



**MEDICINE
SHOULDN'T
BE A LUXURY**



732 - 1 Nicholas Street
Ottawa ON K1N 7B7
Tel: 613.241.4949
Fax: 613.241.4411
Email: access@msf.ca
www.msf.ca



417 Saint-Pierre
Suite 408
Montréal, QC
H2Y 2M4
Tel: 514.397.6828
Fax: 514.397.8570
info@aidslaw.ca

PATENTS, INTERNATIONAL TRADE LAW, & ACCESS TO ESSENTIAL MEDICINES

RICHARD ELLIOTT, MARIE-HÉLÈNE BONIN & CAROL DEVINE

What is the issue?

Currently, over 42 million people worldwide have HIV, and 95% of them live in the developing world. Over 28 million people have already died from AIDS. Every day, 8000 more people die and another 14,000 are infected with HIV, devastating entire countries and regions. Similarly, tuberculosis and malaria kill massively, and many other diseases cause human suffering and economic loss – mainly among the world's poorest and most vulnerable. The vast majority of people living in developing countries have limited or no access to many medicines that have saved and extended the lives of people in wealthier developed countries. The World Health Organization (WHO) estimates that roughly 2 billion people – one-third of the world's population – still lack regular access to essential medicines. Only 5% of the world's people with HIV/AIDS in developing countries who need anti-retroviral treatment currently have access to it. In Africa, the figure is only 1%.

What does this document tell me?

This document answers some common questions about patents and international trade agreements. The rules on drug patents in international trade agreements and domestic laws affect the availability and affordability of medicines. This document explains the connection between patent issues and access to affordable drugs, to help inform advocates for the health of people in developing countries.

What do patents have to do with access to medicines?

Depending on the patent laws in place in a country, market conditions will be created to favour more or less competition between manufacturers of patented and generic drugs (see definitions below). Increased competition results in lower prices; greater affordability contributes to greater access to medicines. Although access to treatment depends on numerous factors, high prices of drugs are one key obstacle. Ensuring comprehensive, sustainable access to affordable medicines requires overcoming this barrier. This cannot be achieved just by relying on foreign aid or charity by drug companies (such as voluntary price reductions or drug donations). Governments' public policy must also promote treatment access.

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* for its products; or a *patent* on a technological invention. A patent gives the patent holder (or “patentee”) the right to prevent others from making, using, importing, or selling an invention in the country where the invention is patented. In other words, patenting an invention gives the patent owner a monopoly over the invention. A country's domestic laws govern the granting of patents, and these laws are affected by international laws.

What is the World Trade Organization?

Established in 1995 after almost a decade of trade negotiations, the WTO has become the central institution in the world trading system. The WTO Secretariat is located in Geneva.

The WTO administers numerous international trade agreements covering a wide range of areas, including intellectual property. These agreements set out 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. 146 countries are members of the WTO, accounting for over 97% of world trade. Other countries are currently negotiating joining the WTO.

Being a WTO member gives a country:

- access, at least in theory, 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 all the major WTO Agreements.

A patent is valid for a limited time (such as 20 years). A patent may come with conditions on, or exceptions to, the exclusive rights of the patent holder.

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? What is a generic drug?

A *patented* drug is a pharmaceutical product which has been recognized as an invention and for which a patent has been granted by the proper authority in a given country (often called a "patent office") under that country's laws. If no patent has been granted, the drug is unpatented in that country. Once the patent expires, the drug is "off-patent". If no patent is in place, others may legally make, use, import or sell that drug. According to the WHO, a patented drug is usually sold under a proprietary or brand name reserved exclusively to the patent owner.

A *generic* drug is a pharmaceutical product intended to be roughly interchangeable with the original drug of which it is a copy. Unless there is a prior agreement with the patent holder (a "licence"), it is an infringement of the patent to make, use, sell or import a generic version of the drug during the patent term. Generic drugs are usually made and marketed after the expiry of patent rights held by the originator company. Usually, a generic drug is marketed either under a non-proprietary or approved name rather than a proprietary or brand name. (Some companies market their generic drugs under a brand name; these have been referred to as "branded generics").

