

Glossary of Key Agreements and Terms

Trade-related Aspects of Intellectual Property Rights (TRIPS): The WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPS) covers patents, undisclosed/commercially sensitive information including trade secrets and test data, and trademarks. The Agreement establishes minimum IP rights and requires countries to put in place appropriate mechanisms (like laws and regulations for example) to enforce those rights. In essence TRIPS creates a predictable, rules-based system for the settlement of disputes about IP issues between WTO members.

The TRIPS Agreement provides flexibility for governments to fine-tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled. For pharmaceutical patents, the flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. The enhancement was put into practice in 2003 with a decision enabling countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory license. In 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement, which will take effect when two thirds of members accept it.

TRIPS Basic Patent Provisions

- **Patenting:** WTO members have to provide patent protection for any invention, whether a product (such as a medicine) or a process (such as a method of producing the chemical ingredients for a medicine), while allowing certain exceptions. Patent protection has to last at least 20 years from the date the patent application was filed.
- **Non-discrimination:** Members cannot discriminate between different fields of technology in their patent regimes. Nor can they discriminate between the place of invention and whether products are imported or locally produced.
- **Three criteria:** To qualify for a patent, an invention has to be new ("novelty"), it must be an "inventive step" (i.e. it must not be obvious) and it must have "industrial applicability" (it must be useful).
- **Disclosure:** Details of the invention have to be described in the application and therefore have to be made public. Member governments have to require the patent applicant to disclose details of the invention and they may also require the applicant to reveal the best method for carrying it out.
- **Exceptions:** The WTO rules governing patents specify that governments may refuse to grant patents for three reasons that relate to public health: inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health; diagnostic, therapeutic and surgical methods for treating humans or animals; certain plant and animal inventions.

The Doha Declaration: In the main WTO Doha Ministerial Declaration of November 2001, WTO members stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health by promoting both access to existing medicines and the creation of new medicines. They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing. They also agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. They then directed the TRIPS Council to determine how to provide additional flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries. (This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in the separate Doha Declaration on TRIPS and Public Health.). The TRIPS Agreement says products made under compulsory licensing must be "predominantly for the supply of the domestic market." This applies to countries that can manufacture drugs by limiting the amount they can export when the drug is made under compulsory license, which impacts countries unable to make medicines and therefore wanting to import generics.

TRIPS and Health Decision on Compulsory Licensing for Export: The legal problem for exporting countries was resolved in August 2003 in the TRIPS and Health decision when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. When members agreed on the decision, the General Council chairperson also read out a statement setting out members' shared understandings on how the decision would be interpreted and implemented. This was designed to assure governments that the decision would not be abused. Carefully negotiated conditions apply to pharmaceutical products imported under the system. These conditions aim to ensure that beneficiary countries can import the generics without undermining patent systems, particularly in developed countries. They include measures to prevent the medicines from being diverted to the wrong markets. They require governments using the system to keep all other members informed each time they use the system, although WTO approval is not required.