

A MATTER OF LIFE & DEATH:



The Role of Patents in Access to Essential Medicines

After more than two years campaigning for improved access to essential medicines for patients in poor countries, MSF's involvement in patent issues at times still elicits surprise: why does MSF, a medical humanitarian organisation, care about intellectual property rights?

The answer is the same as it was in Seattle in 1999, when MSF first addressed the negotiators of the world's trade rules at the 3rd WTO ministerial meeting:

We care because our patients in the developing world are dying. They do not have access to the medicines they need, either because they cannot afford them, or because the necessary drugs don't exist at all. This is an emergency on a global scale: infectious diseases kill more than 14 million people every year.



Some of this suffering could be prevented or alleviated if international trade rules and agreements, such as the TRIPS Agreement (WTO Agreement on Trade-Related Aspects of Intellectual Property Rights), stopped regulating essential medicines as if they were any other consumer product. Medicines aren't Barbie dolls or CDs – they are a matter of life and death for millions of people. Patents can become obstacles in providing affordable treatment, as the examples highlighted in this document demonstrate. MSF intends to continue fighting to put lives before commercial interests.

"The TRIPS Agreement contains important public health safeguards... Countries' rights to exercise these safeguards must be respected." Dr Gro Harlem Brundtland*

Price versus affordability

Although the price of medicines is by no means the only obstacle in providing treatment to patients in developing countries, it remains an important one. The actual production cost of a drug is only a fraction of its commercial price. The high prices of brand name medicines are largely a consequence of patents, which are used to exclude competition on the market for a long period of time. Patent regulations do not differentiate between a patient in a wealthy country and a patient in a poor country, which is why the price of medicines does not correlate with patients' ability to pay.

Patents - instruments of public policy

MSF is not against patents and patent legislation as such. True innovation deserves to be recognised and protected. But MSF wants human lives to take priority over profits and patents. MSF advocates a balanced intellectual property system which takes into account the specific needs and priorities of developing countries and follows the principles outlined in TRIPS: patents should benefit not only the innovator, but also those who need access to the innovation. Patents are not an end in themselves.

Rather, they constitute public policy tools with which to achieve benefits for society as a whole: a patent is a contract between public and private interests. When a patent monopoly is against the public interest – as is the case in many poor countries most affected by the HIV/AIDS pandemic – governments have the right and the obligation to free themselves from that monopoly.

Patents and R&D

It is often argued that patent protection is essential to ensure sufficient research and development for new medicines, and that the reason there is little investment in tropical disease research is because

"We have heard quite clearly that the price of drugs matters – it matters to poor people, and it matters to poor countries." Dr Gro Harlem Brundtland*

patent protection in the countries most affected by these diseases is weak.

But experience has shown that drug development for neglected diseases – conditions that mainly or only affect people in poor nations – will not increase no matter how stringently patents are protected. This is because the people suffering from neglected diseases do not represent a lucrative enough market to drive research.

In fact, patents may even hamper medical research activities by creating control over research knowledge, which can then only be accessed through costly licensing agreements. This kind of arrangement is usually out of reach of governments and research institutes in developing countries.

TRIPS – a problem or a solution?

The WTO TRIPS Agreement sets out the minimum standards for patent protection all WTO Members must abide by. But it also includes rules to counter the negative effects of patent protection. The critical factor in determining the balance between these two elements is the interpretation of the Agreement on a practical level both now and after 2006, when the implementation of TRIPS is

scheduled to be completed by all WTO Members – including least developed countries.

A long way from Seattle

Issues around access to essential medicines are better understood and more widely acknowledged now than they were two years ago, at the time of the 3rd WTO Ministerial Conference in Seattle. There is growing consensus about ways to address the problems. But strategies that are proving effective, such as those helping to reduce the cost of AIDS medicines in developing countries, will soon cease to function unless a pro-public health interpretation of TRIPS is assured.

