WTO OMC

FACT SHEET
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TRIPS and pharmaceutical patents

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Philosophy: TRIPS attempts to strike a balance

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations. The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement.

The balance works in three ways:

- Invention and creativity in themselves should provide social and technological benefits. Intellectual property protection encourages inventors and creators because they can expect to

be extremely high, so private rights also bring social benefits.

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ANTI-COMPETITIVE PRACTICES, ETC

The TRIPS Agreement says governments can also act to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, “unreasonably” restraining trade, or hampering the international transfer of technology.

COMPULSORY LICENSING

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. In current public discussion, this is usually associated with pharmaceuticals, but it could also apply to patents in any field.

The agreement allows compulsory licensing as part of the agreement’s overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term “compulsory licensing” does not appear in the TRIPS Agreement. Instead, the phrase “

IMPORTING UNDER COMPULSORY LICENSING ('PAR.6')

Article 31(f) of 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 — it limits the amount they can export when the drug is made under compulsory licence. And it has an impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

The legal problem for exporting countries was resolved on 30 August 2003 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 will not be abused.

The decision actually contains **three** waivers:

- Exporting countries' obligations under Article 31(f) are waived — any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries.

- Importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.

- Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale.

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 rich countries. They include measures to prevent the medicines from being diverted to the wrong markets. And they require governments using the system to keep all other members informed, although WTO approval is not required. At the same time phrases such as "reasonable measures within their means" and "proportionate to their administrative capacities" are included to prevent the conditions becoming burdensome and impractical for the importing countries.

All WTO member countries are eligible to import under this decision. But 23 developed countries have announced voluntarily that they will not use the system to import: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the US.

After they joined the EU in 2004, another 10 countries have been added to the list: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

And 11 more said they would only use the system to import in national emergencies or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

After that, several potential exporting countries changed their laws and regulations in order to implement the waivers and to allow production exclusively for export under compulsory licence. At the time of writing (September 2006) Norway, Canada, India and the EU have formally informed the TRIPS Council that they have done so.

The 2003 waivers are interim; the ultimate goal is to amend the TRIPS Agreement itself, and a decision to do this was reached in December 2005, accompanied again by a chairperson's statement. The amendment — a direct translation of the waivers — enters into force when two thirds of members accept it.

What does ‘generic’ mean?

Dictionaries tend to define a “generic” as a product — particularly a drug — that does not have a trademark. For example, “paracetamol” is a chemical ingredient that is found in many brandname painkillers and is often sold as a (generic) medicine in its own right, without a brandname. This is “generic from a trademark point of view”.

Sometimes “generic” is also used to

when the TRIPS Agreement came into force (on 1 January 1995), has up to 10 years to introduce the protection.

However, for pharmaceuticals and agricultural chemicals, countries eligible to use this provision (i.e. countries that did not provide protection on 1 January 1995) had two obligations.

They had to allow inventors to file patent applications from 1 January 1995, even though the decision on whether or not to grant any patent itself need not be taken until the end of this period — . This is sometimes called the "**mailbox**" provision (a metaphorical "mailbox" is created to receive and store the applications). The date of filing is significant, which is why the mailbox provisions were set up. It is used for assessing whether the application meets the criteria for patenting, including novelty ("newness").

And if the government allowed the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, it had to — subject to certain conditions — provide the patent applicant an **exclusive marketing right** for the product for five years, or until a decision on a product patent was taken, whichever was shorter.

Which countries used the extra transition period under Article 65.4, wholly or partially? The answer is not entirely straightforward. Thirteen WTO members — Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay — notified "mailbox" systems to the TRIPS Council, indicating that at the time they did not grant patent protection to pharmaceutical products. It is possible that a few other members should have notified the WTO but did not do so.

For more information

The WTO website's gateway to TRIPS: