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**Study Guide**

Committee **WTO**
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# Intellectual Property Rights on Life-Saving Medications and Drugs

## Introduction

The right to own property is often classified as a human right. It is at the basis of individuals' and societies' advancement in order to reach their maximum potential. Yet when it comes to pharmaceutical research and development (R&D), this system does not work, causing major problems to humanity. Part of the problem is that the process of researching and patenting new medications is largely carried out by private firms, thus leading to a strong reduction in access to these medications by the general population.

## Definition of Key Terms

**Intellectual property**: intangible property resulting from the creation of the mind (inventions, artistic works, names, symbols, chemical compositions, etc.);

**Patent**: a government licence giving an individual or a company the exclusive right to make, sell, or use an invention for a limited period of time (after which it expires);

**Patent infringement**: the violation of a patent without the permission of the patent owner (i.e., stealing other people's intellectual property);

**Commercial drug** (also **brand-name drug**): a medication whose chemical composition is protected by a patent and is under a trademark;

**Generic drug** (also **generic**): a medication whose patent expired and which is sold without a brand name;

**Life-saving medication** (also **essential medication**): a drug that, if not used or taken properly in emergency situations, could cause a patient's death;

"**Big pharma**": colloquial name for big pharmaceutical companies;

**Licence**: with licensing, a patent owner can allow somebody else to use their patent in exchange for money.

# Background Information

Nowadays, most research on new medications is carried out in private laboratories on behalf of big pharmaceutical companies. When they discover a new drug, they trial it on patients and if it proves effective and harmless, they apply for a patent and then sell it on the market.

Patents allow private individuals and companies to claim intellectual property (IP) on new medications and drugs. If they obtain the patent, no other company can copy their product and sell it legally. If somebody tries to copy a patented product, the patent owner can sue for patent infringement. In this way, people and companies can profit from their own inventions and discoveries.

In other words, a pharmaceutical patent is a public policy instrument which provides a monopoly on that specific medication, thus economically benefiting the patent owner (the pharmaceutical company): they can freely set the price for their product and they will be able to profit from its sale for a number of years, until the patent expires. In return, the benefit for society at large is that companies, in their pursuit of profit, are pushed to research and develop new and better medicines.

However, the patent system may make many drugs less accessible to lower social classes or to less economically developed countries. This is because companies want to make the most out of their investments in research, and will sometimes set extremely high prices.

This system is also vulnerable to unscrupulous investors. Patents for medicines can be bought and sold, and in 2015, "Pharma Bro" Martin Shkreli famously bought Daraprim, a life-saving medication used for treating seizures and pneumonia related to HIV. He increased its price from $13.50 to $750 overnight. He was later arrested and convicted on fraud charges.

Another problem is the difference in the number and quality of infrastructures and skills dedicated to medical research within the less economically developed countries. Their governments cannot afford to make large investments due to the poor development in this

field. This means that hospitals and healthcare providers in these countries have no choice but to buy drugs from "big pharma," further increasing their profits and intensifying their dependence on them.

Finally, the patent system and patent expirations encourage companies to keep developing new medications, some of which are not really useful, and sometimes dangerous. Patents on brand-name drugs expire after 20 years in the US, after which a company loses its monopoly and generics can be sold. This means that they are always seeking new ways of making profits. Purdue Pharma was doing just that when it pushed OxyContin on the market with misleading information, generating an opioid crisis in the US.

## The WTO and Patent Protection

Patent rights are protected worldwide by the World Intellectual Property Organization, a specialised UN agency. An international patent system makes it easy for people to apply for patents in different countries.

WTO agreements also cover intellectual property rights, which are deemed fundamental to encourage innovation and research. In particular, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was signed by all the WTO members and it established a series of minimum requirements of patent protection that national laws must respect. For example, when it comes to drug patents, TRIPS states that the minimum duration is 20 years.

In 2001, the WTO Ministerial Conference amended TRIPS by adopting the Declaration on the TRIPS Agreement and Public Health (also known as the Doha Declaration), which clearly stated that patent protection must not come at the expense of public health. It afforded more flexibility to countries that need to access essential medications. For example, during "national emergencies," Member States can force big pharmaceutical companies to issue licences for their patents (to local companies, so that a medicine can be manufactured quickly).

The point of the Doha Declaration was to introduce some flexibility so that poorer countries could afford essential medicines better. However, they are still undoubtedly at a disadvantage.

