectual Property Organisation (WIPO): The United Nations agency that serves the world's innovators and creators, ensuring that their ideas travel safely to the market and improve lives everywhere.

7. Patent Thicket: When multiple patents have been accumulated for one product such as its process of manufacturing, its formulation and its methods of use.

8. Evergreening: Branded drug companies to grow their market monopoly and postpone the entry of lower-cost generic alternatives past the expiration of their original patents

9. Compulsory Licensing: A legal process where a government allows a third party to produce, sell or import a patented medicine without the permission of the patent owner in return for fair compensation.

10. Patent Paradox: Self contradiction to the legal process designed to incentivize the creation of life- saving medicines are the exact same process that prevents patients from accessing.

11. Least Developed Country (LDC): A low income nation assigned by the United Nations that is legally excused from by the WTO from applying or enforcing patents and test data protection for pharmaceutical products.

12. Generic Medicine: A pharmaceutical product which has the exact same ingredients as a brand-name drug which leads to the same effect with the same dosage.

13. Trade-Related Aspects of Intellectual Property Rights (TRIPS): A crucial legal agreement managed by the World Trade Organisation (established in 1955) that sets minimum standards for intellectual property regulation which impacts how medicines are patented and dispersed globally.

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