

General Assembly 3 – Social, Humanitarian and Cultural

Establishing protocols to balance the Intellectual Property rights of pharmaceutical companies with efforts to facilitate access to medicines



Forum:	General Assembly 3 – Social, Humanitarian and Cultural
Issue:	Establishing protocols to balance the Intellectual Property rights of pharmaceutical companies with efforts to facilitate access to medicines
Student Officer:	Meike van Lelyveld
Position:	Chair

Introduction

Globally, over two billion people in More Economically Developed Countries (MEDCs) lack access to medicines, including patients in countries such as the United States of America and many European countries. And then we have not yet even started about Less Economically Developed Countries (LED's). This limited access to medicines and treatment has been primarily caused by two things. First of all the extremely high prices of new medicine, this is usually caused by patents and exclusivity rights. The second factor is the lack of medicines, treatment and vaccines for neglected diseases, just because developing medicines for such a small group of patients is not beneficial for big pharmaceutical companies due to the large amounts of money it costs to develop them.

Definition of Key Terms

Intellectual Property (IP)

Intellectual property (IP) is a key term that refers to creations of the mind/intellect and the exclusive rights of their use. The common types of intellectual property rights (IPR) are patents, exclusivity rights, copyrights and industrial design rights. It also includes the rights that protect some jurisdictions trade secrets, trademarks and trade dress. These cover not only artistic works such as literature, films and music but also designs (for example Coca Cola's logo), symbols (Coca Cola's red shape of a bottle), phrases (Coca Cola's "open happiness"), invention or discoveries. Even intellectual property rights themselves are a form of property. This is called intangible property. It should be mentioned that is very well possible to sell property rights, for instance, Coca Cola's entire brand is worth 83.84 billion US dollars.

Patent



This is a license given out by a government that gives the holder of the patent the exclusive rights to manufacture, sell and make profit from a certain new invention. These patents are implemented to support innovation and to ensure fairness in monetizing ideas. Applications for any kind of patent are usually handled by an agency from the government.

In the United States and many other Western countries, most patents are valid for 20 years in total. By granting the right to a company or individual to produce a new product and by eliminating possible competition, these companies and individuals are motivated to continue developing new products. A good example is the pharmaceutical industry where much money is spent on researching and developing medicines. For pharmaceutical companies, patents are essential to earning a profit because the research of a new medicine cost so much more than the production once it is developed. So without these patents, pharmaceutical companies would not want to invest in new research.

Exclusivity of Drugs

There is a slight difference between the exclusivity of a drug and its patent. First of all, different agencies give out exclusivity and patents. The exclusivity of drugs was established in order to promote a balance between the drug competition between various pharmaceutical companies and the innovation of new drugs. Exclusivity implies exclusive marketing rights on a medicine that has been researched, tested and approved according to the country's laws. It should be noted that exclusivity can run concurrently with a patent or not. Exclusivity is granted for seven years for an Orphan Drug (ODE), see the following section for information on ODEs. For a new chemical, exclusivity is five years in the United States of America.

Orphan Drug (ODE)

An orphan drug is a medicine used to treat an orphan disease. These diseases are very rare medical conditions. The exclusivity for these kinds of drugs is seven years. A lot of pharmaceutical companies do not want to focus on these type of diseases because there is a very small market for them because it is a rare disease. This means that there is not a lot of profit to make. This is why governments and organisations try to stimulate the companies to research to these kind of medicines because they feel that citizens with orphan diseases also have the right to proper medication. One of the way they do this is by making it easier in the United States and the European Union to gain marketing approval for an orphan drug. They also try to enlarge the financial opportunities in this field by for instance extending exclusivity periods. Also the actual assignment of the orphan status to a disease or to a drug depends on public policy in many countries. It has already resulted in many medical breakthroughs

that probably would not have been achieved due to the financial opportunities of the researching of the drug, its test and the development.

General Overview

Human Rights

Companies and countries may never choose Human Rights above economic benefits. Article 25.1 of the Universal Declaration of Human Rights states:

*"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and **medical care** and necessary social services, and the right to security in the event of unemployment, **sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.**"*

By deciding to not bring out a medicine so a company can further develop it so when it is finished it will earn more in the future, the company is actually violating the Universal Declaration of Human Rights.

Patents, Exclusivity and International Property

Creating, developing and testing a medicine until it is perfect costs millions and it takes a lot of time. It is reasonable and understandable that a company would want to make profit and will only bring their product on the market if it is perfect so that they can make optimal use of their patent and exclusivity on the market.

