

# HIV/AIDS

## *Antiretroviral*

### Newsletter



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*The aim of this biannual newsletter is to provide health workers in the Region with a brief, up-to-date summary of the latest developments in antiretroviral therapies.*

## TRIPS, INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES<sup>1</sup>

### THE TRIPS AGREEMENT

The Agreement on Trade-related Aspects of Intellectual Property Rights (or the TRIPS Agreement) is an integral part of the World Trade Organization (WTO) Agreements, which create binding international obligations among WTO Member States. The TRIPS Agreement is subject to the WTO's dispute settlement mechanism, which may -as a last resort- allow Member Countries to apply trade sanctions against a non-compliant country, thereby ensuring enforcement of the WTO's rules and agreements.

### TRIPS AND PATENTS

Patents are a public policy tool; they were designed to promote and reward innovation, while at the same time ensuring disclosure of the invention, in order to make it widely known and available. Before TRIPS, countries could -and did- devise a patent regime that was in line with their level of development and their overall national priorities.

The TRIPS Agreement has to a large extent harmonized the standards for patents; notably, it makes it mandatory for countries to ensure that patent protection is available in all fields of technology, for both process and product inventions. Thus, it is no longer possible for countries to exempt pharmaceuticals from patent protection (as a number of countries did before TRIPS came into force). Nor can countries like India continue to limit pharmaceutical patents to process patents only.

The distinction between product and process patents is important, since if a product is patented, only the patent holder may make or sell that product; nobody else may do so, unless the patent holder has given permission (a license). In the case of a process patent, nobody may make that product by using the process that is protected.

<sup>1</sup> This issue of the ARV newsletter is based on information available on 10 December 2002.

However, if someone can produce the same product in a different way, he/she may do so. Since for most pharmaceuticals multiple routes of synthesis can be devised, process patents offer considerably less protection than product patents<sup>2</sup>. By recognizing only process patents for drugs, India implicitly provided incentives for local manufacturers to "invent around" the patent (i.e. to develop a different production method). Generics thus produced are legal in India, and, as a result, generic versions of newly developed drugs are often available relatively quickly in India.

TRIPS furthermore requires that the minimum duration of patent protection be 20 years (prior to TRIPS, the patent term was 20 years in certain industrialized countries, but shorter in many developing countries), and mandates effective enforcement.

The introduction of these TRIPS standards will delay the marketing of generic versions of new drugs, and, thus, the competition they entail. Hence it is anticipated that prices of new drugs will remain high for a longer period of time, which will result in reduced access for many people, notably in developing countries.<sup>3</sup>

### ACCESS TO DRUGS

Access to medicines depends on many factors, notably rational selection and use of drugs, adequate and sustainable financing, affordable prices, and reliable supply systems. Prices are only one factor<sup>4</sup>. Yet prices are an important factor especially in developing countries, since, while in developed countries pharmaceuticals are largely publicly funded, through reimbursement and insurance schemes, in developing countries, typically, 50% to 95% of drugs are paid by the patients themselves (see Figure 1). Thus, in developing countries, prices of medicines have direct implications for access.

<sup>2</sup> The TRIPS Agreement has however reinforced process patents.

<sup>3</sup> TRIPS does not apply retroactively, therefore there are no implications for drugs that were already off-patents when TRIPS came into force.

<sup>4</sup> It should also be noted that patents are not the only reason for high drug prices; distribution costs, high mark-ups and taxes can also play an important role.

**Figure 1: Public spending as % of total spending on pharmaceuticals in selected countries**



Source: WHO/EDM

## SAFEGUARDS AND FLEXIBILITY IN TRIPS

It is however important to realize that TRIPS is a framework agreement; it is to be operationalized via countries' national laws. Moreover, TRIPS does contain (limited) flexibility, as well as some safeguards, which can be used to mitigate the anticipated negative impact on drug prices and on access to drugs.

The most important safeguards are: (i) compulsory licensing; (ii) parallel importation; and (iii) provisions for early working (often referred to as "Bolar provision").

The "Bolar provision" allows testing and regulatory approval of generic versions of a drug *before* its patent expires; thus, it allows generic producers to get ready, so that they can start the production and sale of a generic drug as soon as its patent expires<sup>5</sup>. In this way, a Bolar provision facilitates generic competition.

