World Health Assembly

Merle Beerens and Stefanos Carras

Research Report

The Question of:

Intellectual property rights of generic medicine

Introduction

In our world, both innovation and progress are fuelled by profit. For there to be innovation, there need to be intellectual property rights to help secure a profit for the innovator. In an era of increasingly globalized trade, patents play a key role in the availability and affordability of medicines, as shown previously by the conflict over access to medicine for people living with HIV/AIDS in resource-limited countries. Patents are the most important branch of intellectual property rights and they ensure a monopoly for the new product for a certain number of years, in the hope that the financial income will work both as an incentive and funding for future research.

In the domain of medicine the "war" is between pharmaceutical giants who spend billions developing revolutionary medicine and the companies who can copy the formula after the patent has expired. It is only after the patent time has "elapsed" that generic drugs can be sold in the market at a fraction of the cost of the original branded drug. "Except for their price which is much lower, generic drugs are in every way equivalent to their branded counterparts" (Dr Steven K. Galson). A generic drug does not carry the brand name, which makes it cheaper; this is exactly why Generic drugs have saved millions of lives around the world.

The Committee

The first World Health Assembly (WHA) conference was convened in 1948, two months after the World Health Organization (WHO) was founded. The WHA works as the brain of the WHO, meaning it is the decision-making body. Its main function is to determine the policies of the organization and it is the highest health policy setting body. The WHO realized it would be difficult to develop a hardworking and fast programmes for all health matters requiring international attention during the first year of its existence, and thus accorded high priority to the first WHA for making some key decisions.

The WHA follows the standard rules of procedure, which means it is not an ad-hoc committee. In our conference, we will discuss issues related to major health problems and crises which concern an enormous number of people around the world. Furthermore, in our MUN committee, we are not to be concerned with financial clarifications, as long as proposals stay reasonable.

Key Terms

Generic medicine
A generic drug is a pharmaceutical drug that is equivalent to a brand-name product in dosage, strength, route of administration, quality, performance, and intended use, but does not carry the brand name. Generic drugs generally sell at lower prices.
EXAMPLE: "diazepam" is an example of the chemical (generic) name of a sedative. It is marketed by some companies under its generic name and by other companies under brand names such as Valium or Vazepam.

Excipients
Excipients are the non-active ingredient in the drug product.

Intellectual Property rights
Intellectual property rights refer to the general term for the assignment of property rights through patents, copyrights and trademarks. These property rights allow the holder to exercise a monopoly on the use of the item for a specified period.
I advise you to further research the different types of intellectual property rights

Voluntary Licenses
Patent holders may at their discretion, license to other parties, on an exclusive or nonexclusive basis, the right to manufacture a pharmaceutical product without the risk of being sued for intellectual property infringement.

Compulsory licenses
Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. This is one of the flexibilities in the field of patent protection included in the TRIPS agreement (Trade-Related Aspects of Intellectual Property Rights)

Term of patent
The term of a patent is the maximum period during which it can be maintained in force.

TRIPS agreement
The Agreement on Trade-Related Aspects of Intellectual Property Rights sets down minimum standards for the regulation by national governments of many forms of intellectual property as applied to nationals of other WTO member nations. TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade in 1994 and is administered by the WTO.

General Overview

Innovation in the domain of medicine saves millions of lives globally. However nobody would innovate if there was not a way to secure profit from new ideas. This is guaranteed by what we call intellectual property rights, and although they are of utmost importance, they are also a cause of dispute in the pharmaceutical industry. In many ways they can control the affordability and accessibility of medicine, which is why we must ensure that they function correctly.

Right now the measures which ensure intellectual property rights, patents, and regulate the production of generic medicine are questionable and sometimes corrupt. Furthermore we must keep in mind that both in developed and developing nations many people depend on generic medication for their treatment. Consequently we are faced with some important questions: Should generic medication have fewer regulations, and should developing nations be able to create public health exceptions? If so, how would companies be able to pay for the development of lifesaving medication and what would drive innovators? Before we start addressing the issue we first need to have an overview of the topic.