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 counterfeit 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 belong to the WTO must reflect in their own domestic laws as a condition of membership.

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.

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. This meant that generic copies of these drugs could be made or imported into those countries without first getting permission from the "inventor". 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). So the same drug could be made and sold as long as it was produced through a different, un-patented process. This meant there was no transnational 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 as it comes into effect around the world.

Exclusive patent rights: Under the TRIPS Agreement (Article 28), governments are required to recognize patents on both 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".

Minimum 20-year patent term: All WTO member countries are now required to grant patents on pharmaceutical inventions for at least 20 years from the date of filing the patent application (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 holders to keep generic versions of a medicine off the national market in every WTO member country where they patent that particular drug. The patent holder's monopoly often results in significantly higher prices for patented medicines than in a situation of market competition. (Other factors such as taxes may also raise prices).

"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. Exactly what this clause means is the subject of considerable controversy.

Which countries are bound by TRIPS and when?

All countries belonging to the WTO are bound by the TRIPS Agreement. The WTO classifies countries into 3 categories. 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 kinds of patents. Those countries considered "least

The *Generic Medicines* case at the WTO (2000)

In 1997, the European Communities (EC) 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. This 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 on that drug 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, "limited exceptions" are allowed under Article 30 of TRIPS. The EC dismissed these arguments, alleging "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 giving little consideration to what other, societal benefits were to be gained by limiting this monopoly.

Parallel importing and price variations for 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 \$1.25 to a low of US \$0.20 for a 200 mg tablet.

The price of the anti-retroviral HIV drug lamivudine (3TC) ranged from a high of US \$2.21 to a low of US \$0.14 for a 150 mg tablet, while the price of anti-retroviral AZT ranged from a high of US \$2.63 to a low of US \$0.25 for a 300 mg capsule.

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.

What are essential drugs?

"Essential drugs are those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford."

- WHO Expert Committee on Essential Drugs, Nov. 1999

developed" have until January 1, 2006 to change their laws generally, although this deadline has been extended to January 1, 2016 with respect to pharmaceutical products. Least-developed countries may ask for extensions of this deadline.

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

If a country doesn't comply with a WTO agreement such as TRIPS, other countries can take it before a trade tribunal. One function 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 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. 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 rejects it. Obviously this is highly unlikely. 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 in its "objectives" clause that protecting and enforcing intellectual property rights should contribute to promoting technological innovation and to the transfer and dissemination of technology. Furthermore, TRIPS says this should benefit 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 is 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 that countries are entitled to flexibility in how they meet their obligations to protect private patent rights.

Does TRIPS limit options for increasing 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 (see below). And at the last WTO Ministerial Conference (Doha,

November 2001), member countries issued a *Declaration on the TRIPS Agreement and Public Health* stating that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Whether this "Doha Declaration" will have any positive, concrete effect remains to be seen, and there are still problems in the TRIPS Agreement that have not been addressed (see below). Advocacy is still needed to ensure the maximum flexibility in interpreting the agreement, and in getting governments to use that flexibility to gain access to more affordable medicines. If the necessary flexibility cannot be found, it may be necessary to amend the Agreement to ensure that countries can protect the health of their people as a matter of basic human rights. But formally re-negotiating the text of the agreement is a process that may take years before yielding unknown (and possibly worse) outcomes, while there is an urgent need for access to affordable medicines now. Solutions are both possible and urgently needed.

What are countries' options under TRIPS to improve treatment access?

There are four main aspects of "flexibility" under TRIPS that may be useful for countries to promote access to affordable drugs through their public policy measures. These are briefly explained here.

Exclusions from patentability: A country may prevent the commercial exploitation of some inventions if "necessary" to protect human life and health, by refusing to recognize these inventions as patentable (Article 27). How to determine whether this is necessary, and who decides, are not clear. Such steps taken by a country could be challenged before a WTO tribunal.