The objectives of the TRIPS Agreement are not met if essential medicines are not made available in an effective and equitable manner. This is why MSF is calling on WTO Members to take concrete action now and show that people matter more than patents.

(continued on back page)

*From the closing remarks by Dr Gro Harlem Brundtland, Director General of WHO, at the WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs in Hoesbjoer, Norway, April 2001



© Gael Turine

TRIPS "safeguards" key tools to lower drug prices

When multinational companies have exclusive marketing rights over medicines, they tend to demand high prices which are often unaffordable to the vast majority of people living in developing countries – the price of a medicine is not determined by public health needs nor related to production costs.

It is now well known that there are massive differences in prices of antiretroviral treatments, depending on whether the drugs are protected by patents or not. However, price is also a barrier for the efficient treatment of other prevalent diseases in developing countries, as they require the use of recent antibiotics which are still under patent.

Azythromicin is an antibiotic used to treat respiratory and sexually transmitted infections, which are among the most highly prevalent diseases in developing countries. In Kenya, azythromicin is patented by the pharmaceutical company Pfizer and marketed under the trade name Zithromax®. The Kenyan trade price per 250mg capsule of Zithromax® was

US\$2.70 in October 2001. In India, where pharmaceutical products are not covered by patents, many generic manufacturers compete. Because of this competition, the Indian retail price for Pfizer's Zithromax® is much lower than Kenya's trade price: US\$0.84 in March 2001 (3.2 times cheaper).

The TRIPS Agreement allows for parallel importation, which enables countries to obtain patented medicines at the lowest price available on the market. Developing countries must be allowed to use this legitimate mechanism to reduce the overall cost of medicines. If Kenya were to parallel import India's cheaper Zithromax®, more than twice as many people could be treated on the same budget.

Furthermore, if the Kenyan government issued a compulsory license (another TRIPS safeguard) for azythromicin, generic versions of the drug could be imported from India, where retail generic prices range from US\$0.39 to 0.54. Kenya could then treat five to seven times more patients on the same budget.

TRIPS "safeguards" in use in developed countries

It must not be thought that the TRIPS safeguards are measures limited to developing countries. TRIPS safeguards are also used by developed countries to protect the health of their population.

In 1961 in the UK, the antibiotic tetracycline was sold at a comparatively high price by the patent-holder Pfizer. The British Minister of Health therefore authorised the use of the so-called "Crown Use" (government use) provisions of the UK patent legislation to import generic tetracycline from a manufacturer in Italy, without the permission of Pfizer, to supply the National Health Service. Pfizer responded with a legal challenge, but the House of Lords ruled in favour of the Minister of Health. These Crown Use powers continue to exist in the UK patent legislation today.

More recently, on 18 October 2001, the Canadian government took the decision to "override" Bayer's patent on ciprofloxacin, an antibiotic used to treat anthrax. Canada made this decision to ensure the availability of medicines need-

ed to protect the public in the event of a bio-terrorist attack. A spokesperson of the Canadian Health Ministry justified the decision: "Canadians expect and demand that their government will take all steps necessary to protect their health and safety."

Developing countries want to be able to take equivalent measures to protect their health (see back page). Ironically, the Canadian government is one of the WTO Members that has refused to support the developing countries' proposal.

In the US, senators have asked the secretary of health and human services to take similar measures to deal with the shortage of ciprofloxacin. According to statute 28 USC 1498, which sets out the rules concerning uses of patents by or for the government, the US government does not have to seek a voluntary license or negotiate for use of a patent – any federal employee can use or authorize the use of a patent. The patent owner is entitled to compensation, but cannot prevent the government from making use of the patent.



© L. Hakokongas

MSF provides ARV treatment and counselling to AIDS patients in Surin, Northern Thailand. Reduction in drug prices through generic production would directly benefit patients in countries like Thailand, which counts the highest number of AIDS deaths in Asia. Currently, most Thai people living with AIDS cannot afford ARV treatment, and only a small number of them receive the treatment that could both prolong their lives and improve their quality of life.

