Forum: Economic and Social Council

Issue: The Question of Accessibility of Patent Protected Drugs in LEDCs

Student Officer: Anika Kapur

Position: President

Introduction

Modern medicine is improving healthcare at a rapid rate. As new treatments and drugs are produced, the chances of surviving with a life-threatening illness have vastly increased. Nonetheless, the majority of these treatments require resources that can only be afforded in more economically developed countries. Moreover, imported drugs are largely too expensive for the intended recipients. Essentially, the current system fails to develop affordable and feasible medications that address the needs of those who are most at risk. That being said, the current system does provide a financial incentive for drug development. This has led to the aforementioned vigorous investment and development. Global health advocates are currently looking for alternatives that sustain the progression of medicine while increasing its accessibility.

Key Terms:

Less Economically Developed Countries (LEDCs):

Also known as developing countries, LEDCs are countries that are relatively poorer. These countries are typically characterized by higher birth rates and death rates. LEDCs also have fewer doctors to treat the population. The UN official defines LEDCs as countries that have a gross national income of less than $1025.00 USD, human resource insecurity, and economic vulnerability.

Pharmaceutical:

Any compound that is utilized in the medical industry. Usually provided as a drug or a form of treatment with the purpose of curing an individual, vaccinating and individual or alleviating the symptoms of an individual.
**Patent Protected Drugs:**

A patent protected drug is a drug that only the company with the patent can produce, market, distribute and profit from. These drugs remain patent protected for a period of time designated by the country’s government. This allows a company to set any price for the drug due to the lack of competition. Once the patent expires, other companies are allowed to begin making generic drugs using the same active ingredient or formula. It has been observed that within the first 12 months of patent expiring and generics being released, the price of the original drug decreases by 60%.

**Generic Drugs:**

Drugs that may only be produced after the initial chemical patent of the original drug expires. The generic drug typically contains the same chemical formula as the original. Nonetheless, generic drugs may also have different characteristics or may be manufactured differently but maintain the same active pharmaceutical ingredient (API). Most generic drugs are regulated by individual governments and labeled with the active ingredient and manufacturer.

**Pharmaceutical Patent Abuse:**

The patent system can be manipulated by companies to extend the length of the patent and allow them to control the price of the drug for a longer period of time. This is usually done by finding loopholes in the government’s patent laws or publishing multiple patents. For instance, the twelve most commonly needed drugs are protected by 848 patents. This has prolonged the time for which generics cannot be produced from 12 years to 35 years. This prolonged period means that vulnerable patients must pay more money for treatment.

**Intellectual Property Protection (IPP):**

Intellectual property refers to inventions, arts, or concepts created by an individual. Intellectual property protection is imposed through the use of patents, trademarks, copyrights, and trade secrets.
Background Information:

The Drug Patent System:

The drug patent system was initially created to reward companies for discovering new drugs and treatment that could cure ailments and improve the quality of life of the intended recipients. The idea was that rewarding these patents to companies would incentivize other companies to invest in drug development research. It is undeniable that the creation of this patent system did give way to an unprecedented rate of innovation in terms of the production of medical treatments. However, the existence of these drugs does not matter if they cannot be accessed by the population they are meant to serve.

Drugs patent laws used to vary a lot between nations. This was because intellectual property (IP) rights in general were established on a territorial basis. In other words, IP rights were created by a country’s legislator and applied to conduct within its borders. In medicine, this made it difficult to sell a pharmaceutical internationally and also provided loopholes for actors looking to yield profit on a patented drug produced by another company. While IP rights are still largely ignored by international law, there have been a host of international agreements that have brought uniformity to the application of patent law and intellectual property and established minimum standards. Such standards addressed what could or couldn't be classified as intellectual property and the appropriate length of a patent or copyright. These agreements also established the idea of national treatment. National treatment states that all countries part of the given treaty must protect the patent of foreign inventors to the same extent as national inventors. These treaties are imperative in this new era of globalization and facilitate the trade of pharmaceuticals to make them more accessible.

