

„Improving Access to Generics in Developing Countries“



COMMITTEE GUIDE

WORLD INTELLECTUAL PROPERTY ORGANIZATION



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http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?pagewanted=all&_r=0

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Personal Introduction

Dear Delegates of the World Intellectual Property Organization,

my name is Hendrik Napierala and this year I will serve as one of the two presidents of the World Intellectual Property Organization (WIPO). I am 21 years of age and am currently enrolled at the Charité Medical School Berlin studying Medicine in my second year.



OLMUN 2013 is going to be my ninth overall Model United Nations. It all started in 2008 where I represented Uganda in the Ga3rd-Committee at the OLMUN debating Illegal Organ Trade. I caught fire and in the following years I had various positions ranging from the UK in the Security Council, over Palestine in the ECOSOC [where I was thrown out off the GA] to chairing positions in the UNODC and the ECOSOC. Apart from this I was active at the BERMUN and the ELMUN.

My by far biggest conference was the National Model United Nations 2013 in New York in March. With a total number of about 5500 participants it is not only the biggest but also the most famous MUN of all and parts of the conference are in the real General Assembly Hall in NYC. I represented Mongolia in the Commission on the Status of Women and apart from the conference it was really nice to meet government officials and of course enjoy the city and its unique sights.

I feel very honoured to being able to continue my participation at this years OLMUN and to chair the WIPO together with Onno Winters. But I also want to express my deep connection to our topic which in all honesty is a coincidence. Since the beginning of my studies I work for a non-governmental organization called Universities Allied for Essential Medicines (UAEM) that devotes its interest, time and kow-how to deepen access to medicines in MEDCs and LEDCs by various measures but also to find funding solutions for research on diseases that are not profitable for the big pharma companies. You can see the connection and I hope that my knowledge can help you to understand this issue concerning billions around the globe and what we can do to help because I think that we can make a difference.

Dear Delegates,

My name is Onno Winters, and I am proud to be one of your chairs of this year's WIPO conference at the OLMUN '13. This is my first time that I am chairing a committee at an OLMUN, even though I have attended as a delegate before.



Right now I am 18 years old and I am attending high school as a junior at the Altes Gymnasium in Oldenburg, from where I plan to graduate by 2014. Last year (2011/2012) I spent one year abroad in high school in the United States, more exact in Lynchburg Virginia. Experiencing a different culture, as an exchange student, has been vastly impressive for me and has changed many views on things of mine.

Furthermore I have been taking part in my school's student representation team as an active member for a couple of years by now and since this November I am the City's student speaker. I'm interested in politics, economics, history and international relations.

I cannot wait to open this year's conference and have inspiring dialogues with other distinguished young minds,

Hendrik Napierala and Onno Winters

1. How to use the Committee Guide

This background guide will serve as a brief introduction to the topic. Accordingly, it is not meant to be used as an all-inclusive analysis but as the groundwork for your own analysis and research. You will find further information to words that are highlighted blue in the glossary at the end of this guide. To conduct your research, please consult scholarly materials, including journals, international news, and the United Nations website, amongst others. You will need to familiarize yourself with the work and current operations of the WIPO. Keeping abreast of current affairs will also prove to be valuable in the discussion of this topic, as it is highly likely that it will be affected by current events over the course of preparations before the conference.

2. Introduction

The debate over global drug pricing is one of the most contentious issues between developed countries and the developing world. While poorer nations maintain they have a moral obligation to make cheaper, generic drugs available to their populations — by limiting patents in some cases — the brand name pharmaceutical companies contend the profits they reap are essential to their ability to develop and manufacture innovative medicines.

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With the ongoing globalization, the weak markets of developing countries are often in unfair competition to the strong markets of the industrialized world. Private companies, backed by their governments, are trying to increase their income all over the world. Many times the third world has nothing or little room for reaction, because of their dependence on western aid. The medical issues in the world are not being solved by companies selling their products for the highest price possible. The population simply can't afford many necessary treatments. Neither are they resolved by governments or public companies giving out old and less reliable medicine for lower prices. We have to find a way, to make a compromise between the involved parties which promotes further research while making it affordable for those who need it the most.

3. History

Coming out of the BIRPI the UN established the WIPO as a specialised agency for intellectual property and patents. Its declared aim is to promote progress and research, but also to ensure the protection of immaterial property rights. With 185 member states, the WIPO has the ability to exert influence on a vast group of targeted. The organisation has already made remarkable steps into the right direction of an international patent law. But that does not mean we should stop at this point. An international patent law is yet not realized and still companies sue states for not protecting what they think is theirs.

Ensuring the third worlds access to generic medicine, could be achieved by creating clear guidelines for intellectual properties.

4. The issue

This is only one of many articles published in recent times dealing with our topic. The Indian Supreme Court ruled that Indian makers of generic drugs can continue producing copy-

1 http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?pagewanted=all&_r=2&

cat versions of Gleevec, a drug made by Novartis that provides effective treatment for some forms of Leukemia. Being the most important provider of inexpensive medicines, India maintains its role fighting deadly diseases on a global scale by cutting the prices (e.g. Gleevec 70k → 2,5k p.a.).

