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## WORLD TRADE ORGANIZATION

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### DESCRIPTION OF THE COMMITTEE

The World Trade Organization (WTO) is the only international organization dealing with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible. It does this by:

- Administering trade agreements
- Acting as a forum for trade negotiations
- Settling trade disputes
- Reviewing national trade policies
- Assisting developing countries in trade policy issues, through technical assistance and training programmes
- Cooperating with other international organizations<sup>i</sup>



The World Trade Organization came into being in 1995. One of the youngest major international organizations, the WTO is the successor to the General Agreement on Tariffs and Trade (GATT) established in the wake of the Second World War. So while the WTO is still young, the multilateral trading system that was originally set up under GATT is well over 50 years old.<sup>ii</sup>

The WTO has nearly 150 members, accounting for over 97% of world trade. Around 30 other countries are negotiating membership. Decisions are made by the entire membership. This is typically by consensus. A majority vote is also possible but it has never been used in the WTO, and was extremely rare under the WTO's predecessor organization, GATT. The WTO's agreements have been ratified in all members' parliaments.<sup>iii</sup>



## INTELLECTUAL PROPERTY RIGHTS, PHARMACEUTICALS, AND LEAST DEVELOPED COUNTRIES.

### INTRODUCTION

Health is a widely recognized human right. Documents such as the Universal Declaration of Human Rights and International Covenant on Economic, Social and Cultural Rights “recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>iv</sup> However, not every person in the world has access to healthcare services, which in turn leads to a lot of people living in disease.

An important factor to guarantee the right to health for everyone means that people must have adequate access to medications. However, many people and governments around the world often have problems when trying to purchase medications due to their high costs. The more advanced a medicine is, the more expensive it will be because of the amount of research needed to research and develop it.

**Intellectual property rights** (IPRs), specifically **patents**, are ways of motivating companies into researching and developing new medicines. When a country grants any given company a right over a medicine they developed, they are granting them the opportunity to exclusively produce that medicine. However, this also results in excessively high prices for medications due to the fact that companies can set the price they want on medicines since they have no competitors that they have to beat for customers.

### INTELLECTUAL PROPERTY RIGHTS 101

Intellectual property (IP) refers to creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce.

Intellectual property is divided into two categories: Industrial property, which includes inventions (patents), trademarks, industrial designs, and geographic indications of source; and Copyright, which includes literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs.

*Source:* <http://www.wipo.int/about-ip/en/>

The high prices of medications become a problem when sick people do not have the economic resources to purchase them. **Least developed countries** (LCDs) present this problem more frequently than any other country, since their population usually earns very little money and they cannot spend that money on medicines when they have to buy food and other important goods for their families to survive.

If countries fail to provide patent protection to medicines, pharmaceutical companies will rarely sell their products in these countries, at the risk of having other corporations copying their



products. However, if LDCs do grant patent protection, the prices of medicines will be extremely high, and a large segment of the population will not have access to them. Herein lies the major issue of the topic.

## HISTORY/BACKGROUND

### *The Story of the Current Trade System*

After the Second World War, there was a great need in the international community to organize the world economic system. With this in mind, the **General Agreement on Tariffs and Trades** (GATT) was created. This agreement addressed the three biggest issues of the world economy at that point: “exchange rates, reconstruction and the organization of international trade in goods.”<sup>v</sup> The GATT set the rules for international trade in order to promote free trade and facilitate commerce amongst nations.



Signing of the Uruguay Round in 1993

Source: <http://news.bbc.co.uk/2/hi/business/533716.stm>

However, at the beginning of the 1980s, it became apparent that the General Agreement was no longer well adapted to the realities of trade as it had been in the 1950s. The complexity and volume of world trade were now very different from what they had been 40 years earlier. As the globalization of the economy progressed, international investments saw an unprecedented growth, and trade in services - not covered by the GATT rules - began to be a major interest for more and more countries, and was closely bound up with the increase in global trade in goods.<sup>vi</sup>

A new attempt at regulating international trade was started in what is now know as the Uruguay Rounds. The seeds of the Uruguay Round were sown in November 1982 at a ministerial meeting of GATT members in Geneva. It took four years of efforts to explore and clarify the issues at stake to gradually work towards a consensus, before the ministers decided to launch the “Uruguay Round” while meeting again in September 1986 at Punta del Este, Uruguay. They adopted a program of negotiations encompassing nearly all of the outstanding problems of trade policy, including the extension of the trading system into several new fields, particularly services and intellectual property rights.<sup>vii</sup>