Major Parties Involved and Their Views

Less Economically Developed Countries (LEDCs)

LEDC governments do not have a lot of financial incentive to give to pharmaceutical companies in order to develop and research new drugs. This is clearly a factor that is slowing the development in these countries down. Also, their citizens are more vulnerable for diseases because they are often not educated about matters such as hygiene and STDs. Because these citizens are not well educated, it is not very likely that they have a job that is paying them enough to provide themselves or family members the expensive medicines that they might need.



Major Pharmaceutical Companies

The big pharmaceutical companies have a lot of financial interest in developing and improving medicine. But because developing new medicines is a very expensive and risky investment, most companies try to develop drugs, vaccines or treatments that will be used by a large number of people so that they will earn back their invested money.

World Health Organization (WHO)

The World Health Organization was established by the UN on the 7th of April 1948 and its purpose is to coordinate and direct authority on national and international health in the UN's system. Their work covers a lot of different topics within the health sector such as creating standards and norms for the pharmaceutical industry, monitoring the current health situations globally, providing technical support and taking the lead in relevant health developments. WHO's priority is to establish an universal health coverage. They work together with other NGO's, academia, the private sector, different layers of the civil society and policy-makers in order to create and implement effective health plans. Also they try to achieve universal accessibility to treatment for diseases, vaccinations and medicine.

World Intellectual Property Organization (WIPO)

The World Intellectual Property Organisation is a global forum for services, information, help, cooperation and policy regarding intellectual property (IP). WIPO was established by the United Nations, it is a self-funding agency and it currently has 188 member states. The aim of this organisation is to lead development of a balanced universal intellectual property system which supports and encourages creativity, development and innovation. All their procedures, mandate and governing bodies are described in the WIPO Convention, established in 1967 by WIPO.

Timeline of Events

Date	Description of event
July 14 th , 1967	WIPO Convention
1970	The Swedish non-profit company Apoteket AB with a retail monopoly of any kind of drug was established
March 22 nd , 2007	The United States Court of Appeals for the Federal Circuit to make a patent invalid on the "pharmaceutical salt", that was an active patented ingredient in the pharmaceutical industry but it was turned invalid because it would have a



June 11th, 2013

significant impact in speeding the availability and research of new medicine
The General Assembly adopts The Resolution on Access to Medicines in the
Context of the Right of Everyone to the Enjoyment of the Highest Attainable
Standard of Physical and Mental Health

UN involvement, Relevant Resolutions, Treaties and Events

Because this issue is developing a lot, the UN has already invested time, energy and devotion to this problem in order to solve it as soon as possible. All the different types of UN resolutions and involvement will not be discussed but the most important resolutions and reports will be given for reference:

- The Convention Establishing the World Intellectual Property Organization, 14 July 1967
- The Resolution on Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, 11 June 2013 (A/HRC/23)
- Policy Paper from the Yale Global Health Justice Partnership on A Human Right Approach to Intellectual Property and Access to Medicines, September 2013

Evaluation of Previous Attempts to Resolve the Issue

The problem in short is that monopolies are necessary because there needs to be a financial motivation for big multinational companies for creating, researching and developing new drugs. If there would not be any monopolies, big pharmaceutical companies would not have the resources to develop more different kind of drugs. For governments, it would be almost impossible to motivate companies without monopolies.

This issue has not been prevalent for long due to the fact that advanced medicine has only been available in recent history, this means not a lot of time has passed since the first measures were taken to resolve the issue. This also implies that there has not been so much time to review or evaluate the previous attempts. What can be said is that the laws were successfully implemented, meaning that there has not been many problems and issues up until now.



The Swedish government is the only government that actually took matters into their own hands and tried to find a solution. Already in 1970, they established a non-profit governmental enterprise called "Apoteket AB" that reports to their ministry of finance. This company has a monopoly in the retail of medicine in Sweden. This company purchases extremely large numbers of medicine from multinational pharmaceutical companies for lower prices than they are sold individually. Apoteket sells the drug for even less than they purchased it for because the Swedish government also give them financial help. In this way, medicines are more available for everyone in the country.

Possible Solutions

The most important thing is to make sure that every company and country always chooses human rights above economic benefits. But there are almost no ways a government can achieve this because the only interest of these companies is making profits. A government could decide to partly finance the development of for instance orphan drugs because there currently is no financial interest in developing these kinds of drugs. But such a measure would kind of contradict that human rights are more important than economic benefit. But those kinds of opinions will be different between different governments.

Another way to solve this issue is to encourage dialogue between parties such as governments, NGO's such as the WHO in order to get the best and most effective results. The aim of the written resolution should be to find a balance between still encouraging pharmaceutical companies to develop medicine and ensuring the universal accessibility of all kinds of treatments, vaccinations and medicine. This is difficult and that is why there should be enough space for dialogue between the most important parties.

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