Thailand

US and Big Pharma orchestrate pressure

It is not infrequent that countries encounter pressure to change their intellectual property laws to include patents on pharmaceutical products prior to the TRIPS deadline. Thailand has been subjected to such trade pressure by the US government since 1985.

In 1992, Thailand came under threats of trade sanctions by the US trade representative after a complaint by the US Pharmaceutical Manufacturers Association. The Thai government was unable to resist and amended its

patent law to include pharmaceutical product protection.

Another worrying instance of external pressure on Thailand occurred in early 2000, when the Thai government attempted to issue a compulsory license for the formulation patent of didanosine (ddI), an AIDS drug. The US responded by threatening Thailand with trade sanctions. Worried about potential consequences for its economy, the Thai government ended up rejecting activists' calls for a compulsory license.



© C. Schwetz

39 pharmaceutical companies took the South African government to court over a law intended to protect public health. This caused public outrage worldwide. Support for the South African government poured in, and the companies unanimously dropped the case in April 2001. Six months on, still only a fraction of the country's AIDS patients are receiving the necessary treatment.



Why donations won't solve the access crisis: the example of fluconazole

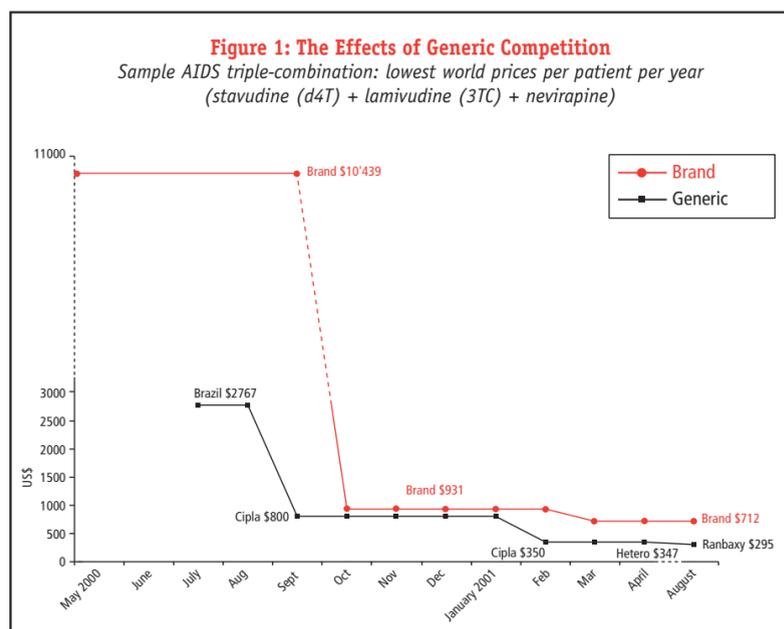
Manufacturer (country of production)	Country of distribution	Price per unit (US\$)
Biolab (Thailand)	Thailand	0.29
Cipla (India)	India	0.64
Bussie (Colombia)	Guatemala (negotiated)	3.00
Pfizer	Thailand	6.20
Vita (Spain)	Spain	6.29
Pfizer	South Africa	8.25
Pfizer	Kenya	10.50
Pfizer	Spain	10.57
Pfizer	Guatemala (negotiated)	11.84
Pfizer	USA	12.20
Pfizer	Guatemala (not negotiated)	27.60

Wholesale prices of 200 mg fluconazole capsules in June, 2000
(Source: The Lancet, Volume 356, Number 9247, 16 December 2000)

Generic competition helps slash drug prices

In May 2000, the price of a brand-name antiretroviral (ARV) drug cocktail was \$US10,400 per patient per year. It was only in October 2000 when a generic producer offered to sell a triple combination cocktail at \$US800 that things began to change. Within a UN-led initiative to cut prices of AIDS cocktails for a small number of developing countries,

pharmaceutical companies dropped their price to \$US931. In February 2001, the generic price dropped again to \$US350, which set off a price war between branded and generic drug makers, reducing the prices of both brand-name and generic drug cocktails. In October 2001, the best world price for a triple-combination drug cocktail had come down to \$US295.