One of the agreements that came out of the Uruguay Rounds is the agreement on **Trade-Related Aspects of International Property Rights (TRIPS)**. This agreement sets minimum standards of protection for patents, copyrights, trademarks and other forms of intellectual property.<sup>viii</sup>

With these protection mechanisms set into motion, corporations and individuals are able to develop new ideas and products with the assurance that these innovations will not be stolen by others and that they will see the efforts put into that development rewarded. TRIPS provides uniform rules to every country in order to promote research on many aspects of life.

## *The Role of IPRs in Pharmaceutical Development*

Patent systems are intended to facilitate the introduction of new pharmaceutical products by stimulating the climate for private investment and encouraging research by pharmaceutical manufacturers – but their role is complex in the case of neglected diseases. The development of medicines is a complex and expensive process with one study estimating that the average cost of bringing a new medicine to market is up to \$800 million. Part of that expense stems from the fact that the vast majority of products never reach the marketplace. In a different context, and based on different assumptions, the Global Alliance for TB Drug Development published a report that made a “rough estimate” of “a total cost of between \$115 million and \$240 million to discover and develop a new anti-TB drug (including the costs of failure).”<sup>xix</sup>

If the purchasing power of those in need is not sufficient to justify an investment in a new medicine, then private industry will generally not invest the funds on its own unless such investment is considered as part of a charitable effort outside of their traditional business model. Companies acting pursuant to market considerations logically invest where they have the greatest opportunity for financial return. Thus, when diseases afflict only patients in developing countries, but few in developed countries, the free market may not support the development of a new medicine, even with patent and data protection.<sup>x</sup>

### CRITICAL THINKING QUESTION

Can you think of ways to find a balance between promoting development and research of new medications and granting access to people with low incomes?

### *Alternatives: Compulsory Licensing, Parallel Imports, and Private-Public Investments*

Several attempts at finding a balance between the rights of people to access medicines and the rights of companies to protect their products have been made. First there is the idea of **compulsory licensing**. Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. The agreement allows compulsory licensing as part of the agreement’s overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder. If a compulsory license is issued, adequate financial compensation must still be paid to the patent holder.<sup>xi</sup>

Another method in which the protection of patents has been broken is **parallel imports**. This method only applies when the patent holder sells the same medicine at different prices in two different countries. Under the parallel import method, a company that is not the patent holder could buy the medicine in the country where it is cheaper and then export that same product into the country where it is more expensive.

For example, suppose Company Zebra has a drug patented in the Republic of Belladonna and the Kingdom of Calamine, which it sells at a lower price in Calamine. If Company Elephant buys the drug in Calamine and imports it into Belladonna at a price that is lower than Company



Zebra's price, that would be considered a parallel or grey import.<sup>xii</sup>

Finally, governments around the world have started partnerships with pharmaceutical companies to contribute money into the research process hence alleviating the financial burden of research from companies. **Public-private partnerships** for the development of new medicines attempt to combine the strengths of the private and public sector in order to simultaneously satisfy both public interests (increased research & development) and private interests (profit potential where markets exist, proof of technology concept [particularly for small companies] and improved corporate profiles [particularly for larger companies]).



The private sector has advantages and skills that are not ordinarily found in the public sector. In particular, the private sector is experienced in converting basic research into a medicine approved for distribution. Public sector involvement provides taxpayer- or charity-supported funding and access to government and university laboratories and researchers.<sup>xiii</sup>

## PAST INTERNATIONAL ACTION

With the adoption of the TRIPS, the international community attempted to find a balance between protection and access. On one hand, the protection granted by the TRIPS encourages inventors and creators because they can expect to earn some future benefits from their creativity and development. This encourages new inventions – i.e. new drugs – whose development costs can be extremely high, so private rights also bring financial benefits.