In the modern era there are a plethora of different treaties that dictate IP rights with the oldest agreement dating back to 1886. The most pertinent treaty to drug patents is the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), established in 1994. Administered by the World Trade Organization, this agreement establishes minimum copyright and patent lengths while also expounding the scope of exceptions and limitations regarding exclusive rights. Unlike prior agreements, TRIPS established a strong framework to mediate
patent disputes using the WTO dispute settlement body. TRIPS also prevents all World Trade Organization members from denying patents to pharmaceuticals or biotechnology products. Before TRIPS, this was a common practice by LEDC governments who felt that such patents made life savings drugs inaccessible and unaffordable to its population.

The current system established primarily by TRIPS outlines that new pharmaceuticals can have twelve years of market exclusivity and that each patent that applies to the drug may prolong market exclusivity by up to 20 years. The duration may vary depending on the type of drugs that are being developed. For instance, to incentivize development on rare diseases, drugs that serve orphan diseases (very rare diseases), have a longer patent time. Once again, this incentivizes development but makes treatment for the patient extremely expensive. This incentive also applies to pediatric pharmaceuticals. It can cost 2.6 billion dollars for drug companies to develop a new compound. Without patent incentives, new drugs would most likely not be developed. Despite the higher price tag of select pharmaceuticals, it is important to note that, after initial development, most pharmaceuticals are fairly cheap to produce. This results in a large profit margin for drug companies and makes the drug industry very lucrative.

The consequences of enforcing drug patents.

The current drug patent system has many flaws. For instance, patent-length despite incentives, it leads companies to only invest in researching drugs that more people will buy at a higher price. This tailors the pharmaceutical industry for individuals living in MEDCs who are willing to pay more for drugs that combat common illnesses such as male pattern baldness. In
other words, diseases and conditions that affect the global poor in LEDCs and are almost obsolete in MEDCs are not invested in as much. This can be seen by the fact that drugs serving acne and male-pattern baldness are constantly being produced with new formulas. In contrast, in the last five years, only one new drug with one new chemical formula has been produced to treat tuberculosis, a disease that led to 1.5 million fatalities in 2013 alone. This is because tuberculosis is not common in developed countries, so does not attract much investment by drug companies.

Another problem with the current drug patent system is the fact that it restricts access to medicine due to the fact that it builds financial barriers to getting treatment. Because patents allow companies to monopolize active ingredients, patients have no choice but to either pay high prices to get treatment or remain sick. It is estimated that 10 million people die each year due to a lack of access to medicine. The patent system may also prevent innovation in some ways as it builds a sense of secrecy and prevents collaboration. In turn, due to the lack of open source data about patent-protected active ingredients, many patent-protected drugs do the same thing and do not provide better treatment than the other drugs on the market.

Human rights agencies are amongst the loudest critics of the current patent system regulating the pharmaceutical industry. The World Health Organization has also spoken out saying, “inequality and discrimination in access to essential medicines remain the key public health challenge of our times. Some critics call for the pharmaceutical industry to devote greater resources to the needs of the poor, while others question whether discovery and distribution of life-saving medicines should be a for-profit enterprise at all” (2016).

The current drug patent system does have some flexibility built in by TRIPS. For instance, Article 31 allows countries to instate mandatory licenses on patented drugs. These licenses essentially allow the production of generic drugs before the patent has expired on the original drug. This licensing system allows necessary drugs to be produced at a lower price and ensures that the company that holds the patent is compensated to some extent monetarily. Article 31 also ensures that generic drugs that treat the same illness and are made elsewhere can be imported by a country without risking access to the patent protected drug. These measures to modify patent law to serve public health needs in Article 31 were reaffirmed and highlighted in the Doha declaration in 2001.
These built in flexibilities to TRIPS were imperative when increasing access to medicine in multiple countries. For instance, over 50 countries, including India, Columbia, and Indonesia, used these flexibilities to spread generic HIV/AIDS pharmaceuticals. That being said, these flexibilities are slowly disappearing as the pharmaceutical industry and the United States lobby for multilateral agreements that restrict these measures.

**The Relationship between MEDCs and LEDCs:**

Developed and developing nations have very different attitudes towards the patent system and international agreements that regulate IP laws and, in turn, the pharmaceutical industry. Developed nations are in favor of establishing strong IP rights in the international realm so that they can reap the full economic benefits of their innovations. In their point of view, new drugs require a lot of investment on behalf of the nation of origin of the pharmaceutical. Not only do they want a return on this investment but they see patents and other IPPs as measures that will make trading with developing countries more secure. On the other hand, developing countries views the establishment of patents and IPPs as measures taken to severely limit their access to the innovations in question. This is why LEDCs often excluded pharmaceuticals from patent law before TRIPS was established; they felt it was an unfair limitation to their development and would adversely affect their population.