Exceptions to patent rights: Under TRIPS (Article 30), a country may create in its patent laws "limited exceptions" to a patent holder's right to exclude others from making, using, importing or selling an invention. Such exceptions are permitted as long they "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 [others]." There has only been one WTO ruling interpreting this article, the *Generic Medicines* case involving Canada's patent laws. (See side box above.)

Parallel importing: Companies often charge lower prices for a drug in one country than in another, taking into account a range of market factors. This means a country with limited resources can sometimes afford more of a patented drug by purchasing it abroad at a lower price and importing it, rather than buying it directly in its domestic market at the higher price the company is charging. Many countries' patent laws say that once a patent owner sells its goods in any country, it has no right to control the resale of those goods. In legal terms, the patent owner has "exhausted" its property rights in the product actually sold – it still keeps the exclusive right to make the product in the first place, but it cannot prevent resale of those units it sells. So an intermediary could buy a patented drug in one country at the lower price being charged by the company, and then resell

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. The Ministerial Conference is the highest decision-making body in the WTO. 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 Communities, Japan, and Canada).

However, developing countries have recently started to demand flexibility in the international trading system to allow them to respond to their health needs. This was evident at the most recent Ministerial Conference, in Doha, Qatar in November 2001, where the question of TRIPS and access to medicines was a key issue.

In the event of disputes, countries can initiate proceedings before a WTO panel to obtain a ruling on whether another country has breached its obligations under WTO agreements. The Appellate Body can overturn panel decisions. Only governments have the right to appear in proceedings.

Domestic capability to make generic drugs

According to Indian experts who spoke to Médecins Sans Frontières:

"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."

the drug in another country at a higher price, but a price that still undercuts what the manufacturer is charging for its patented drug in that country. This is called "parallel importing". The TRIPS Agreement (Article 6) explicitly says that nothing in the Agreement can be used to challenge a country at the WTO for allowing parallel imports under its own laws.

Compulsory licensing: Under TRIPS (Article 31), 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" (i.e., when the holder is not "exploiting" its patent). Compulsory licensing is a key policy tool that governments can use to counter-balance the negative effects of strict patent protection. The TRIPS Agreement does not limit the grounds on which governments are allowed to issue compulsory licences, and this was explicitly reaffirmed in the Doha Declaration. But there are conditions on the use of compulsory licences:

- Usually there must be an effort to first negotiate a voluntary license with the patent owner, "on reasonable commercial terms" within a "reasonable period of time," before a compulsory licence can be issued. But 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 judicial or administrative process has determined that the patent owner has engaged in "anti-competitive" practices. This part of TRIPS is often misunderstood or misrepresented as only allowing compulsory licensing in emergencies or similar situations. Some companies and countries promote this inaccurate understanding of TRIPS because they oppose the use of compulsory licensing (except when it suits their own interests) and so want to limit or prevent its use. It is important to understand that, contrary to these claims, compulsory licensing is not restricted to only cases such as national emergencies. Rather, it is clear from the TRIPS Agreement, and subsequently the Doha Declaration, that each country is free to decide for itself the grounds upon which compulsory licences may be issued.
- 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. This presents a likely barrier to more affordable drugs. Many developing countries lack the ability to produce their own generic drugs, so any compulsory license would need to be

implemented by importing them from other countries that do have this ability. But those countries with a generic drug industry or state-owned manufacturing capacity are prevented by TRIPS from issuing compulsory licenses authorizing the manufacture of generic versions of patent-protected drugs primarily for export to other countries. WTO member countries have agreed in principle that this problem in TRIPS needs to be solved to make it easier for developing countries to access affordable medicines (see below).

Aren't patents needed to recover drug research and development costs?

This argument is often used to justify a 20-year patent protection over innovative processes and products. But it is an inaccurate generalization and does not address the criticisms that overly strict international trade agreements on patents create barriers for poor countries in accessing more affordable medicines.

