EUROPEAN PARLIAMENT
COMMITTEE ON INTERNATIONAL TRADE
HEARING ON TRIPS AND ACCESS TO MEDICINES

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The magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease or alleviate suffering. Each day, close to eight thousand people die of AIDS in the developing world. The reasons for the lack of access to essential medicines are manifold: logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, prohibitive prices and lack of financing for health care.

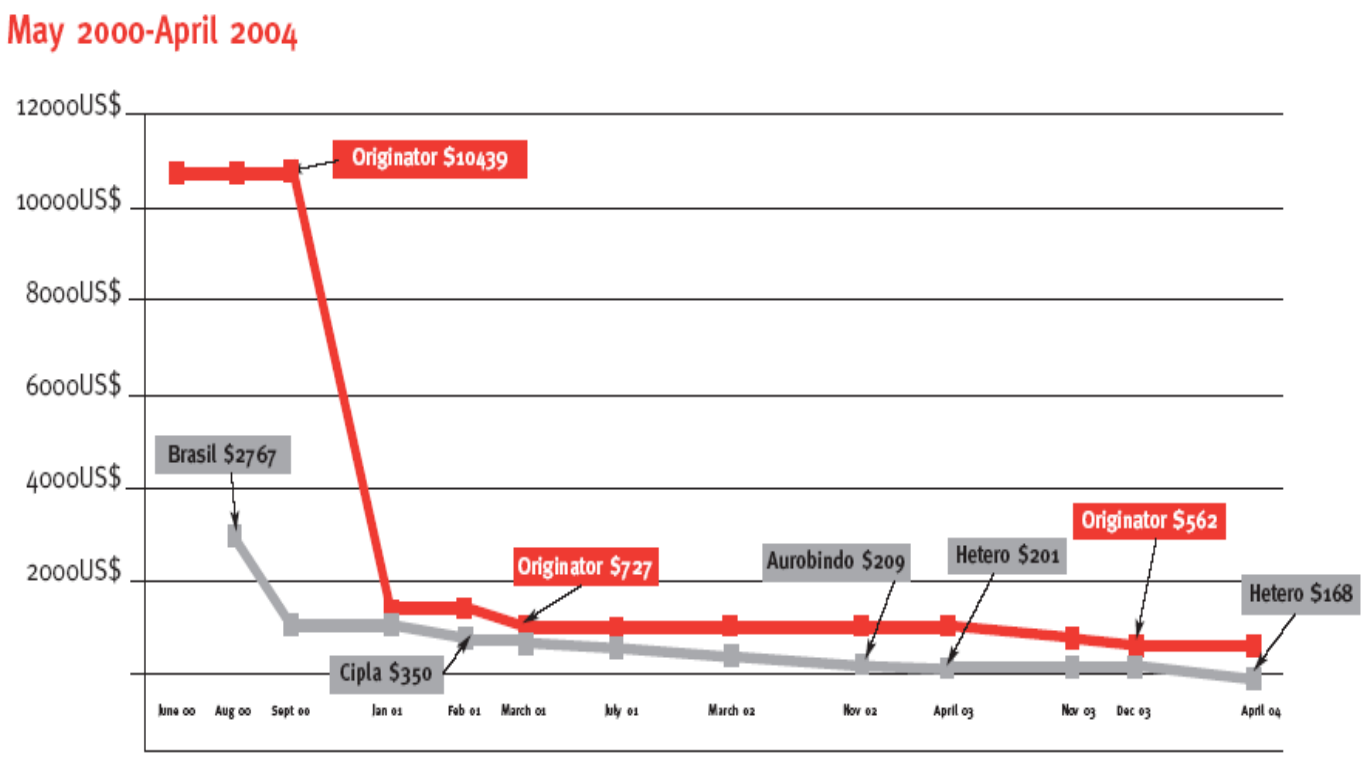
In many cases, however, high drug prices are the main barrier to needed treatments. Prohibitive drug prices are often the result of strong intellectual property protection. Governments in developing countries that attempt to bring down the price of medicines have come under pressure from industrialised countries and the multinational pharmaceutical industry. For instance, in 2001, 39 drug companies took the South African government to court over its medicines act. More recently, Guatemala has come under pressure to implement "TRIPS-plus" data protection rules.