Patents originated in ancient Greece but this form of legal protection assumed greater importance in 15th-century Venice. The birth of the term "medical patent" has become particularly associated with the 18th and 19th centuries. Nowadays, for a pharmaceutical company, the next step after inventing a new drug would be to file a patent for it. This means securing a monopoly for this drug under its brand name. Once granted, a patent can last up to twenty years, but this time may vary depending on the circumstances. For instance, the majority of issued patents have their term extended and such extensions can last up to five years, but after the patent expires the invention is in the public domain. Since the company has invented the medicine, the patent would not allow anyone to copy its chemical basis. The idea is that the profit companies gain from these short monopolies can support and fund further research and act as an incentive for more companies to innovate. But is this how patents work? Unfortunately, there are many problems with the patent system right now. Increasingly, drug companies are not investing in research and development proportionally to the profits they earn from the drugs they bring to market. On the contrary, many have figured out that it's simpler and safer from a financial perspective to buy the rights to drugs developed by others and raise the prices. Therefore the patent protection process now primarily serves the drug companies. An example of such behaviour was revealed in 2015 by a US senate investigation which found that the biopharmaceutical company Gilead, didn't base the price of the drug on its research investments or manufacturing costs, instead, they set the price based on what they determined was the most they could charge while still avoiding bad publicity.

The opposite of branded medication is generic medication, which is of central importance since it plays a significant role in the pharmaceutical industry. As we have discussed previously, when a drug first gets to the market, its parent company initiates a patent for it, to sell it exclusively for a certain number of years. When the patent term has elapsed, other companies can start making a generic product. Generic medication is usually much cheaper than branded, due to the fact that generic medicine companies do not have years of research behind their products, thus they don't need to sell a drug at a high price in order to start making a profit. This often works as fuel for the misconception that generic medication is of lower quality, but it is essential that we clarify that this is false. Before a company can produce and market a generic drug they have to submit a drug application which, among other things, proves that the drug is bioequivalent and pharmaceutically equivalent to the original branded product. Bioequivalence means that the generic product must have the same effect as the branded one; therefore the drug must have the exact same effect on the

body, in the same amount of time. Pharmaceutical equivalence means that the generic medicine contains the same amount of drug compound as the innovator drug, as well as having the same strength, the same dosage form and the same route of administration. This proves that brand and generic products have the same drug molecules. But just because they are bioequivalent and pharmaceutically equivalent does not mean that they are the same in every way. In fact, excipients may vary in the same drug product, as you can see in the "Key terms, p.3" section; excipients are the inactive ingredient in the medicine. As mentioned previously, generic products are usually sold at a fraction of the cost of the original drug, which is why they have managed to save millions of lives in the developing world. Legislation passed in 1951 had the effect of limiting opportunities for manufacturers of generic medicine of satisfactory quality. Why is this so important and how can we alter some of its effects? We can answer that with a different question.

Should generic medication have fewer regulations, and should developing nations be able to create public health exceptions? Many people suggest that the global pharmaceutical industry needs to rethink the role of patent law in the way it operates, or in the very least enforce it correctly. Moreover, this issue is not just about protecting the industry of generic drugs it is also about the life or death of many people. When looking at some statistics it is easy to understand the importance of creating public health exceptions. For example, according to a Medecins Sans Frontieres (MSF) report from 2005, India's generic therapies led to the cost of certain AIDS therapies dropping from as much as 10,000€, to around 200€. Prior to 2005, India did not grant patents on medicines. This strengthened the generic drug manufacturing industry, which exports medicines to treat diseases like HIV/AIDS, malaria and tuberculosis around the world. This behaviour put India in the crosshairs of many pharmaceutical companies from the US and Europe which claimed that patent protection and the profits it generates are crucial for funding further research. Another question that arises is: would having patent exceptions for certain countries excessively harm the profits of such pharma-companies?
Many would argue that such an action, which exists in the lighter form of Compulsory Licenses, would not in fact harm their profits. This is because when we are talking about public health exceptions of this type, the main problem we face is that many people and patients don't have access to branded vaccine, for example, due to economic factors. This means that most likely they would not be able to buy the branded version in the first place; therefore, even if there was a patent on this vaccine, these people would not be the ones who would buy it. Thus, allowing some people in developing countries to use a generic version before the patent term has elapsed would not reduce the research funding for large pharmaceutical companies. However, achieving this needs a lot of restrictions such as ensuring that this exception of a generic product will only be used in the countries that have been deemed to genuinely need it; because if this product was not regulated enough and managed to get to other countries that have not been granted this exception, then consequently, the company could possibly be harmed

