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PATENTS, INTERNATIONAL TRADE LAW AND ACCESS TO ESSENTIAL MEDICINES

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What is the issue?

More than 85% of the world's population live in developing countries, and the vast majority of them have no or limited access to drugs that have saved and extended the lives of people in richer, developed countries. In the developing world, where 95% of the people living with HIV/AIDS are found, 20 million people have already died from AIDS. Every day, over 8,000 more people die and another 15,000 are infected with HIV. The global epidemic is devastating entire countries and regions. Similarly, TB and malaria kill massively and mainly among the poorest and most vulnerable of the global population, given their extremely limited access to effective forms of treatment.

What does this info sheet tell me?

The rules on drug patents set out in domestic laws and international trade agreements affect the availability and affordability of both anti-retroviral drugs and medicines to treat opportunistic infections or communicable diseases that can harm or kill people with HIV/AIDS, TB, malaria and other neglected diseases.

This information sheet answers some frequently asked questions about patents and international trade laws. The goal is to help people understand the connection between patent issues and access to affordable drugs, so that they can be informed advocates for the basic health rights of people in developing countries.

What do patents have to do with access to medicines?

Depending on the patent laws in place, conditions will be created to favour more or less competition between manufacturers of patented and generic drugs (definitions of these terms are offered below). Increased competition is proven to result in lower prices, which in turn contribute to improved access to medicines. Although access depends on numerous factors, high prices of drugs constitute a key obstacle that cannot be addressed in a comprehensive and sustainable manner through foreign aid and drug donations alone.

What is a patent?

A patent is an "intellectual property right" in an invention. Intellectual property rights (IPRs) are rights given to a person or a corporation over mental creations, such as: an author's *copyright* in their book or the rights of musicians in their recordings; a company's distinctive *trademark* on its products; or a *patent* on a technological invention.

A patent gives its owner the right to prevent others from making, using, importing, or selling an invention. In other words, patenting an invention gives the patent owner a monopoly over the invention. A patent is usually granted for a limited time, such as 20 years. A patent is granted under a country's domestic laws, and may come with conditions or exceptions.

What is the World Trade Organization?

Established in 1995 after a decade of trade negotiations, the WTO has become the central institution in the world trading system, with a secretariat located in Geneva.

The WTO administers dozens of other international trade agreements covering a wide range of areas, including intellectual property. These agreements set out "ground rules" for international trade that all member countries must observe.

The WTO also monitors countries' national trade policies, and provides a forum for trade negotiations and for settling trade disputes.

Over 140 countries are members of the WTO, accounting for over 90% of world trade. Several other countries are currently negotiating joining the WTO.

Being a WTO member gives a country:
- access to the markets of other member countries on terms set out by the WTO agreements;
- the option of invoking a mechanism for settling trade disputes;
- and the chance to participate in future trade negotiations.

In order to be a member, a country must sign on to the whole package of WTO Agreements.

What can be patented?
A patented invention can be either an actual *product* or a new *process* for making a product. In order to qualify for a patent, an invention has to meet three criteria: it must be something new, it must not be obvious but actually involve some sort of "inventive step," and it must be usable. Medical drugs are inventions that can be patented.

What is a patented drug? And a generic drug?
According to the World Health Organization's Action Programme on Essential Drugs, a drug that is patented is usually marketed under a proprietary or brand name reserved exclusively to its owner, i.e. the individual or firm granted a patent on that invention.

A generic drug is a pharmaceutical product usually intended to be interchangeable with the invented, patented drug. Unless there is a prior agreement with the patent owner, a generic drug is usually made and marketed after the expiry of patent rights held by the innovator company. A generic drug is marketed either under a non-proprietary or approved name rather than a proprietary or brand name.

