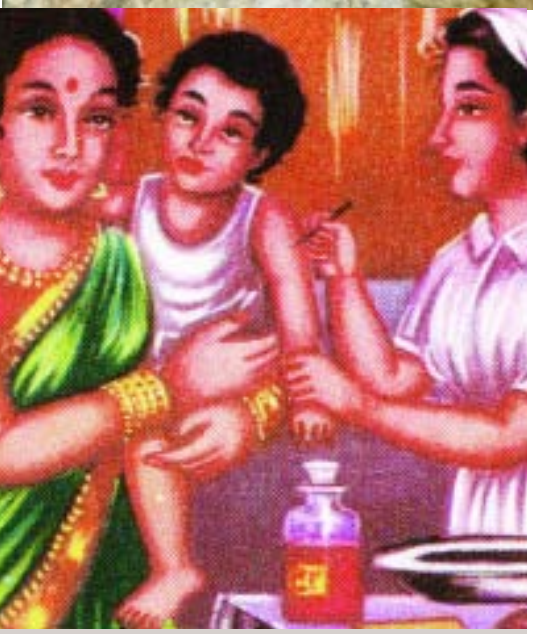
How strong patent protection affects access to medicines

# Patents trade and health



## What is a patent?

A patent is a privilege granted by a government, allowing the holder to exclude others from making, using and selling an invention. Patents provide the holder with an effective monopoly on a particular product or production process. These privileges apply in the countries where they are granted for a limited period (the minimum is now 20 years). In order to prevent patents from harming the public interest, governments retain the right to over-ride them in certain circumstances (using a 'compulsory licence').

The patent system is meant to provide incentives for the research and innovations which society might need. However, there is debate about whether the patent system is the most effective way to achieve this. Many patent-based industries base much of their research on previous public sector innovation, fail to address research needs in areas where there is no market, use patents to block new research and competition and, especially in pharmaceuticals, find ways to extend the privilege beyond 20 years.

# The price of drugs

**Global rules on trade and patents make medicines much more expensive for many people who need them. In poor countries, the difference in price can be a matter of life or death.**

Patented drugs generally cost much more than unpatented 'generic' equivalents. Generic drugs are otherwise identical to the original brand name version. Many developing countries want to make or import generic medicines.

Pharmaceutical companies owning patents on drugs have tried to limit the extent of generic medicine production. They have convinced developed country governments to push for stronger protection for patented drugs when negotiating trade deals with poorer countries. Resulting global trade rules often reflect the narrowly defined interests of a few patent-dependant industries.

One international trade deal is particularly important: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This accord, which is overseen by the World Trade Organisation (WTO), requires WTO Member countries to grant patents on pharmaceutical products. Before TRIPS, more than 50 countries did not do so. Developing countries have argued that TRIPS is fundamentally unbalanced, as it fails to take into account their concerns.

Increasingly, rich countries are pushing their poorer trading partners to adopt more stringent rules than those in TRIPS. Bilateral and regional trade deals now often contain burdensome requirements on patents which poor countries must agree to if they want to gain access to markets in developed countries. Such deals could remove the limited flexibility developing countries have to tailor their laws to their needs within TRIPS rules.

# The US challenge to Brazil

**Brazil has received international recognition for its HIV/AIDS treatment programme, which provides free drugs under the national health system.** In 2001, the USA threatened to take Brazil to the WTO dispute settlement process over its patent laws - potentially jeopardising the drug distribution scheme.

Brazilian law requires the patent holder to manufacture the product in Brazil. If not, the government can issue a compulsory licence to another producer, unless local production is not feasible. Lower cost generic HIV/AIDS drugs are vital for the health care programmes.

Public outcry led the US government to drop the case after negotiations with Brazil.

## Neglected diseases

There are many serious diseases for which little research takes place, because they mainly affect people who cannot afford expensive patented drugs. Examples of these 'neglected diseases' include human trypsomaniasis, leishmaniasis and Chagas disease. Of the 1393 new drugs developed between 1975 and 1999, only 13 were for tropical diseases.

Pharmaceutical companies argue for strong patent protection on the basis that it protects the profits which provide incentives for research and drug development.

For many neglected diseases, there is no connection between stronger patent protection and increased research and development for drugs. Treatments for such diseases are not a profitable market. These diseases need to be tackled globally by a mixture of public sector research in developed and developing countries, greater funding and new not for profit initiatives


# **South Africa**: 39 drug companies sue the government

**In 2001, the question of access to medicines hit the headlines when 39 pharmaceutical companies sued the South African government.**

The companies alleged that a new South African law would have been illegal and contrary to the patent rules in TRIPS. The proposed law would have allowed the import of cheaper drugs from other countries, primarily to address the HIV/AIDS crisis.

Even though South Africa was abiding by the TRIPS rules, the companies only dropped the suit and withdrew following widespread condemnation nationally and internationally in the media and by public health advocates.

# **Public health needs in developing countries**: the example of HIV/AIDS

**The HIV/AIDS epidemic has been especially devastating in many African countries, although the disease is prevalent worldwide.**

Developing country governments have drawn particular attention to the impact of HIV/AIDS – but stress that this is the just the most dramatic example of a wider range of public health problems. The difficulties that people with HIV/AIDS face in obtaining affordable medicines are similar to the problems faced by people with respiratory and cardiovascular diseases, malaria, cancer and TB.