On the other hand, the TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled.<sup>xiv</sup>

In agreeing to launch a new round of trade negotiations, trade ministers adopted a “Declaration on the TRIPS Agreement and Public Health” on November 14, 2001.<sup>3</sup> The Declaration sought to alleviate developing country dissatisfaction with the TRIPS regime. It delayed the implementation of patent system provisions for pharmaceutical products for least developed countries (LDC) until 2016. The declaration committed member states to interpret and implement the agreement to support public health and to promote access to medicines for all.

It also affirmed the right of WTO members to use the flexibilities in the TRIPS agreement to promote these goals. The declaration reiterated that each member has the right to grant compulsory licenses and to determine the terms and circumstances in which they are issued. Each country also has the right to determine what constitutes a national emergency or circumstances of extreme urgency, defining these terms to include public health crises such as “HIV/AIDS, malaria, and tuberculosis and other epidemics.”<sup>xv</sup>



## CURRENT SITUATION

Access to medication is a pressing issue in today's world. According to UNICEF's latest estimate, over 9 million children under five years are expected to die each year. This means that one thousand children under five years old die every hour. More than half of these deaths are caused by diseases which could be treated with safe essential child-specific medicines: acute respiratory infections like pneumonia (17%); diarrhoeal diseases (17%); neonatal severe infections (9%); malaria (7%); and HIV/AIDS (2%).<sup>xvi</sup>

The current epidemics of various diseases around the world also demonstrate the urgency in addressing this pressing issue. For instance, UNAIDS estimated that 33 million people were living with AIDS in 2007, but only 3 million people were receiving antiretroviral treatment in low- and middle-income countries at the end of that year. This represents 31% of estimated global need for treatment.<sup>xvii</sup>

Other epidemics, such as malaria and tuberculosis, and even common diseases such as pneumonia and diarrhea, still amount for the top diseases that cause death among the world's population. Even when all of these diseases have a treatment or can be cured when access to the medication when early and adequately available, it is clear that there is still a lot of work to be done on the issue.

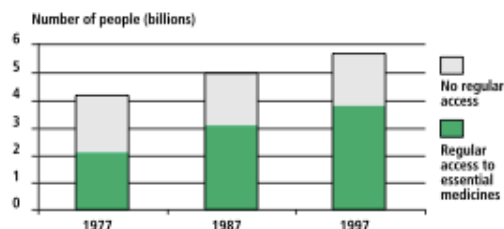
## RECOMMENDATIONS FOR FORMULATING A RESOLUTION

It will be the delegates job to find a balance between the protection granted to the creators of pharmaceuticals and the right of the population to access medications. Delegates should bear in mind at all times that access to health is a human right which needs to be guaranteed for every person in the world.

However, delegates must not forget that without the protection of IPRs, companies and individuals will rarely invest in research and development of new medications. Therefore, delegates must also have the interests of pharmaceutical companies in mind when trying to find a solution to the problem.

Any resolution that fails to encompass both positions and leans towards one more than the other will hardly succeed in solving the issue at hand.

**Figure 1** The total number of people with access to essential medicines has increased from around 2.1 billion in 1977 to an estimated 3.8 billion in 1997



Source:

[http://whqlibdoc.who.int/hq/2004/WHO\\_EDM\\_2004.4.pdf](http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf)

### QUESTIONS TO CONSIDER

1. What are the specific regulations of your country on IPRs for medications?
2. Is your country home to any pharmaceutical corporations?
3. Does your country suffer from specific epidemics? Is there a high mortality rate in your country due to curable diseases?
4. Does the overall population of your country have the resources to purchase medications when needed?
5. Has your country started any specific programs or partnerships to ensure general access to medications?

### TERMS AND CONCEPTS

**Intellectual Property Rights:** Exclusive rights to market, produce and sell a product or creation granted to the author or person responsible for the discovery of said product.

**Patents:** a right granted to the inventor of a new product to exclude others from its making, using, selling, offering for sale or importing for up to 20 years from date of application.

**Least Developed Countries (LDCs):** the poorest and weakest countries of the international community.

**GATT:** an international agreement that deals with the international trade of goods.

**TRIPS:** Agreement on Trade Related Aspects on Intellectual Property Rights, the agreement in the WTO regarding intellectual property rights.

**Compulsory Licensing:** a government forces the holder of a patent, copyright, or other exclusive right to grant use to the state or others, usually philosophically justified as an attempt by the government to correct a market failure. Usually, the holder does receive some royalties, either set by law or determined through some form of arbitration.