Generic drugs should not be confused with counterfeit drugs. "Counterfeit goods are generally defined as goods involving slavish copying of trademarks. According to WHO, a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeits products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging."[1]

What is "TRIPS" or the "TRIPS Agreement"?
This is a shorthand way of referring to the *Agreement on Trade-Related Aspects of Intellectual Property Rights*. The TRIPS Agreement is one of a series of trade agreements administered by the World Trade Organization (WTO). It sets out rules for intellectual property rights that all countries who are WTO members must reflect in their own domestic laws as a condition of belonging to the WTO.

What does the TRIPS Agreement require?
The TRIPS Agreement contains a number of requirements that WTO member countries must satisfy in their national laws.

Before the TRIPS Agreement, most industrialized countries granted patents on drugs, but many developing countries did not. In some cases, countries only granted patents for the *process* of producing an invention (e.g., the method of producing a drug) but not for the *product* (i.e., the drug itself). Because in some countries pharmaceutical products could not be patented, generic copies of these drugs could be made or imported into those countries without first getting permission from the "inventor" (i.e. the firm or individual that had been

[1] World Health Organization - Action Programme on Essential Drugs. *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement*, DAP Series No. 7, 1997 & 1999.

granted a patent in some other country that recognized drug patents). This meant there was no trans-national market monopoly for the patent-holder, so prices of medicines were often lower because of generic competition against the patented drugs. The TRIPS Agreement ends this.

Exclusive patent rights: Under the TRIPS Agreement (Article 28), governments are required to recognize patents on products and processes in all fields of technology, and to give the patent holder the exclusive right to make, use, sell or import the product in their country for a given period of time. During this time, a patent holder may choose to authorize another individual or corporation the right to do these things. This authorization is called a "voluntary license" (see below).

Minimum 20-year patent term: All WTO member countries are now required to grant patents on pharmaceutical inventions for at least 20 years (Article 33). This prevents someone other than the patent-holder from making, using, selling or importing a drug during the period that the drug is still under patent. TRIPS creates a trans-national market monopoly where none existed before, by allowing patent-owners to keep generic drugs off the national market in every WTO member country. The patent owner's monopoly often results in significantly higher prices for patented medicines than in a situation of market competition.

"Non-discrimination": The TRIPS Agreement (Article 27) also requires countries to make patents, and all patent rights, available "without discrimination" on certain grounds. Under TRIPS, countries are not allowed to treat national and foreign inventions differently, nor are they allowed to discriminate between types of products (e.g. pharmaceuticals versus computers). Finally, TRIPS says that countries' patent laws cannot discriminate based on whether a product is imported or locally produced.

Which countries are bound by TRIPS and when?

All countries that are members of the WTO are bound by the TRIPS Agreement. All "developed" countries were required to bring their domestic laws into line with TRIPS rules no later than January 1, 1996. "Developing" countries had until January 1, 2000 to comply - although they have until 2005 for patents on pharmaceutical products if they did not previously recognize these. Those countries considered "least developed" have until January 1, 2006 to change their laws, and may ask for extensions of time.

What if a country doesn't meet its obligations under TRIPS?

If a country doesn't comply with an agreement such as TRIPS, other countries can take it before a trade tribunal. One of the primary functions of the WTO is to provide a forum for countries to settle trade disputes. One of the WTO agreements, the Dispute Settlement Understanding (DSU), sets out a procedure to be followed when a country wishes to challenge the laws or practices of another country.

If a WTO tribunal rules that a country has breached a trade agreement, it "shall recommend" that the country bring its laws or policies into line and may suggest ways to do this. The country then has three choices. It can comply

How does the WTO work?

In theory, the WTO is run by all its member countries. Every two years, the WTO has a Ministerial Conference, a gathering of government ministers, to discuss trade issues and set the agenda for future discussions.

In between these meetings, governments' diplomatic missions in Geneva continue the day-to-day business.

While decisions are theoretically "taken by consensus" among all member countries, in practice decision-making tends to be concentrated with a handful of the wealthiest and most powerful countries – including the group of four referred to as the "Quad" (the United States, the European Union, Japan and Canada).