Because of the lack of development and access to healthcare, communicable diseases affect LEDCs at a disproportionate rate. For instance, diseases such as Tuberculosis and HIV are major concerns. The generic drug industry is of great importance as a result. Because of patent law, the ability of the generic drug industry is limited and pharmaceutical companies possess much of the power when it comes to deciding the price of a drug. Medications that serve a poor population are, in turn, much more limited as they are expensive. This is very problematic when it comes to dealing with bacterial infections that have developed resistance in LEDCs. For instance, of the people suffering from tuberculosis in Africa, 32,000 individuals had a multiple drug resistant form. These patients need newer drugs but can’t access them because they are still patent protected and extremely expensive.

**Past and Current Initiatives:**
Currently, the World Trade Organization has extended a waiver until 2033 which allows the 48 LEDCs to disobey the TRIPS agreement and produce generic drugs that copy patent-protected drugs without facing consequences. This exception on drug patents only applies to the 48 LEDCs and is exclusive to drug patents. Seeing as most drug patents last for 20 years, this waiver extension is vital to protect these areas that are still facing outbreaks in HIV and malaria without sufficient number of healthcare facilities to remedy the situation. Uganda, Rwanda, and Cambodia are amongst the first countries to take advantage of this waiver and begin their own pharmaceutical industry to develop generic drugs. Uganda has specifically partnered with an Indian company by the name of Cipa that produces generic drugs in order to do so. Uganda now hosts the only company in Africa that makes make generic triple-combination antiretroviral drugs.

Going forward, working to strengthen LEDCs ability to manufacture generic drugs is important. This is because they will no longer be able to import generics from more developed countries such as India as the extension only applies to LEDCs. Many countries and NGOs are unsatisfied that the waiver extension is not prolonged indefinitely or at least until no country is classified as an LEDC. A prolonged waiver extension would not harm the drug companies as LEDCs already account for less than 1% of their drug royalties. Nonetheless, the United States has continued to refuse this option. In the meantime, using the waiver to help LEDCs develop a generic drug industry would give them direct and affordable access to the drugs they need the most. These generic drug industries must be heavily regulated by the government, otherwise there could be major health and safety concerns if the pharmaceuticals are not properly produced.

ECOSOC’s Global Public Health Agenda also outlines steps that UN is taking towards lowering prices for patent protected drugs. For instance, it has established UNITAID which has the goal of seeking price reductions for medicines and making them more accessible at a faster pace, especially with drugs that treat HIV, malaria, and Tuberculosis and LEDCs. To do this they are striving to create a patent pool. A patent pool is an agreement between two or more patent holders to license their patents together for an established price. UNITAID is looking to create a patent pool with drugs that address HIV, Malaria, and Tuberculosis.

Timeline:

April 7th, 1948 The World Health Organization is formed with the goal of improving the status of global public health. The organization
was established with two major aims, the first being, "to address the underlying social and economic determinants of health through policies and programmes that enhance health equity and integrate pro-poor, gender-responsive, and human rights-based approaches"

December 22nd, 1971  Doctors Without Borders is founded. Besides providing healthcare services in regions of conflicts, it also strives to aid in countries with endemic diseases.

September 12th, 1978  The Alma Ata Declaration is passed at the International Conference on Primary Healthcare. It emphasizes the need of action by governments to promote and secure healthcare as a basic right for all individuals. It also highlights the role of economic development in increasing access to healthcare for all.

January 1st, 1995  With the establishment of the World Trade Organization, all member countries must agree to the General agreement on goods and services, the general agreement on Trade on tariffs, and the TRIPS agreement. The TRIPS agreement is established as a major document to regulate the drug patent industry on a global scale and curtails major generic drug production and export markets found in India and other countries.

2001  The Doha Declaration is passed, reaffirming the flexibilities in the TRIPS agreement that allows countries to issue a mandatory license on patent protected drugs. It also states that governments are not required to negotiate licensees with pharmaceutical in the case of a national emergency.