*Parallel importation* refers to importation, without the consent of the patent holder, of a patented product that is marketed in another country. Parallel importation allows

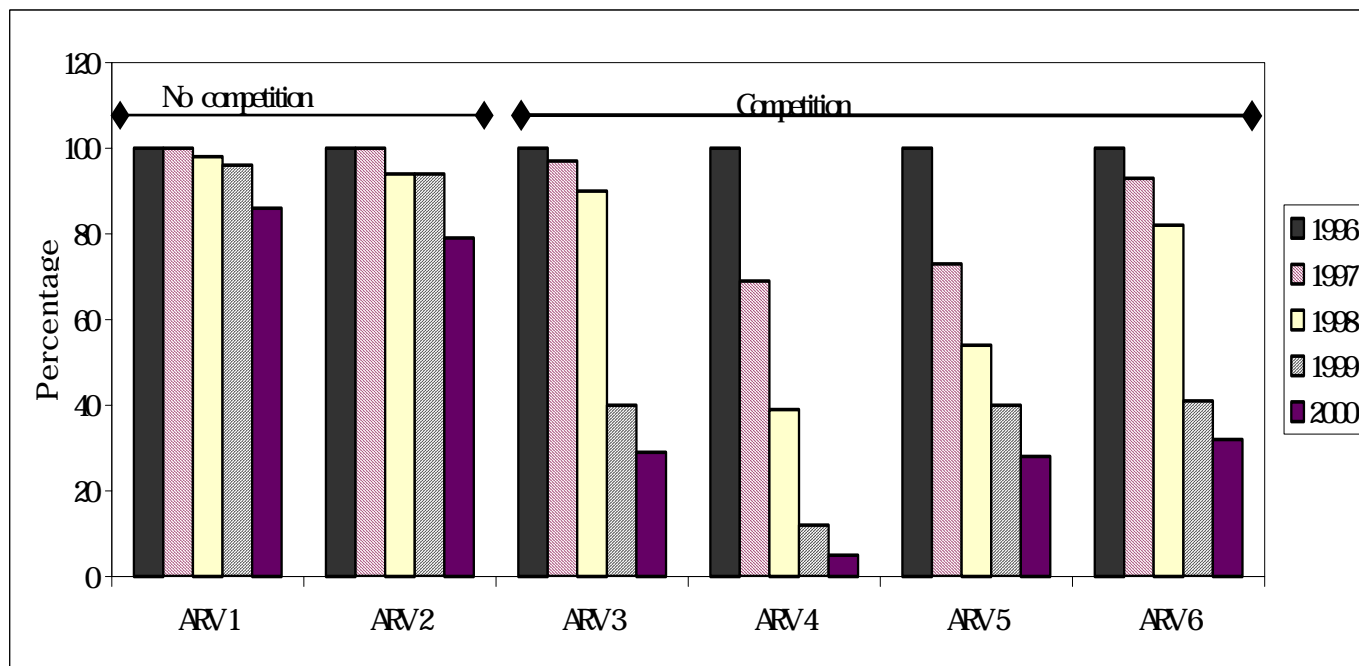
one to 'shop around' for a good price. For example, if a company sells drug X in country A at a price of \$10, while the same company sells the same drug X in country B for \$1, then someone may import drug X from country B and sell it in country A, charging for example \$3. As a result, in this example, country A would save \$7 on product X. In other words, parallel importation also enables competition, but in a different way.

The TRIPS Agreement states that parallel importation cannot be challenged under the WTO dispute settlement mechanism, thus de facto leaving countries the freedom to choose whether or not to allow parallel importation. Moreover, during the WTO's Ministerial Meeting in November 2001, the Ministers clarified, in the Doha Declaration on the TRIPS Agreement and Public Health, that countries are free to use parallel importation.

A compulsory license is a license to use an invention, which has been granted without the permission of the patent holder. A compulsory license can be used to allow the production and sale of generics before expiry of the patent - thus, again, increasing opportunities for competition (and competition drives prices down, as can be seen in Figure 2).

<sup>5</sup> In the absence of such a provision, generic manufacturers can only start the time-consuming process of testing and registration after the expiry of the patent; this can easily delay the marketing of generic drugs for two to three years after patent expiry.

**Figure 2: Influence of competition on drug prices**  
1996 prices taken as reference (100%)



Source: UNAIDS, 2000

The basic rationale for a compulsory license is that since a patent is a privilege granted by the government, the government retains the right to limit that privilege if necessary. Many countries, including many developed countries, have provisions for compulsory licenses in their national laws, and compulsory licenses are allowed under TRIPS.