The pharmaceutical industry remains by far the most profitable in the world, well ahead of companies in all other sectors.² Current profits far exceed what is necessary for a "reasonable" return on their research and development (R&D). This is particularly the case if we consider that drugs commercialized by multinational companies have often been developed with significant public subsidies, both through tax breaks for R&D and by direct government investment in pharmaceutical research.

Furthermore, the revenue companies gain from poor countries is exceedingly small. For example, all of Africa accounts for about 1% of global pharmaceutical sales, even though millions of people need medicines for numerous conditions. Limiting or overriding patents in such countries will have no significant effect on drug company profits, which is their incentive for R&D. In any event, a profit-driven system based on private patent rights provides an incentive only to develop drugs that will be most profitable. Diseases that affect predominantly poor people, who cannot pay high prices for medicines, will not be profitable areas for research, unless there is enough of a wealthy market to make the research investment worthwhile. Initiatives other than patent incentives will therefore be required to stimulate research and development into diseases affecting mainly poor people and countries.

A global patent system with one set of rules does not work with countries at different levels of development or choose different development paths. Most industrialized countries did not adopt their current patent laws until *after* reaching a certain stage of economic, social and technological development. Canada's own generic drug industry developed because of flexibility in drug patent laws (which were amended in the late 1980s and early 1990s to almost completely abolish any sort of compulsory licensing). Imposing the industrialized world's rules on all countries will present an additional barrier to socio-economic development for poorer countries, which can ill afford the high costs of accessing technologies

Health is a Human Right

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.

Everyone has the right ... to share in scientific advancement and its benefits.

- *Universal Declaration of Human Rights (Articles 25&27)*

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 and Cultural Rights (Article 12)*

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition [...] The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health. Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures.

- *Constitution of the World Health Organization*

² "The 2002 Fortune 500." *Fortune Magazine*, April 2002.

HIV/AIDS and Human Rights: International Guidelines

States should enact legislation to provide for the regulation of HIV-related goods, services and information, so as to ensure widespread availability of qualitative prevention measures and services, adequate HIV prevention and care information, and safe and effective medication at an affordable price.

States should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of quality goods, services and information for HIV/AIDS prevention, treatment, care and support, including antiretroviral and other safe and effective medicines, diagnostics and related technologies for preventive, curative and palliative care of HIV/AIDS and related opportunistic infections and conditions.

States should take such measures at both the domestic and international levels, with particular attention to vulnerable individuals and populations.

- *Guideline 6 (revised):
Access to prevention,
treatment, care and support
(September 2002)*

(including medicines) when multi-national corporations hold monopolies on that knowledge. The vast majority of patent-holders are in industrialized countries. World-wide monopolies on that knowledge will "lock in" the existing disparity.

What can be done?

TRIPS itself contains many ambiguities. Much remains unclear about what is and is not allowed under TRIPS, and just how great the "flexibility" supposedly found in the Agreement will be in practice for developing countries that want to pursue policies making medicines (and other health technologies) more affordable. Few cases have been brought to the WTO tribunals that offer clear interpretations, although the decision in the *Generic Medicines* case (see sidebar above) is cause for concern. How the TRIPS Agreement is legally interpreted and implemented 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. Just as important is how wealthy, powerful countries will act toward developing countries that use tools such as compulsory licensing or "limited exceptions" to patent rights in order to address their peoples' health needs.

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 obligations under international human rights law to take steps, individually and collectively, to fully realize the human right to health. This includes making laws that will protect and promote the right to health. According to the UN Committee on Economic, Social & Cultural Rights, 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. The UN Commission on Human Rights, a separate body made up of governments, 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.

What is the Doha Declaration and why is it important?

In November 2001, at the 4th WTO Ministerial Conference in Doha, Qatar, member countries unanimously adopted a "Declaration on the TRIPS Agreement and Public Health." This is a ministerial declaration, issued by trade ministers of the WTO's member countries.

