



G8 Youth Summit 2009

Intellectual Property Rights (IPR) Pharmaceutical Industry vs. Humanitarian Aid



INTRODUCTION TO THE TOPIC

First of all it is very important to mention that it is us – young representatives of the states – who are interested in this problem. For three days we have been searching for better solutions to the agenda and despite having different opinions and views in the beginning we eventually came to an agreement. Not only does it mean that we worked productively but also that we have gained a very positive perspective regarding our future politics. The decisions taken during the G8 Youth Summit represent a unique way to create firm ground for future collaboration and stability.

While the question of Intellectual Property Rights (IPR) in the pharmaceutical sphere has recently emerged on the G8 Agenda, the importance of this matter has already been recognized. This concerns all the developing and developed countries and should be therefore discussed within the framework of the G8.

This consultancy paper will focus on the relationship between IPR and humanitarian aid. It addresses problems within this relationship by putting the regional focus on Africa. Africa is the region with the largest disease burden in the world. This is due to different factors, among which is the lack of private and public funding resulting in weak health systems. Patients therefore not only face a lack of health facilities and health workers but also constraints in terms of medication such as antiretroviral treatment (ART). Developing countries facing high HIV prevalence rely on developed countries for pharmaceutical products to offer treatment to wide parts of the affected population. Due to the current economic situation it is important to promote sustainable and adaptable partnerships within the field of IPR.

We propose to adopt the following three-step program to improve the health situation in developing countries, especially those in Africa, the region that has been focused on by the G8 in Heiligendamm 2007. Firstly, the existing legal framework needs to be adapted to account for the increasing complexity in public health. This is on the one hand done by setting quantifiable public health results and on the other hand by excluding HIV and AIDS from the usual patenting process and by shifting the issue towards more transparent and more rapid medication development. Secondly, incentives for research have to be motivated. This can be done by creating partnerships in research. Thirdly, we address the growing inaccessibility by the mechanism of a patent pool.

ACTION PLAN



STEP 1: Adaptation of the legal framework (TRIPS Agreement)

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for intellectual property regulation. TRIPS include the international regulations to be followed for patents and therefore for pharmaceuticals. We recognize that the regulation system does not adequately meet the needs of the growing HIV and AIDS crisis, we consider that an adaptation of this regulation should be put into place. We also suggest that a global perspective should be adopted concerning HIV and AIDS. Therefore, we recommend that the TRIPS system should be amended, particularly as follows:

- 1) Priority should be given to HIV and AIDS questions in the interpretation of the TRIPS.
- 2) The patent protection term for HIV and AIDS treatment should be reduced.
- 3) Compulsory licensing should be adapted for HIV and AIDS matters.
- 4) International regulation of patent exploitation should be created.
- 5) Member states should adopt work towards a consensus concerning HIV and AIDS.

In order to achieve the abovementioned objectives we propose the following declaration of amendment of the TRIPS agreement. Transitional provisions for the declaration are:

- a) This declaration shall be considered an inseparable part of the TRIPS agreement.
- b) This declaration shall be enforceable on the day of the signature by the 30th country.
- c) All disputes concerning this declaration should be referred to the general dispute settlement provisions of the TRIPS agreement.
- d) The current provisions should be reviewed on a regular basis with respect to the evolution of the HIV and AIDS crisis.
- e) We advise that specific regulations be adopted for similar matters of global crisis.

DECLARATION OF AMENDMENT TO THE “TRIPS” AGREEMENT



1) *Priority*

Art. 8-3: HIV & AIDS issues should have a priority in the application of the TRIPS agreement.

2) *Term of protection*

Art. 12: (and art. 33) However concerning HIV and AIDS patent protection should not exceed a period as agreed upon by the members.

3) *Separate framework*

Art. 27-2: “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.” **Members agree that in the light of this paragraph HIV and AIDS should be considered a matter of *ordre public* and morality or they should be taken into consideration under a separate framework.**

4) *Special regulation for AIDS*

Art. 27- 4: Members should adopt special intellectual property regulations considering HIV and AIDS. They shall provide for the proper distribution of HIV and AIDS medication by an effective *sui generis* system. This provision should be reviewed on a regular basis.

5) *Exceptions to exclusive rights*

Art. 30: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

Members should provide exceptions to the exclusive rights of a patent for HIV and AIDS medicines. On the other hand, the interests of pharmaceutical producers should be taken into account through the calculation of fair royalties.

6) *Acceleration of compulsory licensing procedures*

Art. 31 (b): [...] In essential areas of public health such as HIV and AIDS treatment appropriate measures should be adopted in order to accelerate the respective procedures.

7) *Termination*

Art. 31 (g) : [...] These provisions should have limited application in matters of HIV and AIDS.

8) *Economic value*

Art. 31 (h): [...] The estimation of the economic value of the authorization should reflect the importance of the patent for HIV and AIDS research.

9) *International regulation of patent exploitation*



Art. 31 (i): **Members agree on the constitution of an International Organization which deals with patent exploitation.**

10) *Dispute settlement*

Art. 64-4: **Special attention should be paid to avoid the negative impact of dispute settlement on specific HIV and AIDS regulations.**

11) *LDCs*

Art. 66: **Members should provide the application to this provisions in respect to LDC most touched by HIV and AIDS.**

12) *Reservations*

Art. 72: [...] **Such reservations should not be possible for HIV and AIDS measures.**

With regard to the Doha Declaration of November 2001, we suggest the following clarification: Art. 5 of Doha Declaration: “[...] (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.” **However, due to the extreme emergency circumstances, HIV and AIDS should be a considered a global crisis rather than a national crisis and common measures should be taken.**

Adapting the TRIPS with regard to HIV specific aspects and with regard to quantifiable public health threats, should result in an improved environment for research and thus in higher innovation activity.

STEP 2: Partnerships in Research

In order to stimulate innovations even more, we propose the international promotion of partnerships. This shall result in improved cooperation between developed and developing countries as well as between the public and the private sectors of the countries, respectively.

Targets of the strategy. The international promotion of partnerships will involve the collaboration of the targets outlined briefly in the Table A – Summary of Strategic Targets, and further discussed in this section.



Table A: Summary of Strategic Targets

TARGET	ISSUE ADDRESSED	POSITIVE OUTCOMES	POSSIBLE CHALLENGE
<i>Fostering partnerships</i>	Lack of private funding in developing countries	<ul style="list-style-type: none"> • Increase innovation activities • Accessibility to a broader range of treatments • Accountability of investors for health crisis • React on shortages in local health systems 	Sustainable incentive mechanisms Control mechanisms needed
<i>Increase Effective Dialogue</i>	Lack of transparency in information circulation between countries	<ul style="list-style-type: none"> • Prevent redundancies and allow more efficient public health outcomes • Up-to-date, practical knowledge of current global health issues 	Ensure that other political interests are not coupled with the efforts on health partnerships
<i>Long-term incentive mechanisms</i>	The phased withdrawal of health investments in the developing countries	<ul style="list-style-type: none"> • Initial motivation of investors to participate in sustainable partnerships with developed countries 	
<i>Partnership Guidelines</i>	Minimize existing biases and promote abilities to negotiate	<ul style="list-style-type: none"> • Assisting developing countries in doing the negotiation process • Ensure benefits resulting from research in developed countries and of developing countries • Ability to ensure success due to the prediction of proposal outcomes 	Possible reduction in financial benefits for investors



Fostering Partnerships. Fostering partnerships between the public and private sector aims to address the issue of the present lack of private funding for local research initiatives in developing countries. By influencing local or foreign investors to support the developing research industries, several benefits will naturally result. One positive outcome is the enhancement of innovation activities through the sharing of information and introduction of new resources to the market. This increase in innovation will create healthy competition and stimulate higher rates of innovations in research, which can result in the reduction of market costs due to the broader range of accessible treatments. Partnerships can also create accountability from investors to a global public health crisis, which can result in quicker reaction times on shortages in local health systems.

Partnerships can be encouraged by incentives such as grants and tax cuts for those industries which take the investment risks in developed countries. Periodic market exclusivity could also be considered as a possible incentive for investors. The initiation and monitoring of projects can be performed by an existing third party entity such as the World Intellectual Property Rights Organization (WIPO). Having a separate body involved can ensure enforcement of fair guidelines between countries. Funding should be initially provided by international means such as the Global Funds to Fight Malaria, Tuberculosis, and HIV/AIDS. In the long run however the forum of partnerships should be self-financing and free from subsidiary incentives. Potential challenges include the requirement to establish a system to deter preference within cooperation concerning their selected research topics.