The 1995 World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement sets out minimum standards for the protection of intellectual property, including patents on pharmaceuticals. These standards derive from wealthy Western nations and are not necessarily appropriate for developing countries. The TRIPS Agreement has come under fierce criticism for this "one size fits all" principle because of the effects of increased levels of patent protection on drug prices.

MSF has witnessed the effects of patents on the prices and availability of medicines, in particular newer medicines, and has documented the patent practices in the countries where it works[1]. It should be no surprise that patent protection translates into high drug prices: patents create monopolies and monopolies lead to higher drug prices. As soon as the monopoly ceases to exist, prices come tumbling down. Figure 1 below shows the effect of generic competition on the price of first-line AIDS triple therapy.

[1] Médecins Sans Frontières (MSF) "Drug patents under the spotlight - Sharing practical knowledge about pharmaceutical patents", June 2004.

Figure 1. Effects of Generic Competition on ARV Prices



In addition to their impact on prices, patents may also hamper the development and availability of recommended formulations. An example is the problem of developing fixed dose combinations (e.g. the "three in one" pill for AIDS treatment) when the patents of the individual components are held by different companies. These fixed dose combinations are particularly important in AIDS treatment. Some recommended fixed dose combinations are now available from Indian producers because until 2005 pharmaceutical product patents were not granted in that country and therefore did not create a barrier to formulating these products.

Why do we have patents?

The patent system is a social policy tool which aims to stimulate innovation. The idea is that by providing limited exclusivity to the "inventors" of products, which comes at a price, innovation will be promoted and society as a whole will benefit from the availability of new and improved products.

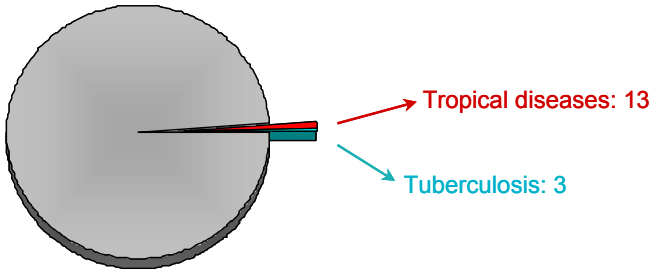
Patents and Research and Development

However, a major problem of the current patent system is the imbalance between rights and obligations: the patent system is intended as a stimulus for innovation, but there is no mechanism for directing that innovation, and as a result many diseases are totally ignored. Drug research and development, which is almost exclusively confined to the private sector, is skewed towards areas that promise a profitable return. This is a logical consequence of the patent-driven R&D mechanism our societies rely on these days. Thus in the last 25 years, almost 1,400 new medicines have been developed, but only 1% of these were for tropical diseases (see figure 2).

These diseases kill tens thousands of people every year, but because they are almost entirely confined to the developing world, they do not represent a profitable market for industry.[2]