As a result of activism by human rights and humanitarian organizations, and the common stand taken by developing countries, the Declaration states that the TRIPS Agreement "does not and should not" prevent countries from taking measures to protect public health, and that the Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

The Declaration also recognizes that the TRIPS Agreement "shall" be read in lights of its "objectives" and principles" (Articles 7 and 8 mentioned above), which include important references to public interests that must be balanced against the

strict protection of private patent rights. It also extended to 2016 (from the original 2006 date) the deadline by which "least-developed countries" must implement patent protection in the pharmaceutical sector in line with the TRIPS Agreement.

Furthermore, WTO Member countries recognized that each country "has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." This is important in light of efforts by some powerful countries and companies to misinterpret the TRIPS Agreement as only allowing compulsory licensing in emergencies or extraordinary situations, when in fact there is no such restriction. The Declaration also states that each country "has the right to determine what constitutes a national emergency or other circumstances of extreme urgency", and indicates that "public health crises, including those relating to HIV/AIDS, tuberculosis, malaria or other epidemics" can represent such a situation. While these diseases are given as particularly pressing examples, it is important to note that nowhere in the Doha Declaration is there any indication that its provisions are limited to specific diseases or health issues. This is a critical issue given the efforts by some countries, since the Doha meeting, to impose this sort of restriction.

The WTO Ministerial Conference is the highest body with the authority to adopt interpretations of WTO treaties. Therefore, the Doha Declaration should, as a matter of law, guide the interpretation of the TRIPS Agreement in a more "health-friendly" direction in future disputes over patents. Those interpretations should also take into account countries' obligations under international law to protect and promote the human right to health. The Doha Declaration may also help developing countries fend off pressure tactics by rich countries who invoke the TRIPS Agreement and threaten to initiate legal disputes at the WTO and to impose possible trade sanctions if developing countries limit private patent rights in order to protect and promote health by making medicines more affordable.

What led to the adoption of the Doha Declaration?

Circumstance, solidarity and activism. In late September and early October 2001, the United States and, to a lesser extent, Canada, were particularly concerned about the possibility of bioterrorism, sparked by several cases of anthrax in the US. In response, both countries sought to stockpile large quantities of the antibiotic drug ciprofloxacin, used to treat anthrax. The drug is patented in both countries by the pharmaceutical company Bayer, and both the US and Canadian governments requested the company reduce the price of its drug significantly. The US government threatened to issue a compulsory license on the drug if price reductions were not forthcoming; the Canadian government went further, and ordered a large quantity of tablets from a Canadian generic drug manufacturer. There had been a handful of confirmed anthrax cases in the US at this time, and none in Canada. Eventually a reduced price was negotiated in each country, without any over-riding of Bayer's patent.

Against this backdrop of events in the weeks before the Doha Ministerial Conference, developed countries like the US and Canada continued to lecture

The "Doha Declaration"

"We recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."

"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. ... [W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

- Declaration on the TRIPS Agreement and Public Health, Fourth WTO Ministerial Conference, Doha (Qatar), 14 November 2001

developing countries with limited resources and millions of dead and dying people about the absolute importance of strict patent protections on medicines and avoiding measures such as compulsory licensing. The double standard was obvious.

In addition, throughout the months before the Doha Ministerial Conference, developing countries had insisted on placing the issue of TRIPS-related barriers to accessing affordable medicines on the WTO agenda, with a view to resolving these concerns by the time of the Conference. The Africa Group of countries, Brazil and India were particularly vocal and active on this issue. Developing countries resisted proposals by developed countries aimed at splitting them as a bloc, and negotiated hard for provisions in the Ministerial Declaration that would address their concerns.

Finally, worldwide campaigning by activists, in both developing and developed countries, helped to increasingly draw the attention of government decision-makers, the media and the public to the issue of the TRIPS Agreement and the consequences of its one-size-fits-all standards of patent protection for developing countries facing tremendous health needs with limited resources.

They also highlighted the successes that had been achieved by Brazil, whose commitment to public manufacturing of generic anti-retroviral drugs had enabled an ambitious treatment programme providing free medicines to over 100,000 Brazilians living with HIV/AIDS, resulting in dramatic decreases in deaths, hospitalisations and illness and considerable cost savings.