Increasing Effective Dialogue. In order to increase the efficiency of the global pharmaceutical industry, continual dialogue between developing and developed countries must exist. Presently, forums are being held as a response to the common interest of increasing effective global communication. One such example was the forum held recently by the International Finance Corporation (IFC) which brought together representatives from the ten nations of Brazil, China,



India, Kenya, Nigeria, Saudi Arabia, South Africa, Thailand, Turkey, and the United Arab Emirates. Promoting effective dialogue will minimize research redundancies and therefore allow for an increase in efficient public health outcomes.

Although information exchanges are encouraged, it would be necessary to ensure that external political interests do not influence efforts on health partnerships. Communications should focus on the improvements to the health of global citizens.

Incentive Mechanisms. It would be necessary to provide initiation incentives to encourage the creation of partnerships. As previously mentioned, such incentives could include the provision of tax cuts, grants and periodic market exclusivity. The incentive mechanisms would be phased out over time as the partnerships themselves would ultimately provide natural incentives. Therefore the purpose of the initial incentives would be to generate motivation between countries. Applying initial encouragement devices would require the consideration of balancing the interests of both partners. Therefore, as each partnership will involve unique criterion regarding the benefits of each stakeholder, the evaluation of the particular conditions must be thoroughly conducted without bias.

Partnership Project Guidelines. Guidelines for structuring productive partnerships should be established with the intention of ensuring the promotion of innovation for current and urgent global medical needs. Without such guidelines, the liberties for selecting partnerships could be subject to bias and capital driven ventures. The guidelines should be established by a common body such as WIPO, and shall not be aimed at enforcement in order to ensure the continued accordance to trade agreements. The existence of such guidelines would also provide a structure for negotiations when establishing partnerships. The guidelines could include such concepts as resource dependencies, long-term goals, and research objectives. Partnership project guidelines may create controversies due to the reduction of selection liberties which can be contrary to the goals of capital maximization. Although controversy may exist, this is a necessary consequence for ensuring the satisfaction of global needs.

Desired Outcomes. Bringing to life the measures planned and implementing new approaches in the cooperation between developed and developing countries will bring about positive results. Firstly, the increase in local funding by means of private sector involvement in the



process will help to define more clearly the strategy of creating regional pharmaceutical manufacturing centres and setting the wheels in motion. Secondly, coupled with the strengthening of new emerging economies and markets this will result in diversification of pharmaceutical research topics and broadening the range of available resources. Thirdly, establishing more fruitful cooperation will positively influence sustainability of local developing markets. Fourthly, the measures will provide reasonable and adequate regional support which is of great importance since it could lead to misunderstanding and instability. What's more, this will result in more effective monitoring of the situation.

Possible challenges. Despite all the benefits that will emerge from the measures proposed, some challenges could still occur. Since public health has become an urgent issue it is very important to keep the urgency of this problem higher than private economical interests of the countries. That means that a special mechanism should be implemented to monitor so that all the developing countries get equal amounts of help regarding their potential needs. Since we are heading to a globalised world and open markets, we suggest promoting equality with the aid supply to the developing world with the regard of national potential in the sphere that would be above the economic interests of the developed countries.

STEP 3: Patent Pooling

At the moment, when a pharmaceutical company develops and registers a new invention, it is granted patent protection for 20 years under the TRIPS Agreement. Our research regarding the HIV and AIDS epidemic and anti-retroviral treatment indicates that these regulations stand in the way of providing maximum access to life saving drugs. The most recent statistics regarding the HIV and AIDS epidemic taken in December 2007 support this: at this time only 31% of the world's population in need of treatment was receiving the appropriate medication. The problem is most severe in Sub-Saharan Africa: of the 32,900,000 people in the world affected by this disease, 22,000,000 are living in this area. Ninety percent of children with HIV and AIDS are living in Sub-Saharan Africa, and they too are being denied access to treatment due to the lack of financial incentive for pharmaceutical companies and researchers to invest in this problem. This is particularly due to the fact that optimal treatment for children is different from optimal treatment in adults. In order to treat HIV and AIDS, the patient must be administered combination of three



separate substances that can be patented by three separate companies. This makes treatment more cumbersome and also prevents the possibility of combining these three drugs into one drug which would be more feasible for the patient to take. Even if a researcher into such treatment gained permission from two of these patent holders, the third could still refuse. As all three are fundamental, denial by any party inhibits progress in the field of research into this epidemic.