However, in recent months, developing countries have started to demand flexibility in the international trading system to allow them to respond to their health needs.

The *Generic Medicines* case (2000)

In 1997, the European Union (EU) challenged a section of Canada's *Patent Act* intended to make it easier for cheaper, generic drugs to come to market as soon as possible. The section in no way limited an original drug company's market monopoly during its 20-year patent term, but simply allowed generic drug companies to stockpile their versions of a drug for sale as soon as the patent expired.

Among other things, Canada argued that the public interest in earlier access to more affordable drugs was a legitimate basis for this limited exception to exclusive patent rights. Theoretically, these exceptions are allowed under Article 30 of TRIPS. The EU dismissed these arguments, complaining of "discrimination" against the pharmaceutical industry.

The WTO panel hearing the dispute ignored Canada's public interest argument. It took a very narrow approach to deciding what were acceptable limitations on patent rights, looking only at the private patent owner's expectation of profits and not considering what other, social benefits were to be gained by limiting this monopoly.

with the "recommendations" by changing its laws or policies. Or, it can decide not to comply with the ruling, and pay "satisfactory compensation" to the country that brought the complaint, presumably on an ongoing basis. Finally, if it does not receive satisfactory compensation, the country with the complaint can request WTO authorization to impose trade sanctions in retaliation. Again by default, the WTO will accept this request unless every country (other than the ones involved in the dispute) rejects it. The country facing sanctions may have an arbitrator decide whether the sanctions are fair.

What does TRIPS say about protecting health?

The TRIPS Agreement itself says that the monopoly rights created by patents need to be balanced against other important interests. It says that protecting and enforcing intellectual property rights should contribute to promoting technological innovation and to the transfer and dissemination of technology. Furthermore, TRIPS says that this should be to the benefit of both producers and users of technological knowledge, and should occur "in a manner conducive to social and economic welfare, and to a balance of rights and obligations" (Article 7).

The TRIPS Agreement (Article 8) also sets out some basic principles that should guide how it gets interpreted. It says that, in shaping their own laws, countries "may take measures necessary to protect public health." It also recognizes that countries may need to take "appropriate measures" to prevent the "abuse" of patent rights by patent-holders or to prevent practices which "unreasonably" restrain trade or negatively affect the international transfer of technology. These measures, however, must be "consistent" with the provisions of TRIPS.

These provisions in TRIPS support the argument (also defended by Canada in the case outlined in side box) that countries should be entitled to flexibility in meeting their obligations to protect patent rights.

Does TRIPS leave options for countries to increase access to affordable medicines?

Yes and no. There are some parts of TRIPS that countries can use to promote access to affordable medicines for people living with HIV/AIDS and other diseases. However, there are still many areas of uncertainty in the interpretation of the TRIPS Agreement. Advocacy is still needed to ensure the maximum flexibility in interpreting the agreement. Some argue that should such flexibility not be formally acknowledged, it might be necessary to amend the Agreement to ensure countries can protect the health and human rights of their people. But renegotiating the text of the agreement is a risky process that may take years before yielding unknown outcomes.

What are countries' options under TRIPS?

There are four main aspects of TRIPS that may be useful for countries to promote access to affordable drugs.

Exclusions from patent admissibility: A country may prevent the commercial exploitation of some inventions if "necessary" in order to protect human life

and health, by refusing to recognize their patent admissibility (Article 27). How to determine whether this is necessary, and who decides, are not clear.

Exceptions to patent rights: Under Article 30, a country may include in its patent laws "limited exceptions" to the rights of a patent owner to exclude others from making, using, importing or selling an invention, taking into account the legitimate interests of others. But these exceptions must not "unreasonably conflict with the normal exploitation" of the patent, and may not "unreasonably prejudice" the patent owner's legitimate interests. There has only been one WTO ruling interpreting this article, the *Generic Medicines* case involving Canada's patent laws. (See side box in previous page).