In addition, projects by humanitarian NGOs such as MSF and others in many countries showed that it was possible to deliver drugs for HIV/AIDS and other conditions even in settings with limited resources, and the "in-the-field" experiences of these organizations illustrated how high prices for patented drugs were often a significant barrier to accessing medicines.

Activists highlighted the immorality of developed countries insisting on strict patent protections in developing countries that provide little profits for wealthy pharmaceutical companies, at the cost of millions of lives. In the end, in an effort to preserve the institutional legitimacy of the WTO, the developed countries decided they had to at least be seen to respond to the demands of developing countries and the criticisms of activists. The Doha Declaration on the TRIPS Agreement and Public Health was the outcome.

Did the Doha Declaration solve TRIPS-related problems of access to drugs?

No. The Doha Declaration represents an important step forward. But problems remain to be addressed, and the track record at the WTO in the year following Doha does not bode well. Some countries and patent-holding multinational pharmaceutical companies immediately dismissed the Declaration as being a merely political statement without legal significance, and continue to ignore, and

"I have no watch, but I haven't missed a dose!"

"There are some people who say that in Africa people will not be able to take drugs because they cannot tell time. I can assure you that although I have no watch, since I started taking my triple therapy [of antiretroviral drugs] in August last year, I haven't missed one dose. ... We are using generic medicines from India in the [MSF] program in Malawi, which keeps the price as low as possible. The less expensive the drugs, the less expensive the program, and the more people can be treated. ... I would like to ask those people who say we should only do [HIV] prevention: If this epidemic were claiming so many lives in your community, would you really accept letting all of us already living with HIV die?"

- Fred Minandi, person living with HIV/AIDS from Malawi, 2002 International AIDS Conference

even undermine, both its letter and its spirit. Many areas of uncertainty in the interpretation of TRIPS remain, and opposition by wealthy countries has stalled post-Doha efforts to maximize flexibility for developing countries.

What problems remain with TRIPS after the Doha Declaration?

One major problem is a restriction in TRIPS – specifically in Article 31(f) – on "compulsory licensing", namely the requirement that the license must be used "predominantly" for supplying the domestic market of the country issuing it. This means countries with private generic drug companies or state-owned manufacturing capacity are prevented from issuing compulsory licenses allowing the manufacture of generic versions of patent-protected drugs primarily for export to other countries. This restricts possible sources of supply for the majority of developing countries that cannot afford high prices of patented medicines but lack domestic capacity to manufacture their own generic versions.

In the Doha Declaration (paragraph 6, see sidebar), WTO member countries recognized this problem and pledged to solve it within a year. However, over a year and several million deaths later, WTO members had failed to reach an agreement on a solution that would overcome this TRIPS obstacle and enable countries lacking manufacturing capacity to make effective use of compulsory licensing on a par with countries that do have this capacity.

As the WHO has stated to the WTO Council for TRIPS: "[T]he basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product."³

Throughout the negotiations that followed the Doha Declaration, wealthy countries (the US, European Communities, Canada, Japan, Switzerland and others) rejected proposals from developing countries and NGOs for simple, straightforward solutions to achieve this end. Instead, in WTO negotiating sessions they put forward "solutions" containing various limitations that would render these solutions off-limits to many developing countries and impractical for those countries that would be covered, and that would hinder generic drug production worldwide. Some proposals not only reneged on the commitment stated in Doha, but were also worse than the TRIPS Agreement itself, containing restrictions on compulsory licensing that are not even found in the original treaty.

For example, the US, the European Communities, Canada, Japan, Switzerland, Australia and others all supported measures that would exclude middle-income developing countries from the solution and impose a potentially costly legal mechanism for implementing it. They were also keen to impose on developing

The Doha Declaration and compulsory licensing

"We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and report to the General Council before the end of 2002."

- *Doha Declaration*,
paragraph 6

³ Statement by WHO representative, WTO Council for TRIPS session, 17 September 2002.