November 9th, 2015  The World Trade Organization extends the TRIPS waiver for LEDCs, allowing them to produce generic copies of patent protected drugs until 2033 instead of until 2016.

January 1st, 2016  The UNESCO Sustainable Development Goals are enacted with goal three being “Good Health and Well Being”. A big part of goal three is not only ensuring innovation for access to healthcare for all.

October 3rd, 2017  The World Intellectual Property Organization (WIPO) and the International Federation of Pharmaceutical Manufacturers and
Associations (IFPMA) sign the Patent Information Initiatives for Medicines to clarify regulations regarding patented medicines and patent regulations and make them more accessible.

Prominent Countries and Organizations:

United States of America:

The United States has acknowledged that there needs to be a balance between fostering innovation and ensuring that the products of such innovation are accessible. When companies develop a new treatment or drug that improves quality of life, they are rewarded with a 12-year patent. While the United States is perhaps the biggest defender of drug patent laws, its population has experienced an unreasonable increase in drug prices in the last decade. Doctors and patients have called for reforms to the system. Nonetheless, on the international stage, the USA does not support a TRIPS waiver extension for LEDCs.

European Union:

The European Union supports an extension for the TRIPS waiver until all countries develop past the classification of an LEDC.

Canada:

Canada has published many reports that emphasize that the country’s overarching commitment is to ensure access to healthcare as a basic human right. As seen by their response to major dispute involving the TRIPS agreement, they recognize that it is meant to have a liberal interpretation and allow countries to implement it in a flexible manner. While Canada was hesitant to agree with the Doha declaration, it ultimately affirmed that countries should be able to put the status of public health over the regulations of patents and trade. Canada strives to find a balance between protecting IP rights as much as possible while still ensuring healthcare is accessible to all.

Uganda:

Uganda has pushed for a permanent waiver to be granted to LEDCs to allow them to continue to produce generic drugs of compounds that are still protected under a patent. The United States was one of the only developed nations to deny Uganda’s request. Uganda has also
recently taken advantage of a TRIPS flexibility and stated they will not enforce pharmaceutical patents in the interest of public health.

**India:**

India is the major provider of generic drugs for LEDCs. It not only exports generic drugs to countries directly but it also sells them to non-profit organizations such as Doctors Without Borders and UNICEF. In total, India is responsible for 20% of the generic drugs on the global market. However, Global Patent laws and new trade agreements are restricting the number of drugs that India may manufacture. India has rejected many patent drugs from being sold in India such as applications from Novartis, which manufactures cancer drugs and Gilead which manufacturers Hepatitis C drugs. In turn, it may produce cheaper versions of the drugs. At the same time, it has also accepted many patents for TB and HIV drugs. As the World Trade Organization becomes stricter, India will lose its ability to produce generic versions of patent-protected drugs.

**South Africa:**

In the 1990s, South Africa enacted the Medicines and Related Substances Control Amendment Act. This was meant to combat increasing rates of HIV and allowed the country to substitute patent drugs with generic alternatives, ensured transparent pricing for all pharmaceuticals, and established that they would continue to import patented drugs in a parallel manner. As a result of this act, 39 pharmaceutical companies, with the support of the United States government and the European Commission, sued South Africa for violating TRIPS.

**Brazil:**

Brazil has a history of issuing compulsory license for certain drugs. For instance, in 2006 it issued a compulsory license for the AIDS drug Efavirenz. Without the license, it cost $1.57 per tablet, which is a standard price in countries of middle income. The lowest the company Merck was willing to sell it at was $1.10, but with the license, Brazil was able to import generic tablets from India that cost fifty cents each.
Thailand:

Thailand’s first patent law was issued in 1979 but did not cover much regarding pharmaceutical patents beyond processing them. In 1986, the United States Trade Representative negotiated with Thailand to include pharmaceutical patent products more heavily. After much negotiation, an amendment was added in 1992 which added more patent protection and established a committee to monitor patents and drugs. This committee was later dismantled. People in Thailand do not have sufficient access to antiretroviral drugs. Some estimate that less than 5% of the 1 million infected have access to antiretroviral therapy.