The purpose of a Patent Pool. In an attempt to find a compromise between the need for humanitarian aid and incentive for researchers and developers, we are proposing the idea of a patent pool to circumvent this conflict of interests. A patent pool would in essence be based at an independent organization, to which inventors would come to submit their patents. This organization would then act as a one stop patent shop, in that other developers could use the patented products in exchange for a fair royalty which would be paid to the patent holder. Researchers would also be able to come to the patent pool in order to try to develop further innovations, for example medication designed specifically for children.

Advantages of the Patent Pool: Pharmaceutical Companies. We propose that pharmaceutical companies would obtain two years of direct market access from the time the patent is granted, after which time they would submit their patent to the pool and receive royalties from other developers who wish to use their invention for the remainder of the 20 year patent term. We propose that companies which submit their patent to the pool will be granted a concession for instance substantial tax breaks to be negotiated on a country by country basis. We propose that companies who use the pool would benefit from legitimate competition, as opposed to losing massive profits to trade on the black market. We propose that the patent pool would encourage companies to continue developing products and promote a healthy atmosphere of competition amongst companies in order to maximise the returns on royalties paid by users of their products. We propose that this solution fits in with the importance of Corporate Social Responsibility and that companies who submit their patents to the pool would benefit from enhancing their reputation amongst consumers.

Advantages of the Patent Pool: Researchers. We propose the creation of an international comprehensive database, which would provide third parties with details, such as who is using the patent pool, as well as highlighting the benefits of using such a system. We propose that the creation of one, single body would increase the accessibility of information and this would lead to increased and faster progress within the research community.

Advantages of the Patent Pool: Society. We propose that a much higher percentage of the public



would gain access to treatment as a result of lower prices engendered by increased competition among producers. We propose that the public would benefit in the long term when there is increased research and development and innovations. We propose that the public would be protected from potentially harmful drugs which are unregulated on the black market.

Infrastructure. We propose that the World Intellectual Property Organisation be the primary regulatory body in regard to patent pools. In addition, there is the possibility that the World Health Organisation plays a role in tandem with the WIPO to take pressing health issues into consideration. We propose that the monetary needs necessary to implement and run the patent pool be provided by the Global Fund to Fight Malaria, Tuberculosis, and HIV/AIDs.

ALTERNATIVE SOLUTIONS

Re-assess the President Emergency Plan

Introduction. In 2003, U.S. President George W. Bush initiated the President's Emergency Plan For AIDS Relief, which dedicated \$15 billion over 5 years toward fighting the HIV and AIDS epidemic in Africa. The funds are directed toward resource-limited countries which have high HIV and AIDS prevalence rates. The program began distributing generic medication in 2005 as a way to maximize resources and reach the greatest number of people possible. PEPFAR was revised and renewed in 2008, increasing the funds dedicated to the program to \$48 billion through 2013 (PEPFAR, 2008).

This program entails a dual approach toward addressing the growing HIV and AIDS problem. The first approach involves providing treatment and care to those already infected and has shown to be extremely successful. The program has provided treatment to 2.1 million men, women and children through September 2008 and increased the share of children receiving PEPFAR treatment from 3% to 8% in the first four years of the program. In terms of caring for those persons who already have HIV and AIDS, PEPFAR provided HIV and AIDS counselling and testing for approximately 57 million people and provided care for more than 10.1 million people affected by HIV and AIDS, including over 4 million orphans and vulnerable children. The second aspect of PEPFAR entails the prevention of HIV and AIDS infection through education initiatives. As of September 2008, PEPFAR reached approximately 58.3 million people through community outreach programs that



educated about the prevention of sexual transmission of HIV and AIDS. Additionally, PEPFAR supplied 2.2 billion condoms worldwide and supported nearly 16 million pregnancies to prevent mother-to-child transmission of the disease. In 2008, PEPFAR has partnered with a total of 2,667 organizations, of which 86% were local to the affected area.

Proposal. We, the technical experts on intellectual property rights at the Model G8 Youth Summit, propose that the G8 recognizes the recent achievements by PEPFAR and actively supports this approach in the future. To do so, we aim to split the initiative into two halves, the treatment and care sphere and the prevention and education sphere. The money currently dedicated to the program by the United States will be earmarked toward the first sphere of the program, of which the United States will be the primary provider. The additional G8 member countries will undertake the prevention and education aspects of the initiative. This will allow the United States to dedicate all of the allocated \$48 billion toward providing treatment for HIV and AIDS infected individuals, while relegating their role in the prevention and education to the other G8 countries.