Although all this seems incredibly helpful, we must bear in mind that for each solution proposed for the issue there are many things that need to be cleared, such as the mechanisms that would manage to ensure that everything proposed in a solution will actually happen. Beforehand, we tried to clarify as well that some companies manage to continue making profit through the patent system, without needing to innovate. Surprisingly others say that the patent I.P. rights protection is not enough for the medical companies to make profit.

In conclusion, there is a strong need to reaffirm the problems of the relation between intellectual property and generic medication, and also to reform the patent system which is now in place. There are many different problems within the issue all stemming from the start of the medical patent system. By improving the functionality of the medical industry we will improve the lives of millions of people around the world. This is why we wish to remain actively engaged with the matter.

Major Parties Involved

Stakeholders are groups of people, organizations or countries that are greatly affected by, and closely related to the problem. This means that they either play a role in the existence of the problem, profit from it, or they could be considered victims.

Arguably one of the most important stakeholders of this issue are LEDC's and developing countries. Since a large number of their population cannot afford branded medication, they depend on generic drugs. This means that a patent time for a lifesaving drug will not allow these people to get hold of it for a large amount of time. For example, in India there have been many campaigns fighting against the pharmaceutical industry, which is fiercely protecting its Intellectual property rights, for affordable medicine. India has been trying to use legal measures to overturn patents so that its generic drug companies (which produce a fifth of the world's generic drugs) can undercut bigger companies, whilst in the meantime saving millions of lives. Moreover, a more general stakeholder would be the people who can't afford branded medication, whether that is in LEDC's, developing or developed countries.

The next big stakeholders are the big pharmaceutical companies; largely thanks to them we have very fast paced progress and innovation in the industry, however this does come at a cost as we have mentioned previously. Any decision taken by a resolution would affect these companies considerably. Furthermore, companies which produce generic drugs are also stakeholders, since for example changing patent terms would alter their rate of production.

Timeline of Events

1888, → The American Pharmaceutical Association (APhA) published the National Formulary to help prevent counterfeiting of branded products.

1906 →Passage of the Federal Food and Drugs Act. First law to require product labeling in an effort to prevent misbranding and adulteration, and it enabled the government to take action if a product caused significant harm.

1928 →Many mainstream drugs are beginning to enter the market and concern is voiced that generic substitution might be deceptive.

1938 →Federal Food, Drug, and Cosmetic Act. The FDCA designated products introduced after 1938 as new drugs and required them to be proven safe through manufacturer testing and FDA clearance before they could be marketed.

1951 →APhA passed state legislation. Although these laws helped prevent substitution of low-quality products, they limited opportunities for the manufacture of generic products of sufficient quality.

1967 → After a cost-effectiveness analysis of drug products conducted by Congress, the use of generic products by federal health and welfare programs was strongly encouraged to safeguard against inflated pricing arising from lack of competition. This helped move generic medicines into the forefront.

1984 →The Hatch-Waxman Act, allowed the FDA to approve applications to market generic versions of brand-name drugs released after 1962 without repeating efficacy and safety research. Furthermore it allowed manufacturers to extend their patent protection for up to 5 years.

1994 →The patent term of drugs manufactured in the U.S. was extended from 17 to 20 years after filing.

1998 → 39 pharmaceutical companies filed a lawsuit against South Africa. They hoped to stop the government from producing the generic drugs that would have made treatment affordable for the country's AIDS victims.