Governments everywhere want to have available the necessary public policy tools to address national health requirements, in whatever form these might appear. Developing countries need to be free to over-ride patents in the interest of public health where necessary, without having to fear reprisals from rich country governments.

nts to unduly delay or restrict generic competition"

ICTSD/UNCTAD, *Intellectual Property Rights: Implications for Development*, 2003, p 99

# Public health takes priority

**Fierce attacks on public health policies in Brazil and South Africa convinced developing countries that there was a need to take action to reaffirm their rights.**

**"Although pricing is only one of the factors that determine access, it is a highly significant one. Three recent studies…predict price increases of twofold or more with full implementation of TRIPS requirements in developing countries."**

WHO, "Intellectual property rights, innovation and public health", May 2003, Doc A56/17

At the WTO meeting at Doha in 2001, developing countries introduced a declaration to clarify that public health takes priority over patent rules in the TRIPS agreement. After tough negotiations with developed countries, they achieved this objective. The Doha Declaration on the TRIPS Agreement and Public Health recognises that TRIPS "does not and should not prevent [WTO] Members from taking measures to protect public health".

It is rare for developing countries to achieve such a clear recognition of their rights at the WTO. The Doha Declaration spells out in detail the need for rules on patents and trade to be interpreted and implemented so as to "promote access to medicines for all".

The Declaration clarifies that governments have the right to over-ride patents using a 'compulsory licence' to produce lower cost drugs, and to determine the grounds upon which it can be done. It also emphasises that TRIPS does not prevent governments from establishing national legal systems to allow for the parallel importation of cheaper medicines if they wish. The poorest, least-developed countries were also allowed to ignore TRIPS rules on pharmaceutical products until 2016.

The Declaration left one item outstanding – the problem of what countries with insufficient or no manufacturing capacity for medicines can do. Even if they issue a compulsory licence to produce generic drugs, they have no industry that could do so. They need to find a country where generic drugs could be made and then exported to them. But under TRIPS rules this could be challenged. WTO Members were given until the end of 2002 to find a solution.

Instead of helping craft a workable solution, developed countries loaded the draft agreement with bureaucratic conditions. Even then, the USA only joined the consensus at the end of August 2003, eight months past the deadline, after concessions were made to some of the pharmaceutical industry's demands.

Governments must now move from words to action. Countries able to produce medicines need to start exporting generic drugs to address the urgent health needs in developing countries. Poor countries should be free to act without facing pressures from rich country pharmaceutical firms or their governments.

## Cutting the cost

**It costs about US$10,000 per year per person to treat an AIDS sufferer with an AIDS drug cocktail in rich countries.** Generic manufacturers can supply these drugs for around $300 in some developing countries. The availability of cheaper drugs has also led manufacturers of patented drugs to lower their prices, but not usually to the same levels.

In late 2003, the WHO announced that a quality-assured twice-a-day pill is available to treat AIDS although it did not specifically recommend it. Médecins san Frontières (MSF) also announced that this pill could be provided for an annual cost of $140 by an Indian generic manufacturer. MSF pointed out that there were still some patent barriers to the use of this pill.

# Ways forward...

## Questioning the rules

There is a need for greater public involvement in policy making on the privileges society grants to patent holders. Attention from the media and public health advocates has already had an impact in important fields such as access to medicines.

A wider range of interest groups need to engage in policy-setting and decision-making on these issues for real change to happen. Only then are we likely to get rules on patents that reflect the broader public interest and the needs of the poor. In the long term, this requires a fundamental reform of the decision-making processes that set public policy.

## Getting involved

**1. Are other organisations near you involved in the debate?** These could include labour unions, environmentalists, businesses, faith-based organisations, law associations, health advocates, universities, or consumer groups. If not, suggest they start thinking about these issues and looking at how they affect people locally and globally.

**2. What actions might you usefully take to influence decision-makers?** This might involve contacting parliamentary representatives, government departments and ministries. You might be able to raise awareness about the issues at stake, for example, by writing a letter to a local or national newspaper.


## On-line resources:

**World Health Organisation (WHO)**
http://www.who.int/en

**World Trade Organisation (WTO)**
http://www.wto.org/

**Médécins Sans Frontières (MSF)** - Access to Essential Medicines Campaign
http://www.accessmed-msf.org/

**Oxfam International**
http://www.oxfam.org

**Consumer Project on Technology**
http://www.cptech.org/ip/health/

**International Centre for Trade and Sustainable Development (ICTSD) / UN Conference on Trade and Development (UNCTAD)** – Project on IPRs and Sustainable Development
http://www.ictsd.org/iprsonline

**Global Treatment Action Campaign**
http://www.globaltreatmentaccess.org/

**International Federation of Pharmaceutical Manufacturers**
http://www.ifpma.org/

**UK Commission on Intellectual Property Rights**
http://www.iprcommission.org/

**Canadian HIV/AIDS Legal Network**
http://www.aidslaw.ca

**Royal Society** - Keeping Science Open
http://www.royalsoc.ac.uk/policy/

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The Quaker United Nations Office (QUNO) in Geneva and Quaker International Affairs Programme (QIAP) in Ottawa are working in cooperation on these issues. QIAP and QUNO seek to promote greater equity and justice in world trade to benefit the poor and support protection of the environment, by working with government representatives at the World Trade Organisation (WTO), inter-governmental organisations and public interest organisations in Geneva, Ottawa and elsewhere.

For more information, see the other briefing papers in this series. These and other resources are available on our websites or on request from one of the addresses below.

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