Parallel importing: Manufacturers sometimes charge lower prices for a drug in one country than in another. This means a country with limited resources can sometimes afford more of a patented drug by purchasing it abroad and importing it, rather than buying it directly at home from the manufacturer at the higher price.

Patent laws in most countries say that once a patent-holder sells its goods, it has no right to control the resale of those goods. In other words, the patent-holder has "exhausted" its property rights in that sold product (although the patent-holder still has the exclusive right to make the product in the first place, preserving its monopoly on the "know-how" behind the invention.) So an intermediary could buy a patented drug in one country at the lower price being charged by the manufacturer, and then resell those drugs in another country at a higher price, but one that is still lower than what the manufacturer is charging for its patented drug in that country. This is "parallel importing" of a drug. The TRIPS Agreement (Article 6) explicitly says that nothing in it can be used to prevent a country from allowing parallel imports.

Compulsory licensing: Under TRIPS, a country's laws may allow the government or the courts to issue a "compulsory license," which permits either the government, an individual or a company to use a drug (i.e. produce or import a generic drug) without the authorization of the patent owner. Compulsory licenses are usually granted on grounds of general interest such as public health, economic development, national defence and the absence of working (when the holder is not "exploiting" its patent). The TRIPS Agreement does not limit the grounds on which governments are allowed to issue compulsory licences.

But there are restrictions to the use of compulsory licenses:

- Usually there must be an effort to negotiate a voluntary license with the patent owner "on reasonable commercial terms" within a "reasonable period of time." Importantly however, this attempt at negotiation with the patent holder is not required if the drug is to be used for "public non-commercial use," if there is a "national emergency" or other situation of "extreme urgency," or if a legal process has determined that the patent owner has engaged in "anti-competitive" practices.

Parallel importing and price variations for HIV/AIDS drugs

A recent survey by MSF, UNAIDS, UNICEF and WHO found worldwide variations in the price of fluconazole, an antifungal drug used to treat oral and vaginal candidiasis (yeast infection) and the deadly cryptococcal meningitis, ranging from a high of US $7.25 to a low of US $0.20 for a 200 mg tablet.

The anti-retroviral drug lamivudine (3TC) ranged from a maximum price of US $0.43 to a low of US $0.14 for a 150 mg tablet.

For poor countries with very limited health budgets and millions of people with HIV/AIDS, or for poor people with little income to spend on medicines, obtaining drugs at the lowest possible world price through parallel importing can make a significant difference.

- If a compulsory license is issued, the patent owner is entitled to be paid "adequate remuneration" (e.g. either a symbolic fee acknowledging the inventor or a proper royalty in lieu of financial compensation for lost sales). The competent authority may also decide that the license should be granted free of charge. The TRIPS Agreement does not say how this should be determined.

- Furthermore, the license must be used "predominantly" for supplying the domestic market in the country issuing the license (unless the license is issued to remedy anti-competitive practices by the patent owner). This presents a likely barrier to accessing affordable drugs: many developing countries don't have the ability to produce their own generic drugs and would need to import them from other countries that do. But those countries that do have a generic drug industry may not be allowed under TRIPS to issue a compulsory license for the manufacture of a patent-protected drug primarily for export to other countries. This restriction in TRIPS may need to be amended to make it easier for developing countries to access affordable medicines.

States' Obligations

The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The steps to be taken by the States Parties... to achieve the full realization of this right shall include those necessary for... the reduction of... infant mortality and for the healthy development of the child; ...and the prevention, treatment and control of epidemic diseases.
- International Covenant on Economic, Social & Cultural Rights (Art. 12)

Don't countries have an obligation to protect the health of their people?
Yes. In addition to governments' ethical duty to act in the public interest, countries have an obligation under international human rights treaties to take steps, individually and collectively, to fully realize the universal human right to health. In particular, this includes making laws that will protect and promote the right to health.