Some developing countries, such as Thailand, Brazil and India, have the capacity to produce high quality generic drugs. The local manufacture of fluconazole, a medicine used to treat AIDS-related meningitis which affects up to 25 % of AIDS patients in certain countries, has led to 95% cuts in the price of this essential drug in Thailand.

license to allow generic production, Pfizer promised to provide a donation of fluconazole. But it was almost a year later before patients finally started receiving the drug. Since spring 2001, Pfizer has offered the possibility of a similar donation to 50 least developed nations.

An adequate response to the overwhelming burden of infectious diseases will never be possible through donations from multinational pharmaceutical companies. Companies must offer prices equivalent to those of generic drugs in developing countries, and governments in those countries should issue compulsory licenses and encourage parallel imports of drugs.

The chart above illustrates how the price of the same drug varies in different countries according to whether or not the drug is under patent by the patent holder, Pfizer.

In March 2000, as a response to calls by South African activist groups for a price reduction or a voluntary

South Africa

Public opinion forces Big Pharma to back down

In 1997, the South African government passed the "Medicines and Related Substances Control Amendment Act", a law intended to make medicines more affordable through mechanisms which included allowing parallel importation, enforcing generic substitution, and price controls.

Objecting to many of the provisions included in the Act, 39 pharmaceutical companies filed suit to block the legislation from coming into force. Their claim that the legislation was unconstitutional and in violation of South Africa's commitments under the WTO's TRIPS Agreement was immediately countered by a public outcry at the pharmaceutical industry's desire to put profits before poor people's lives. The companies were also criticised for being opposed to provisions in the South African law already in use elsewhere in the world.

Public protests centred around access to antiretroviral treatment: the cost of

patented medicines was at the time the main obstacle to bringing life-saving treatment to South Africa's 4.7 million people living with HIV/AIDS.

300,000 people from more than 130 countries signed an international petition launched by MSF calling on the companies to drop the case. The European Parliament passed a resolution urging the companies to drop the case, a position echoed by ministers from a number of European governments.

Finally, on 19 April 2001, yielding to the powerful combination of public pressure, solid legal argumentation, and government resolve, the 39 pharmaceutical companies announced they were unconditionally dropping the lawsuit.

An MSF programme in Khayelitsha, a township outside Cape Town, recently became the first and only project to distribute antiretrovirals in government primary health care facilities in South Africa.

Kenya

Health before profits

Kenya's parliament passed an important law in June 2001: the country's new Intellectual Property Bill allows for the importation and production of more affordable medicines for HIV/AIDS and other diseases. This was a major victory for the coalition of Kenyan activists and organisations, including MSF, who have

been working together to improve access to medicines and encouraged policy-makers inside Kenya and internationally to adopt a pro-health Industrial Property Bill. The new Bill includes safeguards such as parallel imports and compulsory licensing, with explicit mention of high prices as grounds for issuing compulsory licences. The challenge for the Kenyan government is now to work to expand treatment access by implementing the provisions in the new bill.



Public pressure was instrumental in passing Kenya's new IP Bill and providing hope for Kenyan AIDS patients. An estimated 2.3 million adult Kenyans are living with HIV/AIDS, but so far, less than 2000 of them have received treatment. Kenya can change this by issuing compulsory licences and producing or importing affordable generic medicines – not only AIDS drugs, but other essential medicines as well.

If all new medicines are patent protected, like most AIDS medicines now, generic competition will be stamped out.



(continued from front page)

Poor patients at risk

The urgent need to find a sustainable global solution to the imbalance between intellectual property rights protection and saving lives has been particularly visible in the case of HIV/AIDS. Since the early 1990's when

cocktails" within the reach of a handful of people on the ground, both in MSF's projects and in many developing countries in general. It has also helped push the global debate on the right to access AIDS treatment. But long-term solutions at an international level are necessary to ensure that these important gains do not vanish. TRIPS cannot stand in the way of protecting public health.