The Treatment and Care for Infected Individuals. The United States will focus all of the dedicated \$48 billion toward purchasing and distributing generic medications to the focus countries in Africa. More specifically:

1. Continuing to provide life-saving treatment to those most in need.
2. Increasing the share of children who receive medication.
3. Caring for those affected by HIV/AIDS, including orphans and other vulnerable children.
4. Providing tuberculosis treatment for HIV/AIDS infected patients.
5. Expanding counseling initiatives.
6. Testing patients for HIV/AIDS so as to begin a treatment regimen more quickly and thus more effectively.

The Education and Prevention Program. Priority will be given to an on the ground, comprehensive education program, which accounts for HIV/AIDS prevalence among specific populations, and according to the risks that exist within specific populations. The education of youth will be the primary focus, and to this end we will implement youth specific education programs. We support the idea of local, youth-led community programs to help youth, their parents



and the broader community to personalise the risk associated with early sexual activity, sex outside marriage, multiple partners and cross generational sex. We support the idea of training and educating youth mentors to provide education about the risks involved in the aforementioned sexual practices for young people who lack sufficient adult supervision. We support the idea of a media campaign to publicise abstinence, fidelity and HIV counseling and testing. We believe that the education program would be most effective if it was implemented as far as possible at the local level and by involving the local leaders of small communities in the education process.

Normalized Cost/Royalties INDEX

Formulating a Normalized Cost/Royalty Index would target the current imbalance between the comparison of cost and royalty values for developing and developed countries. As the current liberty within the quantification of financial amounts fails to meet the needs of both parties, such a common index could provide the needed foundation. The Index would act as a factor based on the particular needs of each country involved. It could possibly follow a similar framework to the United Nations Human Development Index (UN HDI). This factor could ensure proportional reimbursement and sale costs within the pharmaceutical market. The factor would encompass the following illustrated relationship,

$$\text{INDEX}_{(\text{country})} (\$) = \frac{\text{Market Value}_{(\text{general})} (\$)}{\text{Overall Country Demand}_{(\text{specific})} (\#)}$$

where,

$\text{INDEX}_{(\text{country})}$ represents the particular Royalty that must be reimbursed to the producer, or the approximate cost that must be paid;

$\text{Market Value}_{(\text{general})} (\$)$ represents the current product market value; and

$\text{Overall Country Demand}_{(\text{specific})} (\#)$ represents the factor proportional to the specific public health demand of a country.

Therefore, a decrease in the purchase price and royalty amounts will depend on an increase in demand. By creating a relationship between the seller and the buyer, mark-ups and bias towards either party will be minimized.



The Market Value of a product is accessibly obtained from industry budgetary reports. On the other hand, defining the criteria for Overall Country Demand (OCD) will require collaboration efforts of the various countries involved. OCD will require the evaluation of criteria including statistics such as mortality rates, gross domestic product, percentages of infected population, percentages of available markets, and percentages to sanitation amenities. In order to initiate such a solution, the framework of a currently established global body, such as the G8 & O5, or the United Nations could be followed.

Naturally the implementation of such a categorizing system will bring about operational and deterministic challenges. Operational challenges include the necessity to establish monitoring and enforcing bodies and measures, increased processing time for market release, the requirement for periodic updates to the OCD factor, and possible reduction in overall capita. Theoretical challenges can arise from the selection of the particular criteria that will be encompassed by the index, satisfying the individual needs of citizens who are not ranked by the index, and the controversy resulting from the OCD criteria selection. Despite these challenges, the need to balance the interrelationship the Cost/Royalty to particular country needs still exists.

SUMMARY

We, the technical experts on intellectual property rights at the Model G8 Youth Summit, feel that this proposal is both well-rounded and specific. It takes into account the overwhelming necessity of providing access to lifesaving medications to the greatest number of people regardless of their financial situation while also providing patent protection and compensation to the pharmaceutical companies for their important innovations. This model generates many advantages for pharmaceutical companies, researchers and the public and is an issue ripe enough to generate support both in developing and developed countries. Our hope is that other countries will join with the G8 to implement this proposal to the fullest extent possible. International cooperation on this issue will be essential in order to maximize the possibilities for success and allow us to adequately address the global HIV/AIDS epidemic with a united front.



LINKS

TRIPS :

http://www.wto.org/english/tratop_e/TRIPS_e/tripsfactsheet_pharma_2006_e.pdf

http://www.wto.org/english/docs_e/legal_e/27-trips.pdf

DOHA DECLARATION :

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf

PEPFAR:

Link- <http://www.pepfar.gov/guidance/75836.htm>