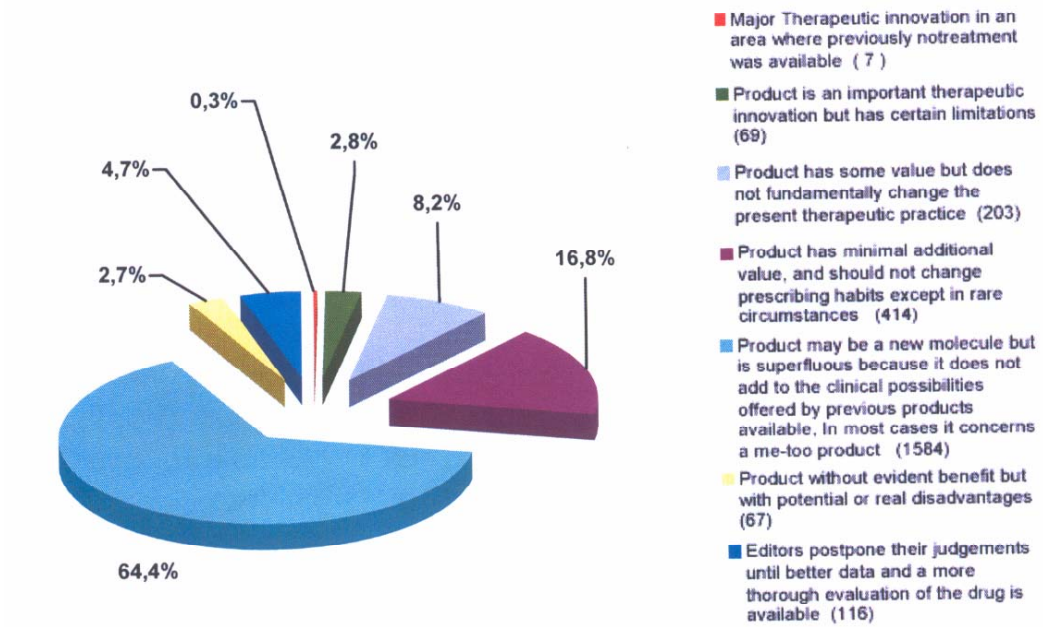
Figure 2. Drug Development Outcome

1975-1999: **1393** new chemical entities marketed



Patent protection has increased over the last 20 years, but the mean innovation rate has fallen, with an increase in the number of 'me-too drugs' of little or no therapeutic gain, as shown in figure 3 below. This global crisis in innovation has of course a disproportionately heavy impact on the needs of people in developing countries.

Figure 3. Innovation in France 1981-2001



Adapted from Prescrire International, April 2001/Vol 10, n° 52 p 54

[2] Trouiller P, Olliaro P, Torreele E, Orbinski J, Laing R, Ford N. Drug development for neglected diseases: a deficient market and a public-health policy failure. *Lancet* 22 June 2002 359;9324: 2188-2194.

By adopting the Doha Declaration on TRIPS and Public Health in 2001, the WTO recognised some of the concerns raised by developing countries regarding access to medicines. The Doha Declaration lays out the flexibilities contained in the TRIPS agreement which countries can use to overcome the barriers posed by patents. It also extends the "transition period" - during which Least Developed Countries (LDCs) are not obliged to enforce or grant patents on pharmaceuticals products - until 2016. The EU supported the Doha Declaration as an important tool to help increase access to medicines.

However, in recent years, we have seen a systematic dismantling of the Doha Declaration through bilateral trade agreements with the United States, which include so-called "TRIPS plus" provisions: these annul the achievement of Doha and confirm the lack of political support for the use of TRIPS flexibilities.

Post 2005

Following the full implementation of the TRIPS Agreement as of 1 January 2005 in India and the few other developing countries not yet granting pharmaceutical patents, access to new drugs is expected to become more difficult. For example, most of the ARVs currently available at affordable prices come from India. Successful AIDS programmes such as those of Brazil and Thailand were possible because key pharmaceuticals where not patent-protected and could be produced locally at much lower costs.

From 2005 onwards, all new drugs may be subject to at least 20 years of patent protection in all but the least developed countries and the occasional non-WTO country such as Somalia, Palestine or Macedonia. A number of developing countries that are presently scaling up AIDS treatment have expressed their concern to the World Health Organization about the effects of TRIPS implementation in India.[3]

Because TRIPS implementation will affect both producers in key manufacturing countries and countries that are dependent on these manufacturers for raw materials, prices will be kept high and new medicines will be made inaccessible for the majority of the population in developing and least developed countries. Generic producers will also be blocked from developing fixed dose combinations until the relevant patents on the individual components of the combinations expire. In other words, access to essential medicines could become dramatically more difficult in the coming years if no further action is taken.