But this also implies several problems the all Nations are facing and we are trying to discuss and explain some of them. But first we can split these issues into several blocks.

A) Research oriented pharmaceutical companies mostly in developed countries providing us with innovative products to fulfil the need of treating complex diseases that were untreatable years ago who are afraid that they will lose their profit if generics are coming into the countries they are mainly operating in.

B) Middle income countries such as but not limited to India that focus on generic drugs providing themselves but also other countries with low-cost drugs.

C) All the other countries, mainly LEDCs, which are completely dependent of medicines and neither have the know-how to do research on their own nor produce. That implies their complete dependency on A) and B).



But let us now go more into detail and experience these three positions. We will give a few examples and try to show you what different positions there are. Afterwards we will try to give you some hints what could evolve in the future by taking in account already existing structures and discussed resolutions.

A) Research costs for new drugs are often said to be in the billions. That is not quite true because opportunity costs are taken into account and thus increasing the amount at the end. But just adding the real costs we still see a sum ranging between 50 and 200 million dollars, which is on the one hand way less but still a considerable amount of money that only few companies, whatever field they are in, can afford. That however is only indirectly connected to the profit that can emerge from specific innovations. Seeing a profit of sometimes up to 25% is a lot more than most of all the other fields (automotive, finance...) and is therefore a very attractive market with limited access at the same time. This limited access is a major problem especially for the MEDCs because research infrastructure is missing and financial funding is not secured. Another point is that the innovation (and therefore the resulting possibility of profit) is connected to intellectual property rights, in particular patents (explained above). For the pharmaceutical companies in the industrialized countries that is probably the biggest insurance to secure future income.

B) These two points are the cause why companies in countries like India specialise on imitating products that are not secured by patents anymore. They may be not the newest but are still well tested drugs that can improve the health situation a lot. For example with antiretroviral therapy this is very important and prices fell from 10000 Dollars per year per patient too less than 100 Dollars

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in about ten years. Here the fear of the big companies are located because they feel attacked and want their innovation to be secured longer. That is why they go to court and try to step up against the makers of the generics. Some critics also accuse the generic medicines producing companies of not following guidelines for the sterile production of drugs, which could eventually cause harm to the consumer. Still it can be seen that generics save the life of millions already.

C) A big problem for LEDCs is their dependency on imports, which is why measures have to be found to ensure that they are provided with all necessary means to have full access to medicines. The easiest way of course is to give them the generics that can be bought for a low price but at the same time one could argue that there is again the problem with the intellectual property. So the United Nations have to find a solution to separate the cost of the drug and the profit because innovation makes the price higher and is therefore preventing the poor from getting necessary drugs. You can easily see that this is difficult to resolve because there are a lot of different views included not forgetting the big lobby of the pharmaceutical companies especially in the western countries so not only good measures have to be found but also multilateral agreements are absolutely necessary.

PRICE IS THE DIFFERENCE		
Medicine	Generic price*	Branded equivalent
Combiflam	₹2.13	₹10.53
Aspirin	₹1.63	₹9.50
Diclofenac	₹3.85	₹36.85
Paracetamol	₹1.88	₹21.50
Amoxicillin	₹4.24	₹42.62
*Prices for a pack of 10 tablets		
■ India is world's single largest producer of generic medicines, with a 20% share in the global market		

Source: Rajasthan Medical Services Corp

We hope that this serves you as a short introduction into the topic. With our provided sources you can get a deeper view insight but also just type some of the major points into your keyboard and you will find a good coverage of everything mentioned before with a lot of different opinions and far more content. What is missing now maybe are some proposals that could help you evolving a strategy for the lobbying process later working out your country's opinion. We do not want to go into too much detail because then we would take all work away from you and this is not the intention of the committee guide. It shall serve as an introduction into the topic and provide you with the tools to find more information. Especially the resolutions and papers we provide are a good starting point for draft resolutions and policy papers. Feel free to get some insights but please do not copy and paste them. We of course know them as well and will recognise that. Also copying is boring, or is it not? We do not want to have you to resign because of plagiarizing, like some of our politicians!

Now some major achievements from the past and possible future outcomes:

1) The TRIPS-Agreement (http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm)

Look through it and find minimal standards for IP regulation.

2) The Doha Declaration (http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

This is a must read! Only one and a half pages long but summarizing really important points.

3) The Indian Supreme Court ruling on the Novartis case (<http://de.scribd.com/doc/133343411/Novartis-patent-Judgement>)

Only for real hardcore people. Really long and technical but giving a deep insight into the issue.

4) The Indian Patents Act (<http://nbaindia.org/uploaded/Biodiversityindia/Legal/14.%20The%20Patents%20Act,%201970.pdf>)

Also an interesting read.

5) CIPIH Report (<http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>)

To understand the topic in its depth this is a really good start.