According to the UN Committee on Economic, Social & Cultural Rights, in respecting the right to health, States should also ensure that this right is given consideration in international agreements (such as TRIPS) and should ensure that these agreements do not negatively affect the right to health. A separate body, the UN Commission on Human Rights, has also recognized that access to medication in the context of pandemics such as HIV/AIDS "is one fundamental element" for realizing everyone's right to health.

The UN Declaration of Human Rights

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including... medical care.
- Universal Declaration of Human Rights (Art. 25)

Everyone has the right... to share in scientific advancement and its benefits.
- Universal Declaration of Human Rights (Art. 27)

Aren't the patent rights helping firms to recover their costs of researching and developing drugs?
This argument is often used to justify a 20-year patent protection over innovative processes and products. However, some different conclusions were drawn from several countries' experience.

According to Indian experts who spoke to MSF, "the Indian generic industry has been able to supply many developing countries with affordable medicines, largely because it has been able to develop to an advanced stage under protective legislation tailored to India's needs. India's 1970 patent law, which granted "process" but not "product" patents for pharmaceuticals, was the backbone that allowed the industry to mature to the point where it is today – a leading global producer of quality generic drugs and raw materials, that has the ability to invent new manufacturing processes of drugs through reverse-engineering, and can carry out original R&D [research and development]. Evidence from the Indian pharmaceutical industry indicated that since TRIPS was negotiated, the Indian drug industry has increased R&D but for *diseases of*

the West, not for those endemic to India. As with all market-driven companies, Indian R&D priorities were driven by the size of potential markets rather than medical needs. The example is telling, as India is one of the few developing countries with domestic R&D capacity."

Initiatives other that patent incentives will therefore be required to stimulate research and development into diseases affecting mainly the poor and marginalized communities.

What can be done?

Experts agree that TRIPS itself contains many ambiguities. Much remains unclear about what is and is not allowed under TRIPS. Few cases have been brought to the WTO that offer clear interpretations, although the decision in the *Generic Medicines* case is cause for concern. But how the TRIPS Agreement is legally interpreted will have a significant impact on whether and how countries can protect and promote access to affordable medicines.

Therefore, vigorous advocacy in favour of a flexible interpretation of TRIPS is required in the short term, to avoid new constraints being imposed on developing countries in the coming years. At a special TRIPS Council meeting on health issues held in June 2001, a consensus among developing nations and European countries has begun to emerge in a positive direction. However, major players such as the US are still working very hard to promote a much more restrictive approach. Canada has shown encouraging signs but is still vague in its statements and appears to be adopting a wait-and-see strategy rather than making firm commitments towards clearly defined practical implementation options.

"Discussions on access to medicines come at a time when even access to food is being questioned as a right. We must always remember that access to medicines is a right, not something that should be determined by charity or subsidies for the poorest of the poor."

--Mira Shiva, *All India Drug Action Network*

What do advocates say is needed?

At this stage, most governments as well as health and development activists are working towards the adoption of a political declaration by the 3rd WTO Ministerial Conference in Doha, Qatar, in November 2001. Such declaration confirming that the Agreement offers clear and sufficient flexibility to favour health needs would provide developing countries' governments the assurance they need to adopt measures to promote public health – without fear of litigation or other bilateral pressure from major trade partners. They also advocate for a moratorium on disputes concerning TRIPS and access to health commodities.

Though there are some compelling arguments to amend the Agreement, experts and activists generally agree that at this point it is better to push for maximum flexibility under TRIPS rather than to focus energy on amending the Agreement, which will have to be reviewed in due course in any case. In the meantime, least developed countries (LDCs) can request an extension of time before fully implementing TRIPS. It is therefore important to continue pushing to make the most of existing safeguards and options under TRIPS, and to put these measures into action for improved access on the ground.

What about other trade agreements?