Faced with these new challenges, the public health safeguards affirmed in the Doha Declaration, such as compulsory licensing or government use, will become even more important. It is imperative that producing countries such as Brazil, Thailand and India routinely make use of compulsory licenses or "government use" provisions, including allowing the export of these medicines, to enable generic competition to drive prices down. Strong political resolve will be needed to do this.

Production and export of generic medicines

In 2003, the WTO adopted the "August 30th decision" which allows the export of medicines produced under a compulsory license – this is restricted in the TRIPS agreement by the requirement that a compulsory license be 'predominantly for the domestic market'. The August 30th solution is needlessly complex, however, and is not likely to remove the real threat of

[3] Letter from Dr Jim Kim, Director WHO HIV/AIDS department to the Minister of Health of India dd. 17 December 2004.

dwindling generic production in countries such as India[4,5]. The mechanism is based on a drug by drug, country by country and case by case decision-making process which ignores the fact that economies of scale are needed to attract interest from producers. Without the pull of a viable market for generic pharmaceutical products, manufacturers cannot rationally be expected to want to take part in the production for export system.

Certain countries, including EU member states and the European Commission, have taken the initiative to implement the decision. Given the complexity of the WTO solution, one would expect that the implementation by potential exporters would at least be straightforward, without introducing extra barriers.

Unfortunately, this is not necessarily the case. For example, in Canada, the implementation of the August 30th decision contained limitations that were rejected by WTO Members at the time of negotiating the solution, such as a list of eligible countries, as well as a limited list of approved medicines that can be produced and exported in generic form to developing countries. But the medicines list does not include the fixed dose AIDS drug combinations which are recommended by WHO and are vital for scaling up AIDS treatment in developing countries. Although it is foreseen that the list can be reviewed, the Canadian experience shows that new medicines have been excluded from the list following lobbying from the drug industry. For example, the company Bayer successfully lobbied to keep its pneumonia therapy, moxifloxacin, off the list of medicines.

The proposal put forward by the European Commission does not include such limitations, but it is also far from ideal. For instance, the Commission's proposal requires prior negotiations with the patent-holder, even though this is not required by TRIPS in public non-commercial uses and/or emergencies (art 31 b). The proposal also seems to restrict the license for manufacturing purposes only, which could make the solution useless in case patented raw materials need to be imported - a likely scenario, since for example the raw materials for ARVs mostly come from outside the EU. The solution also does not offer the possibility for non-governmental actors such as NGOs, churches or the UN to make use of the system, even though they are often the prime suppliers of medicines.

Even if these issues are resolved, in the best of worlds implementation in good faith of a text that is basically flawed cannot possibly yield real solutions.

Regretfully, these hollow measures are often hailed as great progress, and the public and parliamentarians are led to believe that access problems have been resolved and that affordable medicines will now become available and no further action is needed. Such an approach would be disastrous.

Once again, the AIDS crisis shows us why. First-line triple therapy is now available for as little as US$140 per patient per year. But resistance to first-line ARVs is as inevitable in poor countries as it is in rich ones. When patients need to switch to second-line treatment, they will face treatment costs as high as US$5,000 per patient per year.

[4] A country in need of a certain product which is not available (for example because it is not marketed, or because the price is too high) will have to inform the WTO about its intention to import and indicate the type of product and quantities needed and – if it is not for governmental use and / or an emergency - will have to seek a voluntary license from the patent holder(s). A potential producer in an exporting country needs to be identified. This producer - assuming there is one willing to invest in production for a limited market (the quantities need to be defined beforehand based on the request from one or several countries) – must then request and obtain a compulsory license from its national authorities, adapt its production line and capacities, and pay royalties to the patent-holder.

[5] Correa, C. Access to drugs under TRIPS: A not so expeditious solution. Bridges 8(1), p.21-22.