Malaysia:

Malaysia if often used as a case study to demonstrate how patent law can create inequality in drug trade between MEDCs and LEDCs. MEDCs export high-value patent drugs and LEDCs are prevented from manufacturing them and forced to buy imported ones at a high cost. The WHO surveyed the population in Malaysia and discovered that drugs prices rose about 28% annually from 1996 to 2005. Malaysia relies primarily on Germany, France, and the United Kingdom to import drugs and domestic medical research is severely limited. In 2006, Malaysia enacted a compulsory license that allowed it to import cheaper version of antiretroviral drugs from India.

Indonesia:

Only 55% of the essential medicines listed for Indonesia by the WHO organization on the DOEN are generic drugs. Generic drugs also represent a small fraction of drug prescription in Indonesia so the population is forced to choose between paying a lot for treatment or not seeking treatment at all. Moreover, the branded generic drugs in Indonesia are sometimes more expensive than the patented drugs.

Kenya:

Kenya has faced the issue of counterfeit pharmaceuticals emerging onto the market. 306 generic medications used to treat malaria were found to be counterfeit by the WHO. While are imported medicine was found to be legitimate, patents enacted have made imported drugs too expensive to serve the Kenyan Population at large. Like many African nations, Kenya used to rely on India to import generic drugs. However, as India issues patents to companies and stops
producing generics, Kenya and the African Union have shifted their focus towards developing generic drugs within Africa. Kenya is also focusing on how to filter substandard and counterfeit drugs out of the market.

The World Health Organization (WHO):

The World Health Organization has provided a lot of information regarding the current state of healthcare accessibility in LEDCs through population surveys and other monitoring methods. The WHO has published a full report that assesses the impact that TRIPS has had. It proposes many recommendations such as the fact that the most essential drugs should be subjected to patents and that all countries should create a list of necessary medicines based that is personalized to their region and state of development.

World Trade Organization (WTO):

When the WTO was established, a prerequisite for membership was that all countries would sign onto the TRIPS agreement along with two other documents. The World Trade Organization is responsible for mediating any disputes that arise as a result of a TRIPS violation. It also convenes every year to discuss topics that include the international drug patent industry.

UN Resolutions and Relevant Documents:

- TRIPS Agreement, 1 January 1995
- The Doha Declaration, 2001
- A/HRC/RES/32/15 (Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health), 1 July 2016
- A/HRC/RES/32/16 (Promoting the right of everyone to the enjoyment of the highest attainable standard of physical and mental health through enhancing capacity-building in public health), 1 July 2016
Possible Solutions:

Voluntary License Agreements:

Communication between pharmaceutical companies and LEDC governments could be facilitated to develop specialized licensing agreement to LEDCs. While direct negotiation might not be possible without the involvement of a third party such as the WHO, patent pools could be established to allow for generic drug development. To purchase said patent pools, funding from the IMF or World Bank could be used.

Public-Private Partnerships:

Public-private partnerships can help develop the pharmaceutical industry and generic drug industry in LEDCs to give them direct access and power over the specific drugs needed to treat their population. This has previously worked between the Ugandan government and an Indian drug company. Efforts like this to facilitate communication and cooperation between the public and private sector could be expanded to aid development. Partnerships could also be established to create a different price for a pharmaceutical depending on the country’s level of development.

TRIPS Waiver Extension:

As discussed previously in this report, coming to an agreement on terms to issue a TRIPS waiver could allow LEDCs to temporarily provide the necessary pharmaceuticals to their population at an affordable price while they develop and exit the LEDC classification. Other measures could be thought of that give some sort of exemption to LEDCs without issuing an entire waiver.

Guiding Questions for your resolutions:

❖ What measures can be implemented to increase access to healthcare that respect the current patent agreements?

❖ Should an indefinite extension be given to LEDCs on the TRIPS waiver?
❖ Does TRIPS properly address the state and scope of the international protection of intellectual property in the pharmaceutical market?

❖ How can LEDCs develop pharmaceutical industries to serve the needs of their own population?

❖ How can the safety of generic drugs meant to serve populations in LEDCs be ensured?

❖ How can communication be facilitated between major pharmaceutical companies and the governments in the WTO?

❖ What role does economic development play in increasing access to healthcare?

Bibliography:


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