TRIPS is one international trade agreement that affects access to affordable drugs, and is the one that affects the majority of the world's countries. But other, regional trade agreements are being negotiated, and there is a real danger that these agreements could go even further than TRIPS in hindering access to essential medicines. For example, some countries negotiating the Free Trade Agreement of the Americas (FTAA) are pushing for sections in the final treaty that go even further than TRIPS in granting exclusive patent rights and limiting countries' options for balancing patents against promoting public health and human rights.

Similarly, MSF, the World Health Organization and the UN's Joint Programme on AIDS (UNAIDS) have warned that a treaty signed in February 1999 between several French-speaking countries in central and west Africa is more restrictive than necessary under TRIPS. The Bangui Agreement imposes even stricter conditions on the use of compulsory licences and prohibiting parallel imports from countries outside the bloc of countries that sign the agreement. Advocates have urged these countries not to ratify the Bangui Agreement, and certainly not before they are fully bound by TRIPS.

Governments must ensure that trade agreements do not hinder access to affordable medicines, especially in developing countries.

WHERE CAN I GET MORE INFORMATION ABOUT GLOBAL ACCESS TO HIV/AIDS DRUGS AND OTHER ESSENTIAL DRUGS?

Médecins Sans Frontières / Doctors Without Borders Canada is the Canadian branch of the international medical relief organization. MSF is leading a global **Campaign for Access to Essential Medicines** (www.accessmed-msf.org) that includes action taken in Canada (www.msf.ca/access/index.htm).

The **Canadian HIV/AIDS Legal Network** (www.aidslaw.ca) focusses on legal and human rights issues related to HIV/AIDS. Its website includes a list of key resources on the issue of access to treatment for people living with HIV/AIDS in developing countries (www.aidslaw.ca/Maincontent/issues/cts/selectedresources.htm).

The **Interagency Coalition on AIDS and Development (ICAD)** brings together HIV/AIDS and development organizations. ICAD has produced several factsheets on international development issues relating to HIV/AIDS, including "Access to HIV/AIDS Treatment in Developing Countries." All of these are available on its website (www.icad-cisd.com).

The **International Council of AIDS Service Organizations (ICASO)** has produced a background paper on compulsory licensing and parallel importing that explains in more detail how they may improve access to essential drugs (available at www.icaso.org).

Oxfam is a global NGO focussing on health and food security and democratic rights, and has been active in lobbying for global trade rules that put patients before pharmaceutical company profits. Reports about the pharmaceutical industry are available on-line (www.oxfam.org.uk and www.oxfam.ca).

The **Global Treatment Access Campaign (GTAC)** is a network for communication and organizing advocacy efforts for access to essential medications for AIDS and other diseases. The website (www.globaltreatmentaccess.org) is maintained by the Health GAP Coalition in the US, and provides action tools and updates, with a particular focus on lobbying the US government. Position papers, press releases, and background documents are available.

The **Consumer Project on Technology** (www.cptech.org/ip/health) is a public interest advocacy organization in the US with a key project on intellectual property and health issues. The website contains a wealth of materials, particularly detailed information about the pharmaceutical industry, and a listserv on pharmaceutical policy issues for up-to-date postings.

The **Joint UN Program on HIV/AIDS (UNAIDS)** website (www.unaids.org) includes numerous documents on global HIV/AIDS issues, including a report on the patent situation of HIV/AIDS-related drugs in 80 countries and an infosheet on "Pharmaceuticals and the WTO TRIPS Agreement: Questions & Answers." It also includes updates on the global epidemic.

The website of the **World Trade Organization** (www.wto.org) provides access to the full text of the TRIPS Agreement (and other WTO treaties) and a searchable database of documents, including decisions of panels and the Appellate Body.

The **World Health Organization** (www.who.int) maintains an on-line catalogue of publications, some of which are themselves on-line, including its above-cited report on *Globalization and Access to Drugs* and a sheet on TRIPS and access to drugs.