"Human rights and fundamental freedoms are the birthright of all human beings; their protection and promotion is the first responsibility of governments."

- *Vienna Declaration and Programme of Action, adopted by 171 states at the UN World Conference on Human Rights, 1993*

"People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off."

- *Kofi Annan, UN Secretary-General, 26 April 2001*

"We are angry. Our people are dying. Without treatment, the 28 million people living with HIV/AIDS on our continent today will die predictable and avoidable deaths over the next decade. More than 2 million have died of HIV/AIDS just this year. This constitutes a crime against humanity."

- *Declaration of Action, Pan-African HIV/AIDS Treatment Access Movement, Cape Town, 25 August 2002*

"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*

countries complicated, burdensome requirements to prevent lower-priced medicines from being diverted into wealthy country markets, even though developed countries could more easily take appropriate border measures.

Very importantly, these wealthy countries sought to restrict any "solution" to apply only to a handful of diseases, claiming that the Doha Declaration was only intended to apply to HIV/AIDS, tuberculosis, malaria and similar "infectious epidemics" or problems of "comparable gravity and scale". (The exact language being proposed varied over the course of the negotiations.) In December 2002, the WTO negotiations reached a deadlock, when the US refused to endorse a compromise accepted by all other countries because it insisted that any solution be limited to a short list of specified diseases (which did not include many health conditions that kill massively in developing countries).

Any such "solution" would mean countries needing to import generic drugs would be unable to make effective use of compulsory licensing for any health needs not on the list. As one expert put it: "The US wants to have a global debate over the issue of the scope of diseases. [The US President and Trade Representative] want to argue that the diseases their own children receive treatment for are off limits to poor children in poor countries. They cannot win this argument."⁴

In early 2003, proposals at the WTO continued to perpetuate this double standard. In February, the TRIPS Council chair proposed to restrict use of compulsory licensing for many developing countries to "national emergencies or other circumstances of extreme urgency". Activists have pointed out that wealthy countries do not have to declare national emergencies to make use of TRIPS safeguards, so why should developing countries have to do so?

As of printing, this issue remained unresolved. In the meantime, activists are urging governments to use existing TRIPS safeguards as much as possible. Many organizations, including MSF, recommend a solution that is simple, workable, and economically viable. Many activists, including MSF, support the proposal made in September 2002 by the WHO, which recommends a solution based on Article 30 of the TRIPS Agreement. Under this article, WTO members may override patent rights to permit production and export of generic versions of patented products if it is needed to address the health needs of a third country.

What about other trade agreements dealing with patents?

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

⁴ James Love, Consumer Project on Technology. CPTEch statement on collapse of Doha paragraph 6 negotiations, 20 December 2002.

essential medicines. For example, MSF, the WHO and the UN's Joint Programme on AIDS (UNAIDS) have warned that a treaty signed in February 1999 between several 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 prohibits parallel imports from countries outside the bloc of countries signing the agreement. Advocates have urged these countries not to ratify the Bangui Agreement, and certainly not before they are required to implement TRIPS.

What is the FTAA? And what is at stake for millions in the Americas?

Similarly, some countries negotiating the Free Trade Area 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. The FTAA is a proposal for the largest "free trade" zone in the world, covering 800 million people in 34 countries in the Western hemisphere (all except Cuba). So far, the US negotiating objectives include proposals for even more stringent provisions on intellectual property than are found in TRIPS, which would further restrict options like compulsory licensing for countries that need less expensive medicines. If these proposals make their way into the final text of the treaty, the FTAA will serve as a model for other bilateral and regional agreements that will undermine the Doha Declaration region by region and country by country.

What must governments do? What must advocates demand?

Removing patent-related barriers to more affordable medicines in developing countries is not the only step that must be taken, but it is an important one. Governments must ensure trade agreements do not hinder access to affordable medicines, and advocates must insist on this and on the resources needed to save millions from avoidable death.