**Parallel Imports:** a non-counterfeit product imported from another country without the permission of the intellectual property owner.

**Public-Private Investments:** a government service or private business venture which is funded and operated through a partnership of government and one or more private sector companies.



## RESEARCH AID

Watch this video before you start your research. It will present you with a general overview of the topic:

- <http://www.youtube.com/watch?v=jEKC4bTKxu8>

If you need more information to better understand intellectual property rights visit the following website by the World Intellectual Property Organization:

- <http://www.wipo.int/about-ip/en/>

The World Health Organization has an entire section on medicines with a specific website for IPR related topics. You can find a lot of useful information and reports:

- <http://www.who.int/medicines/areas/policy/globtrade/en/index.html>

The World Trade Organization has also dedicated a webpage to the specific issue of pharmaceuticals and IPRs. Here you will find comprehensive reports on the subject as well as past actions taken by the WTO:

- [http://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm)

Here you can find a list of the least-developed countries in the world as well as the criteria under which they are considered as such:

- <http://www.unohrlls.org/en/ldc/related/62/>

A great and thorough report on the matter is the report by WHO on the TRIPS Agreement and the related aspects of pharmaceuticals and access to medications. You can find the report here:

- <http://www.who.int/medicines/areas/policy/who-dap-98-9rev.pdf>

The following is a debate held at the “WTO Forum” between both sides of the issue: pharmaceutical companies and the general population and its right to access medications. Both participants present key points that support both positions:

- <http://www.youtube.com/watch?v=FGwPiKxmpDI>

Many NGOs also lobby to make essential medicines available to the people that need it most, including 1999 Nobel Prize winners Medecins Sans Frontieres (MSF, or Doctors Without Borders). While this article is a couple of years old, it does show the lengths in which NGOs were willing to take developing countries (in this case, Brazil and South Africa:

- <http://www.aegis.com/news/dmg/2002/MG020203.html>

## REFERENCES

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<sup>ii</sup> “The multilateral trading system- past, present and future”  
[http://www.wto.org/english/thewto\\_e/whatis\\_e/inbrief\\_e/inbr01\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr01_e.htm)

<sup>iii</sup> “The Organization” [http://www.wto.org/english/thewto\\_e/whatis\\_e/inbrief\\_e/inbr02\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr02_e.htm)

<sup>iv</sup> International Covenant on Economic, social and Cultural Rights,  
<http://www2.ohchr.org/english/law/cescr.htm>

<sup>v</sup> “Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement”



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<sup>viii</sup> “The WTO, Intellectual Property Rights and the Access to Medicines Controversy”

[http://www.ipmall.info/hosted\\_resources/crs/RS21609\\_050928.pdf](http://www.ipmall.info/hosted_resources/crs/RS21609_050928.pdf)

<sup>ix</sup> “The Development of Medicines for Developing Country Diseases: the Role of Intellectual Property” [http://www.wipo.int/edocs/mdocs/mdocs/en/isipd\\_05/isipd\\_05\\_www\\_103972.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/isipd_05/isipd_05_www_103972.pdf)

<sup>x</sup> “The Development of Medicines for Developing Country Diseases: the Role of Intellectual Property” [http://www.wipo.int/edocs/mdocs/mdocs/en/isipd\\_05/isipd\\_05\\_www\\_103972.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/isipd_05/isipd_05_www_103972.pdf)

<sup>xi</sup> “Obligations and Exceptions”

[http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm#grounds](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#grounds)

<sup>xii</sup> “Obligations and Exceptions”

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<sup>xiii</sup> “The Development of Medicines for Developing Country Diseases: the Role of Intellectual Property” [http://www.wipo.int/edocs/mdocs/mdocs/en/isipd\\_05/isipd\\_05\\_www\\_103972.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/isipd_05/isipd_05_www_103972.pdf)

<sup>xiv</sup> “Philosophy: TRIPS attempts to strike a balance”

[http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm01\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm)

<sup>xv</sup> “The WTO, Intellectual Property Rights and the Access to Medicines Controversy”

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<sup>xvi</sup> “10 facts on children and medicines”

<http://www.who.int/childmedicines/facts/en/index.html>

<sup>xvii</sup> “UNAIDS Global Facts and Figures”

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