	3TC/d4T/NVP (1st line)	TDF+ddI+LPV/r (2nd line)	2nd line vs 1st line
Western country[6]	US$8773/year	US$13151/year	1.5 times more expensive
Developing countries	US$154/year Cipla Triomune[7]	US$3950/year Originator products	26 times more expensive
Reduction	**- 98 %**	**- 70 %**	

This discrepancy needs to be tackled urgently. The price of first-line drugs came down dramatically because countries that did not grant pharmaceutical product patents were able to produce generics and stimulate competition. The challenge will be much greater for second-line drugs. Now that key manufacturing countries will no longer be able to produce generic versions of new drugs, bringing down the price of a single source product is going to be much more difficult.

Sources of affordable versions of new medicines will dry up. While the 2001 Doha Declaration on TRIPS and Public Health offers measures to access existing generics, much more needs to be done to ensure the production of generic second-line drugs.

The Commission has supported tiered pricing by drug companies by taking measures to prevent trade diversion. The anti-trade diversion mechanism put in place by the Commission proves to be of limited value in so far as it lists only one company which has products for which affordable versions are already available from other sources[8,9].

In the post 2005 era where all drugs may be patented in most countries in the world, a lot more action will need to be taken to ensure that drug prices are set at a level the people who need them and their communities can afford. Essential medicines are not a luxury whose availability can be left to private market forces only.

While it is easy to get lost in the legal details, it is crucial not to lose the human picture in this discussion. The fact is that effective medicines that dramatically increase the life expectancy of people living with AIDS became available in Europe and North America a decade ago. Today, 40 million people in the developing world are infected with HIV, and six million people need access to these medicines NOW. Only 400,000 do. The result is that, at the end of today, another 8,000 people will have died of AIDS.

Recommendations for the European Parliament

The way in which medicines are researched, developed and sold today leads to grave inequities. The European Parliament should ensure that European and global rules that affect the R&D and availability of medicines are driven by health needs rather than industrial or commercial considerations. Faced with the rise of infectious diseases such as AIDS, TB, and malaria, and the increasing marginalisation of health problems that do not affect the developed world, strong voices are needed now more than ever to defend global public health.

Ensuring access to the fruits of innovation for even the poorest patients and promoting health R&D as a global public good requires global action. We ask the European Parliament to put R&D

[6] Australian EXW prices: "Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners, May 2004. Exchange rate used for conversion (1Australian $=0.72213 US$, May 1, 2004)
[7] Clinton Foundation price (FOB) + 10 % due to transportation and importation taxes.
[8] Council Regulation 953/2003 to avoid Trade Diversion http://trade-info.cec.eu.int/cgi-bin/antitradediversion/index.pl
[9] Médecins Sans Frontières (2004) Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries (6th Edition), www.accessmed-msf.org.

for neglected diseases at the top of its agenda and ensure sufficient, sustainable and long-term financing to address the R&D needs and work towards a change in the way health R&D priorities are set and financed.

We urge the EP to address the dismantling of the Doha declaration, which is advancing insidiously through US-initiated Free Trade Agreements. We welcome former trade Commissioner Lamy's concerns about the FTAs expressed at the 10th anniversary of the WTO TRIPS Agreement, and we hope that the new Commissioner shares these concerns. We regret that the Commission has not yet taken action, for example by raising the issue at the WTO TRIPS Council.

The EP should also ensure that the Commission provides strong political support to countries that use the TRIPS flexibilities and offers technical assistance. We also ask you to encourage the Commission to engage with the Indian government to ensure that the new Indian patent policies allow the continued production and export of generic versions of newer medicines.

The EP should assess the effectiveness of the current EU trade diversion mechanism in bringing drug prices down and explore more effective ways to force prices of innovator products to a level people in developing countries can afford.

Finally, we appeal to you to ensure that the implementation of the August 30th decision in Europe is free from additional conditions and restrictions.

The European Parliament should actively involve itself in these issues, for instance by discussing with colleagues in other countries the need to change the rules governing drug supply today. By playing an active role in international debate, the European Parliament can have an important role in ensuring access to essential medicines for all people.

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