MSF calls for a commitment to the Doha Declaration

WTO members must make a clear commitment to the Doha Declaration as the ceiling for all bilateral and regional trade agreements, and reaffirm their statements that they will not pursue retribution against countries that implement TRIPS-consistent safeguards. Wealthier nations such as G8 countries should provide political and technical support for implementation of the Doha Declaration at the national level in developing and least developed countries.

... but some countries are renegeing in FTAA talks:

"The promise of Doha is that the TRIPS Agreement can and should be interpreted and implemented in a manner "supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." The FTAA Agreement threatens to make it impossible for countries in the Americas to exercise the rights re-confirmed in Doha. As a medical humanitarian organization, we cannot accept the subordination of the health needs of our patients and millions of others to U.S. trade interests. In order to ensure the protection of public health and the promotion of access to medicines, we therefore must recommend that intellectual property provisions be excluded from the final FTAA Agreement altogether."

- Letter from MSF to US
Trade Representative,
February 2003

Taking action!

Canadian civil society organizations concerned with HIV/AIDS, human rights, and international development have been working on the issue of global access to medicines and the human right to health.

The **Global Treatment Access Group (GTAG)** came together in mid-2001. The member organizations have taken a variety of initiatives to raise public awareness of the trade policy issues related to global health and to raise these concerns with the Canadian government.

GTAG has also advocated for increased Canadian contributions to the Global Fund to Fight AIDS, TB & Malaria, and for increased aid to develop health infrastructures where these are under-funded or inadequate. A national civil society summit, "Global Health is Human Right", in mid-2003 is part of GTAG's efforts to mobilize Canadians and Canadian civil society in support of a common platform with key demands to the Canadian government for action.

For more information about GTAG, contact:

Richard Elliott
Canadian HIV/AIDS Legal Network
Tel (415) 595-1666
relliott@aidslaw.ca

Michael O'Connor
Interagency Coalition on
AIDS and Development
Tel (613) 233-7440
moconnor@icad-cisd.com

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 undertaking a global **Campaign for Access to Essential Medicines** (www.accessmed-msf.org) that includes action in Canada (www.msf.ca/access/index.htm).

The **Canadian HIV/AIDS Legal Network** (www.aidslaw.ca) focuses on legal and human rights issues related to HIV/AIDS. Its website includes a section on global access to treatment, including campaigning materials produced by the Legal Network and by the **Global Treatment Access Group (GTAG)**, an affiliation of civil society organizations advocating for an improved Canadian response to global health issues (www.aidslaw.ca/Maincontent/issues/care-treatment.htm#B2).

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 **Interagency Coalition on AIDS and Development (ICAD)** (www.icad-cisd.com) brings together HIV/AIDS and development organizations. ICAD has produced several fact sheets on international development issues and HIV/AIDS.

The **Global Treatment Access Campaign (GTAC)** is a network for communication and advocacy efforts for access to essential medicines. The website (www.globaltreatmentaccess.org) is maintained by the Health GAP Coalition in the US, and provides action tools and updates, with a focus on the US government.

The **Consumer Project on Technology** (www.cptech.org/ip/health) is a public interest advocacy organization in the US with a project on intellectual property and health issues. The website contains a wealth of materials, including detailed information about the pharmaceutical industry, developments at the WTO and elsewhere, and various country- and issue-specific sections. CPT also operates the best listserv on pharmaceutical policy issues; postings are in a public archive on the website.

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; a report on sources and prices of selected drugs for people living with HIV/AIDS; a list of quality pre-approved drugs and drug manufacturers; an info sheet on "Pharmaceuticals and the WTO TRIPS Agreement: Questions & Answers"; and the *International Guidelines on HIV/AIDS and Human Rights* (see Revised Guideline 6 on access to prevention, treatment, care and support). UNAIDS also produces regular updates on the global epidemic.

The **World Health Organization** (www.who.int) maintains an on-line catalogue of its publications, some of which are also on-line, including its report on *Globalization and Access to Drugs* (cited above), an info sheet on TRIPS and access to drugs, and an excellent primer called "25 Questions and Answers on Health and Human Rights".

The **World Trade Organization** website (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.

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