In the Annex you can find more texts dealing with the topic. There you can also find articles by different NGOs and official texts by the WTO and others.

We also urge you to look up the topic on the internet and find some sources yourself, especially the position of your country. It is really easy and shouldn't be too difficult to find. Otherwise contact us and we try to help but keep in mind that we are busy as well.

5. Research

As the public discussion about generics is mainly driven by ideologies and lobbyists, it is of the utmost importance during the whole research to analyse the source you are using and you should make sure whether your text is credible and correct or not. It is important to start your research as soon as possible so that you do not run out of time. However, you will still need to get updates on your country's position just before the conference as there frequently take place summits and discussions on that topic, so that countries publish statements or reports or even change positions.

Your research should be focused on two main points: Primarily it is of the utmost importance that you are familiar with the problem itself. What is it based on and how is everything linked together. This knowledge will help you understand different positions and allows you to connect them.

Secondly it is very important that you know as much as possible about the country you will be representing: ITS history, current policy, religion, socio-economic structures, etc. and especially its opinion on our topic to be able to make informed and realistic decisions in the debate. The quality of debate depends significantly on your ability to negotiate in consideration of your country's interests and policies. Hence, try to bring not your own opinion but rather the opinion of your country.

We would also advise you to look at current proposals and develop your own draft resolution using these proposals as a basis, but going a step further by developing new approaches yourself. These approaches should not be too general. A good resolution recommends specific measures and actions. If you do all this thoroughly you can look forward to an interesting debate!

6. What do you have to bring to OLMUN 2013

1. You will be required to come to OLMUN 2013 with a draft resolution and a policy statement. Please send them to us by **May 16th**. For tips on how to write a resolution please read the OLMUN Handbook 2013 or contact us via wipo@olmun.org. Each draft resolution should be at least one page long but should not exceed two pages.
2. For those who are attending an OLMUN conference for the first time, there is a document available called "*Rules of Procedure*", which will include the most important information about the procedure during the conference. You will find this besides the OLMUN Handbook on our website. However, we would highly recommend all delegates to read the Rules of Procedure, because there might be slight changes in comparison to the years before and it is useful to call all rules to your mind again.
3. Before we will start lobbying, you can present your countries opinion to the house by means of reading out your policy statement. Your policy statement should shortly (not more than 150 words) outline the three major points of your resolution. This is really important because of two facts. First the other delegates will get an over- view about your countries opinion and it therefore makes the start of the lobbying process easier. On the other hand it is a good way for „First Timers“ to speak in front of a big crowd and loose the fear that might be there.
4. Most importantly, bring yourself and all your enthusiasm about MUN-conferences. Bring your willingness to debate and compromise, but also your openness to meet exciting new friends. Bring all your excitement to make this year's WIPO an experience we will not forget for a long time.

If you have any questions concerning our council's topic, your country's policies, how to conduct your research, procedural matters, how to write the resolution or any other issues, please feel free to contact us at wipo@olmun.org. We also would correct your resolutions or policy statements according to style and content and send it to other delegates as well. Furthermore it has proven to be useful for a smooth debate to get in touch with your fellow delegates prior to the conference using the OLMUN-Forum at www.olmun.org. In this forum you can exchange your ideas, resolutions, tactics, policy statements or more useful research sources you have discovered. Both emailing and forum are a good opportunity to make pre-lobbying and get to know more about the other countries in anticipation. You can also find useful information in the OLMUN Handbook.

We are looking forward with lively anticipation to another interesting and constructive MUN experience with all of you from June 4th to June 7th!

Yours sincerely,

Onno Winters and Hendrik Napierala

7 Annex

7.1 Links

http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm
TRIPS

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
DOHA DECLARATION

<http://nbaindia.org/uploaded/Biodiversityindia/Legal/14.%20The%20Patents%20Act,%201970.pdf>
INDIAN PATENTS ACT

<http://de.scribd.com/doc/133343411/Novartis-patent-Judgement>
SUPREME COURT RULUNG

<http://www.who.int/intellectualproperty/report/en/index.html>
CIPHI REPORT

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944814/>
A LIFETIME TO TREATMENT, great article

<http://utw.msfaccess.org>
UNTANGLING THE WEB: PRIZES AND PATENT STATUSES OF ANTIRETROVIRAL THERAPY

7.2 More Information

<http://www.msfaccess.org/content/trips-trips-plus-and-doha>

http://www.wto.org/english/news_e/news11_e/trip_23nov11_e.htm

http://www.wipo.int/treaties/en/ip/wct/trtdocs_wo033.html

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0029:EN:HTML>

[http://www.worldtradelaw.net/reports/wtopanelsfull/india-patents\(panel\)\(ec\)\(full\).pdf](http://www.worldtradelaw.net/reports/wtopanelsfull/india-patents(panel)(ec)(full).pdf)

<http://patentoppositions.org>

<http://www.msfaccess.org/content/medicines-shouldnt-be-luxury>

<http://www.msfaccess.org/our-work/overcoming-barriers-access/article/1358>