Previous attempts to solve the issue

Intellectual property rights, usually restrict the availability and accessibility of affordable medicine in LEDC's. Such countries are fighting pharmaceutical giants in order to get hold of compulsory licenses. A key decision came in 2012, when India issued a compulsory license for Bayer's cancer drug sorafenib (Nexavar), allowing a local company Natco to produce a generic version. A compulsory license allows a company to produce a patented product without the consent of the patent owner.

The TRIPS agreement first allowed such flexibilities, ever since it took effect in January 1995. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement between all the member nations of the World Trade Organization (WTO). It sets down minimum standards for the regulation by national governments of many forms of intellectual property as applied to nationals of other WTO member nations. There have been previous agreements but TRIPS has a powerful enforcement mechanism. States can be disciplined through the WTO's dispute settlement mechanism.

The Future

A significant amount of time has passed since a large party has reconsidered or altered the mechanisms of securing intellectual property rights and their relation to generic medication. Thus a new, bright and revolutionary resolution is needed. Furthermore, we cannot stress enough how important it is that you follow the approach of your country while forming ideas for your resolution, and try to think of what group of people your resolution will help in the future. I will not analyse in detail the different perspectives of each nation, but it is self-evident that a country like India, which focuses considerably on generic medication, will have a different view compared to Germany which has a large branded drug industry.

It is highly significant that we realise that if this issue is not acted upon then the present situation would either continue with all the harms that we have discussed previously, or in a worst case scenario this could lead to more complications and problems. As pharmaceutical companies would gain more power, cases like the one in South Africa in 1998 would become more familiar and routine. In 1998 numerous companies tried to stop South Africa from encroaching on their patents and making cheaper medicines for their country. In the instance of 1998, the lawsuit against the developing country was finally dropped but we must ensure that lawsuits of this kind cannot be filed in the first place. Otherwise, such examples are bound to reoccur due to the inflexible patent system currently in place, in effect, this would mean more deaths as a result of the lack of affordable drugs.

Important Decisions a Resolution Must Take

Delegates, here you will find ideas which will help guide you through what your resolution must address. But bear in mind that included are only the most basic things that you must make clear in your resolution, there are many other aspects that individual countries or groups of countries should talk about.

When writing a resolution it is imperative that you ask yourself what your country's policy is. For example, if your country has an important industry for the production of generic medicine, then it is more probable that it would support a more flexible type of patent. Furthermore, try to think of how your resolution could help bring both short-term and long-term solutions to the issue. Moreover, researching the overall relation of your country to the topic, looking into past treaties it might have signed and past actions that it was part of, can help you have a better understanding of your country's policy.

Other things that you will need to consider are certain moral or practical dilemmas. You will need to contemplate how pharmaceutical companies are actually at fault? Is it just the patent system or does their aggressive and possibly opportunistic stance really play a role? To reach a conclusion you will have to understand their point of view of the issue and try to see why they may have it in the first place. As we have said many times previously, you should also consider if these companies would lose some motivation to innovate if we had more generic medication in the market? To understand this you can look into past examples and how those companies fared in different situations. If you come to the conclusion that they would lose some will to innovate, then you could to try to think of alternative methods of motivating them. Finally, to grasp the importance of each of these decisions that you must make, you should understand that a resolution on this issue would impact the life of billions of people throughout the world.

Further Reading

Here you can find some websites that may help you while doing your research:
Generic drugs:
https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm506040.htm
I would advise you to look into WHO texts and articles such as:
http://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf
To further understand patents:
https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm
https://www.youtube.com/watch?v=RrN7IxvAJto&list=PL8dPuuaLjXtMwV2btpcij8S3YohW9gUGN&index=4
Generic Drug "war":
https://www.youtube.com/watch?v=o7xzf9ZwzTY
https://www.bmj.com/content/348/bmj.g1533

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http://www.who.int/global_health_histories/first_world_health_assembly/en/
http://www.abc.net.au/news/2017-09-28/what-india-pfizer-patent-decision-means-for-region-health/8981206
https://nesri.org/programs/what-is-the-human-right-to-health-and-health-care
https://yaleglobal.yale.edu/content/strict-international-patent-laws-hurt-developing-countries