TRIPS mentions that a compulsory license can be issued for reasons of national emergency or extreme urgency, public non-commercial use and other reasons. However, it is important to note that TRIPS does *not* limit the grounds, or reasons, for issuing a compulsory license. But the TRIPS Agreement does specify *conditions* which are to be imposed by governments when issuing a compulsory license. These conditions include:

- case-by-case decision
- first try to obtain a voluntary license
- adequate remuneration to the patent holder
- predominantly for the supply of the domestic market
- a compulsory license should be non-exclusive and non-assignable.<sup>6</sup>

<sup>6</sup> The list is not exhaustive; moreover, certain conditions may be waived in specific circumstances. For instance, the condition to first try to obtain a voluntary license does not apply if a compulsory license is issued to remedy anti-competitive behavior of the patent holder, or in case of an emergency.

So while these conditions have made the process somewhat cumbersome, it is possible to issue a compulsory license in a TRIPS-compliant way.

However, the safeguards provided for in TRIPS can only be used when incorporated in the national law. Therefore, it is important that countries design and enact legislation which allows them to protect the public interest, including the public health interest.

In addition, as mentioned above, there is some flexibility in TRIPS. For example, one of the conditions for issuing a compulsory license is that the patent holder should receive adequate remuneration. But TRIPS does not define “adequate”, leaving countries some leeway in this respect.

Similarly, TRIPS leaves countries free to use either very strict or more flexible criteria for patentability. Applying flexible criteria of novelty and inventiveness enables, for example, the issuing of patents for formulations or for isomers of known drugs, thus allowing pharmaceutical companies to apply for additional patents, and providing them with opportunities to expand the duration of protection beyond that of the original patent. In this way, originator companies can seek to postpone generic competition.

Yet whether this flexibility is actually used in order to facilitate access to medicines ultimately depends on national standards and (administrative) procedures.

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## OTHER TRIPS PROVISIONS

Patents are not the only type of intellectual property rights addressed in TRIPS, and some of the other forms of intellectual property can also have implications for access to drugs. For example, TRIPS mandates protection of undisclosed data submitted to national drug regulatory authorities in order to obtain marketing authorization for new drugs. These registration data have to be protected against disclosure and against unfair commercial use. Thus, the national authorities may not publish such data or share them with competing (e.g. generic) companies.

Some parties however try to argue for *data exclusivity*, which means that the regulatory authorities would not be allowed to rely on these data for the purpose of registration of generic versions of the drug. By implication, as long as the exclusivity lasts, generic producers would either have to submit their own data - which would oblige them to repeat the clinical trials and other tests - or they would have to delay the launch of their product until the end of the exclusivity period. Therefore, data exclusivity diminishes the likelihood of speedy marketing of generics, and delays competition and price reductions.

TRIPS mandates data protection, but not data exclusivity and national laws need not have requirements that are more stringent than TRIPS.

Similarly, it is important that national trademark laws do not hinder pro-public health measures such as generic prescription, generic substitution and/or requirements that a drug's label includes the generic name.

## THE EXPERIENCE OF THAILAND AND BRAZIL

Two countries that are at the forefront of the fight against HIV/AIDS, especially with regard to making HIV/AIDS drugs, including antiretrovirals (ARVs), available and affordable, are Thailand and Brazil. Thailand focuses on producing and selling generic ARVs at the lowest possible price<sup>7</sup>, while Brazil is providing free ARV treatment in its public health facilities. Their strategies with regard to intellectual property rights are summarized below.

### THAILAND

The Government Pharmaceutical Organization (GPO) in Thailand is producing a number of generic ARVs. The GPO is only producing products that are not patented in Thailand, or for which the Thai patent has expired. One important drug, didanosine or ddI, is still under patent in Thailand; however, the patent only applies to ddI tablets. Hence the GPO has been producing ddI powder. The

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<sup>7</sup> The Thai Ministry of Public Health also provides free or subsidized ARV treatment to some patients through its *access to care* programme and via copayment schemes.

powder form, while not as convenient or as accurate a dosage form as tablets, does not infringe upon the patent.