The problem does not even only concern LEDCs. Among developed countries, those with public healthcare systems can negotiate the prices of some drugs, while others are at the mercy of private companies. Moreover, even in public systems, hospitals sometimes need to pay absurd prices for more and more specialised medicines (for example, cancer treatments).

## COVID-19 Vaccines

The vital need to ensure a worldwide access to medications was exposed by the COVID-19 pandemic. The World Health Organization (WHO) said that if COVID-19 vaccines had been

properly distributed to poorer countries, the pandemic would have lasted less. Some used this to argue that patents on certain medicines, such as the COVID-19 vaccines, should be lifted to make sure everyone could manufacture them. Others said that this would have taken away the incentive for pharmaceutical companies to develop the vaccine, so that in the future, we will never see such a quick development of a new medicine.

What is certain is that while vaccines are not life-saving medications strictly speaking, they played an essential role in the recovery from the pandemic. The need for a better distribution of quality, affordable healthcare became clear.

| TRIPS stage | Legislative position | India | Brazil | South Africa | China | Remarks |
|---|---|---|---|---|---|---|
| Pre-TRIPS | 1. No patent protection for pharmaceuticals.<br>2. Process patent only.<br>3. Limited duration for pharmaceutical patent protection. | To encourage the generic production of drugs and to develop imitating capacity, India prohibited product patents and allowed only process patents for pharmaceuticals.<br>Process patent for pharmaceuticals granted only for seven years. | Eliminated both process and product patents for pharmaceuticals. | Provided both product and process patents for pharmaceuticals in the pre-TRIPS period without any substantive examination. | Did not grant process and product patents for pharmaceuticals until 1984. The 1984 patent law amendment introduced granting of patent protection on process, and the 1992 amendment introduced granting of patent protection on pharmaceutical products. | India allowed process patents only during the pre-TRIPS regime, whereas Brazil eliminated patent protection for pharmaceuticals altogether; South Africa provided both product and process patenting even during the pre-TRIPS period. |
| Transitional period: until 1 January 2005 for developing countries and until 1 January 2016 for LDCs (extended to 1 July 2021) | Utilisation of full transition period. | Utilised the full transition period and introduced TRIPS-compliant patent law in 2005. | Approved a TRIPS-compliant patent law (Industrial Property Law 9.279) in 1996 and implemented it in May 1997. | Undertook to become TRIPS-compliant in 1997. | Officially became a WTO member on 11 December 2001 and during accession negotiations committed itself to reforming its IPR regime.<br>Accordingly, it adopted TRIPS-compliant patent law on 25 August 2000, which entered into force on 1 July 2001. | Brazil and South Africa introduced TRIPS-compliant law several years before the 2005 deadline, whereas India waited until the expiration of the whole period. |

# Possible Solutions

There is a delicate balance between, on the one hand, rewarding companies for their research efforts and incentivising them to produce better and better medicines, and on the other, making sure everyone can access life-saving medications. LEDCs will want to make sure the benefits from new scientific findings and medicines are shared, while some developed countries will tend to be protective of their own companies.

Delegates may focus on:

- ➔ Calling for patents to expire earlier in the case of life-saving drugs, or banning patents on them altogether;
- ➔ Monitoring the imbalance in access to life-saving drugs regularly;
- ➔ Providing infrastructure at public prices;
- ➔ Rewarding research rather than companies;

- ➔ Treating the R&D results related to life-saving medication as public goods rather than private property by:
  - ➔ Democratising the pharmaceutical production system;
  - ➔ Implementing a global patent pool based on the free exchange of research results without the traditional proprietary restrictions;
- ➔ Nationalising the entire pharmaceutical R&D activities related to life saving drugs;
- ➔ Limiting the participation of private pharmaceutical companies into the production and distribution of drugs in the market.

# Sources & Useful Links

Patenting of life-saving drugs has created a global health crisis where human life has become a commercial commodity. | Impact of Social Sciences

Intellectual property and access to medicine | Oxfam

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https://heinonline.org/HOL/LandingPage?handle=hein.journals/cqhe20&div=41&id=&page=

Martin Shkreli as the Face of US Health Care - The Atlantic

THE PATENT LAW

Patent Expiration and Pharmaceutical Prices | NBER

Pharmaceutical patents and the TRIPS Agreement

WTO IP rules amended to ease poor countries' access to affordable medicines