Prices of all new medicines will inevitably shoot up, far beyond the means of patients in need.

the TRIPS Agreement was negotiated, the world has changed drastically. A decade ago, no-one anticipated that in 2001, a total of 36 million people worldwide - a vast majority of them in sub-Saharan Africa - would be infected with HIV.

The example of anti-retroviral (ARV) drugs for AIDS shows how TRIPS affects poor countries. The fall in ARV prices over the past year (see figure 1 on previous page), achieved through a combination of vigorous generic competition and international public pressure, has brought these "AIDS

The case of AIDS drug prices also helps illustrate what is to come if all new pharmaceutical products come under patent in 2006, when all WTO members have to implement the TRIPS Agreement. The implications for the majority of the world's population living in developing countries are daunting. If all new medicines are patent protected, like most AIDS medicines now, generic competition will be stamped out. As a consequence, prices of all new medicines will inevitably shoot up, far beyond the means of patients in need. The lever that has brought the price of AIDS drugs down will be lost.

The lever that has brought the prices of AIDS drugs down will be lost.



MSF supports developing countries' recommendations to the 4th WTO Ministerial Conference

The WTO Ministerial Conference should express clear political support for an interpretation of the TRIPS Agreement that protects public health. The meeting should result in a Ministerial Declaration stating that "nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health". This wording was suggested in a draft declaration put forward by 60 developing countries in the September 2001 TRIPS Council Session on Access to Medicines.

A strong declaration would help protect the lives of people in developing countries. Not only would it have an impact on how the TRIPS Agreement is interpreted by the WTO dispute settlement panels, but also on how national legislation is assessed by the TRIPS Council in the future.

In addition, the Ministerial Declaration should explicitly acknowledge the following points:

 An intellectual property rights system is needed which will guarantee more equitable sharing of the benefits of technological development and advances between the populations of developed and developing countries. Ways must be sought to correct the imbalance between the current unbridled exercise of private property rights and public interest.

 The failure of the present intellectual property rights system to provide incentives for research and development for neglected diseases should be addressed.

 The TRIPS January 2006 deadline for implementing patent protection for pharmaceutical products in least developed countries must be extended if countries wish to do so.

 No bilateral pressure should be allowed between Members to push for an early adoption of patent protection for pharmaceuticals in developing or least developed countries, or for more stringent rules than required in the TRIPS Agreement.

 The right to parallel import medicines, as allowed for in TRIPS, must be affirmed. Parallel import refers to the importation of a patented medicine, without the consent of the patent holder, from a foreign market where this patented medicine is sold or marketed at a lower price. This important policy instrument enables developing countries to bring down the cost of medicines in their own market by encouraging competition.

 The right of developing countries to issue compulsory licenses, which allow the production or import of a generic medicine without the consent of the patent holder, must be affirmed in order to lower the acquisition costs of medicines. The grounds on which a compulsory license is issued should not be limited. In addition, a cross-boundary practice of compulsory licenses should be enforced so that, in countries with no or limited drug manufacturing capacity, needs can be fulfilled through importation. No Member should be penalized for taking this step.



For more information:
www.accessmed-msf.org

Campaign for Access to Essential Medicines
Médecins Sans Frontières
Rue du lac 12 CP 6090
CH-1211 GENEVA
Tel ++41-22-8498 405
Fax ++41-22-8498 404
e-mail access@geneva.msf.org

Médecins Sans Frontières (MSF) is an independent humanitarian medical relief agency aiding victims of armed conflict, epidemics, and natural and man-made disasters. Founded in 1971, MSF currently works in more than 80 countries around the world. The organization was awarded the Nobel Peace Prize in 1999.

Design: Graphic Solutions Genève
Printing: SRO Kundig SA