Pharmaceuticals and the WTO TRIPS Agreement:

Questions and Answers

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What is TRIPS?

The Agreement on Trade Related Intellectual Property Rights (TRIPS) was negotiated with other international trade agreements during the Uruguay Round trade negotiations of the GATT (General Agreement on Tariffs and Trade) from 1986 to 1994. As one of the World Trade Organization (WTO) agreements, it is totally binding for all WTO Member States (whether a previous GATT Member or a new WTO one)[1].

The TRIPS Agreement sets minimum standards in the field of intellectual property (IP) protection (such as copyrights, patents, and trademarks) that all WTO Member countries have to respect. To achieve this goal, WTO Members have to modify their intellectual property laws to make them consistent with the new WTO standards. For instance, the TRIPS Agreement states that all patents shall be available for at least 20 years from the filing date, whereas before TRIPS the patent term varied greatly among countries (7, 10, 17 or 20 years). All WTO Members have to incorporate this 20-year patent term in their own patent law.

What will change with TRIPS?

Before the Uruguay Round and TRIPS, pharmaceutical patents and other intellectual property rights on drugs were widely recognized among major **industrialized** countries, but not in many **developing** countries. As there were no international standards on the scope of patent protection, countries had very different regulations on IP protection according to their own needs. In the pharmaceutical sector, some 40 countries did not provide patent protection for pharmaceutical products. Patents were simply not available for pharmaceutical inventions in these countries, which implied that no one could claim an intellectual property right on such products. As a result, copies of medicines protected by a patent in other countries were widely available, usually at a lower price than the original patented drug. The copies were either manufactured by local companies or imported, without having to ask the patent holders' permission. This practice is now coming to an end. Copies of patented drugs will remain on the market but it will no longer be possible to manufacture and market copies of **new patented medicines** in those 40 countries, unless the original manufacturer has chosen not to seek any patent protection there.

Under the TRIPS Agreement, all WTO Members have to make patents available for pharmaceutical inventions in their countries[1]. A company that has invented a new pharmaceutical product or process has, since 1 January 1995, been able to apply for at least a 20-year patent protection in any WTO Member country. The inclusion of pharmaceutical patents in the new WTO/GATT rules has the potential to exacerbate the problem of access to drugs in developing countries, by limiting or even disabling direct competition (generics) to new medicines until the relevant patents expire (unless licences are granted).

When does TRIPS apply?

It is only in regard to transitional periods that the TRIPS Agreement takes into consideration Member States' different levels of economic development. Developed countries were given until 1996 to comply with TRIPS standards by modifying their patent law if necessary, developing countries had until 2000, and least-developed countries have until 2006 (with possible renewal). The transition periods were provided to developing and least-developed

[1] Taking into account the transitional periods allowed to developing and least-developed countries by the TRIPS Agreement.

countries to give them enough time to implement the various TRIPS standards on intellectual property rights (copyrights, trademarks, patents, etc) at national level.

However, as patents were not available for any pharmaceutical products in some developing countries in the pre-TRIPS era, a supplementary transitional period is allowed for countries still not granting patents for pharmaceutical products when the WTO came into force in 1995. This 5-year supplementary period means that the developing countries affected do not have to grant pharmaceutical products patents before 2005, unless they decide to revise their patent law before then.

Which drugs will be affected by the new patent rules?

The TRIPS Agreement requires WTO Member States to introduce patent protection only to products "invented" after 1 January 1995[2], i.e. products for which a patent application has been filed in a WTO Member State after 1995. This means that, in accordance with TRIPS, products already on the market cannot be given patent protection, because if they are already marketed, they are not new, and so do not meet the TRIPS conditions necessary to grant a patent. Therefore, only new drugs or new indications, formulations or processes invented after 1995 should be patentable in all WTO Member countries.

However, because developing and least-developed countries are entitled to transitional periods, and some will not grant drug patents before 2000, 2005 or 2006, a special provision in the TRIPS Agreement preserves the novelty of drugs that may be invented between 1995 and the end of the transitional periods. Developing and least-developed countries not granting drug patents must have a system, often referred to as a "mail-box" system, to store patent applications as from 1995 until the transitional period expires. At this time, the various patent applications waiting in the "mail-box" will be examined according to the TRIPS standards and, if granted, the patent term, which starts from the filing date, will last for what remains of the 20 years.

What are developing countries' obligations under TRIPS?

Since all WTO Members are bound by the TRIPS Agreement, its minimum standards for IP protection must be included and implemented in national laws within the transitional periods allocated. These are only minimum standards however, and WTO Member countries may provide for greater IP protection than required in the Agreement. For instance, in Europe and the United States, pharmaceutical patents may be extended (beyond 20 years) for up to 5 years, to compensate for the long delays in obtaining marketing approval for a drug. The patent extension will vary from country to country (since there is no international standard) depending on the date of marketing approval. However, the pharmaceutical patent cannot be extended for more than 15 years from the date of marketing approval in European countries, and 14 years in the United States.

The main TRIPS standards, relating to pharmaceuticals, that countries must include in their patent law are:

- availability of patents for both pharmaceutical products and processes inventions that are new, involve an inventive step (i.e. non-obvious) and are capable of industrial application (or useful);
- protection of the product directly obtained using a patented process;

[2] Or a year before, if priority is claimed.

- availability of procedures at national level to enable patent owners to protect their rights against infringement.

In addition, if exceptions to patent rights and compulsory licences are incorporated in patent legislation, they should be, respectively, limited and conditional to conform with the TRIPS Agreement.

Further reading

Further information on intellectual property rights for pharmaceuticals and on aspects of access to HIV/AIDS related drugs are available in the following references and web links:

- Patent situation of HIV/AIDS related drugs in 80 countries
- http://www.who.int/medicines/
- http://www.unaids.org/

Intellectual property rights and pharmaceuticals

- WHO/EDM. *Globalization, patents and drugs – an annotated bibliography*. Health Economics and Drugs, EDM Series No. 9. Geneva: World Health Organization; 1999 (WHO/EDM/PAR/99.6).
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Access to HIV/AIDS-related drugs

- *Technical update: Access to drugs.* UNAIDS Best Practice Collection, 1998.
- WHO. *Model prescribing information. Drugs used in HIV-related infections* (WHO/DMP/DSI/99.2).
- WHO/DAP. *Guidelines on standard treatments and essential drugs for HIV-related conditions. Access to HIV-related drugs*. Geneva: World Health Organization, 1997.
- WHO/UNAIDS. *The implications of antiretroviral treatment.* Geneva: World Health Organization; 1997 (WHO/ASD/97.2).
- WHO. Technical and policy guidance modules on antiretroviral treatments for health planners and policy makers (WHO/ASD/98.1 and UNAIDS/98/7).