Recently, following a challenge by nongovernmental organizations representing people living with HIV/AIDS, Thailand's Central Intellectual Property and International Trade Court ruled that the ddI patent is only valid for tablets containing 5-100 mg ddI<sup>8</sup>. Thus, it would now be possible for generic producers, such as the GPO, to produce ddI tablets outside that dosage range (e.g. tablets containing 125 mg ddI).

### BRAZIL

Brazil, like Thailand, has a government-owned company that produces generic versions of certain ARVs, which are not under patent in Brazil. In addition, Brazil has used the fact that it is capable of producing generic versions of crucial HIV drugs, and that it would be willing to issue a compulsory license if necessary, to negotiate substantial price discounts for those drugs that are patented. So far, this strategy has been quite successful, and Brazil has not yet had to actually issue a compulsory license.

## OPTIONS FOR OTHERS

So what can other countries do? What options are available to increase access to HIV/AIDS drugs? Clearly, the answer will vary considerably from country to country, depending on relevant national laws, production capacity and other factors. But in principle, the following options exist:

**Countries with pharmaceutical production capability** could initiate local production of generic versions of those drugs that are not patented or whose patents have expired<sup>9</sup>. They could also consider, if their national law and regulations allow, to issue a compulsory license for the production of generic versions of those drugs that are patent protected.

**Countries where local production is not feasible or not viable** can import generics, for example from India, provided the drug concerned is not under patent in their territory. In case the drug of interest is patent protected in the importing country, parallel importation could be considered, as long as national legislation allows it - and if a cheaper source of the drug can be found.

The option to (parallel) import obviously is also open to countries that have manufacturing facilities. Yet a problem looms: major international producers of generics are primarily located in countries such as India, which in a few years will have to comply with TRIPS

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<sup>8</sup> Note however that the patent holder may appeal this decision. In the meantime, nongovernmental are further challenging the patent, seeking its complete revocation.

<sup>9</sup> The first generation of ARVs that were patented in the 1980s will continue to come off patent.

(see Figure 3; India falls in category c). Once India starts implementing TRIPS, its pharmaceutical enterprises will have to wait until patent expiry before they can commence the production of new generics. Thus, even when patents in their own territory do not stand in the way, importing countries may, in the not-too-distant future, face problems finding a source of supply of generic versions of new drugs.

On the other hand, countries that lack national production capacity would face difficulties in making effective use of compulsory licensing provisions. The basic problem is that while the importing country could issue a compulsory license for importation of the drug from abroad<sup>10</sup>, foreign companies would - because of TRIPS' condition that a compulsory license should be

issued "predominantly for the supply of the domestic market" - face potentially severe restrictions on their capacity to export.

During the WTO meeting in Doha, Ministers recognized this limitation, and instructed the WTO's TRIPS Council to find an expeditious solution to this problem. There are however diverging views, and, consequently, considerable debate, on how to best tackle this inconsistency. If this is solved without imposing cumbersome new conditions, a fundamental constraint to making drugs available will have been removed, especially for those countries that depend on importation of medicines.

<b>Figure 3: Deadlines for implementation of the TRIPS Agreement</b>	
a) Developed countries	1996
b) Developing countries (except those under c)	2000
c) Developing countries that did not grant pharmaceutical product patents prior to TRIPS	2005
d) Least developed countries	2016*

*\* The original TRIPS implementation deadline for least-developed countries was 2006; however during the WTO Ministerial Meeting in Doha, it has been agreed to extend this deadline*

## **FURTHER READING**

1. Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement – WHO, Geneva, 1998.
2. The TRIPS Agreement and Pharmaceuticals – (ASEAN workshop report) MOH/WHO, Indonesia, 2000.
3. Integrating Public Health Concerns into Patent Legislation in Developing Countries – South Centre, Geneva, 2000.
4. Implications of the Doha Declaration on the TRIPS Agreement and Public Health – WHO, Geneva, 2002.
5. Protection of Data Submitted for the Registration of Pharmaceuticals – South Centre/WHO, Geneva, 2002.

Documents 1, 2 and 4 (as well as other relevant materials) can be downloaded from:  
[http://www.who.int/medicines/organization/ood/trips\\_med.shtml](http://www.who.int/medicines/organization/ood/trips_med.shtml).

Documents 3 and 5 can be found at:  
<http://www.southcentre.org/publications/pubindex.htm#documents>

## **ACKNOWLEDGEMENTS**

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<sup>10</sup>Using a compulsory license for importation appears to be permissible under TRIPS.