



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 earn some future benefits from their creativity. This encourages new inventions, such as new

The TRIPS Agreement

Article 7 *Objectives*

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 *Principles*

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits.

- The way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps technological progress and technology dissemination and transfer. After a period, the protection expires, which means that the invention becomes available for others to use. All of this avoids “re-inventing the wheel”.
- 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, and the 2003 decision enabling countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory licence.

What is the basic patent right?

Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions.

A patent is not a permit to put a product on the market

A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied. Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market.

Under TRIPS, what are member governments’ obligations on pharmaceutical patents?

IN GENERAL (see also “exceptions”)

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. *Article 27.1.* Patent protection has to last at least 20 years from the date the patent application was filed.

Article 33

The TRIPS Agreement

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application⁽⁵⁾. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.

(5) For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.

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**. *Article 27.1*

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). *Article 27.1*

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 holder to disclose specifications of the patented product or process and they may require the patent holder to reveal the best method for carrying it out. *Article 29.1*

Exceptions

ELIGIBILITY FOR PATENTING

Governments can refuse to grant patents for three reasons that may relate to public health:

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health – *Article 27.2*
- diagnostic, therapeutic and surgical methods for treating humans or animals – *Article 27.3a*
- certain plant and animal inventions – *Article 27.3b*.

Under the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not “unreasonably” conflict with the “normal” exploitation of the patent. *Article 30*.

RESEARCH EXCEPTION AND “BOLAR” PROVISION

Many countries use this provision to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval – for example from public health authorities – without the patent owner’s permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the “regulatory exception” or “Bolar” provision. *Article 30*

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO

The TRIPS Agreement

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions 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 third parties.

The TRIPS Agreement

Article 8

Principles

[...]

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

[...]

dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled “Canada – Patent Protection for Pharmaceutical Products”)

ANTI-COMPETITIVE PRACTICE, ETC

The TRIPS Agreement says governments can also act, again subject to certain conditions, 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. *Articles 8.2 and 40*

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 “**other use without authorization of the right holder**” appears in the title of **Article 31**. Compulsory licensing is only part of this since “other use” includes use by governments for their own purposes.

Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder.

For example: Normally, the person or company applying for a licence must have first attempted, unsuccessfully, to obtain a voluntary licence from the right holder on reasonable commercial terms – *Article 31b*. If a compulsory licence is issued, adequate remuneration must still be paid to the patent holder – *Article 31h*.

However, for “national emergencies”, “other circumstances of extreme urgency” or “public non-commercial use” (or “government use”) or anti-competitive practices, there is no need to try for a voluntary licence – *Article 31b*.

Compulsory licensing must meet certain additional requirements. In particular, it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and usually it must be granted mainly to supply the domestic market. Compulsory licensing cannot be arbitrary.

The TRIPS Agreement

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

[...]

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

[...]

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

[...]

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

[...]

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

[...]

WHAT ARE THE GROUNDS FOR USING COMPULSORY LICENSING?

The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. In Article 31, it does mention national emergencies, other circumstances of extreme urgency and anti-competitive practices – but only as grounds when some of the normal requirements for compulsory licensing do not apply, such as the need to try for a voluntary licence first. *Doha declaration 5(b) and (c)*

PARALLEL IMPORTS, GREY IMPORTS AND 'EXHAUSTION' OF RIGHTS

Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner (or trademark- or copyright-owner, etc) or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.

For example, suppose company A has patented a drug, which it makes under patent in the Republic of Belladonna and the Kingdom of Calamine, but sells at a lower price in Calamine. If a second company buys the drug in Calamine and imports it into Belladonna at a price that is lower than company A's price, that would be a parallel or grey import.

The legal principle here is "exhaustion", the idea that once company A has sold a batch of its product (in this case, in Calamine), its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch.

The TRIPS Agreement simply says that none of its provisions, except those dealing with non-discrimination ("national treatment" and "most-favoured-nation treatment"), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. In other words, even if a country allows parallel imports in a way that another country might think violates the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. *Article 6 and Doha declaration 5(d)*

THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

Some governments were unsure of how these TRIPS flexibilities would be interpreted, and how far their right to use them would be respected. The African Group (all the African members of the WTO) were among the members pushing for clarification.

A large part of this was settled at the Doha Ministerial Conference in November 2001. In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments 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. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016.

The Doha declaration

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

[...]

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

[...]

The TRIPS Agreement

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

On one remaining question, they assigned further work to the TRIPS Council – to sort out how to provide extra 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 health.)

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 problem 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. The decision waives exporting countries’ obligations under Article 31(f) – any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries, provided certain conditions are met. The waiver is interim, the ultimate goal is to amend the TRIPS Agreement itself within the first half of 2004.

Carefully negotiated, these conditions aim to ensure the 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 are listed in the decision as announcing 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.

Another 10 countries about to join the EU said they would only use the system to import in national emergencies or other circumstances of extreme urgency, and would not import once they had joined the EU: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

And 11 more said they would only do so 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

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 mean copies of patented drugs or drugs whose patents have expired – “generic from a patent point of view”. This is not necessarily different since patented drugs are almost always sold under a brandname or trademark. When copies of patent drugs are made by other manufactures, they are either sold under the name of the chemical ingredient (making them clearly

generic), or under another brandname (which means they are still generics from the point of view of patents).

If a pharmaceutical is patented in a country and is illegally copied (infringing patent protection) in that country, it is not “generic”, particularly if it is also illegally marketed under a registered trademark. Similarly, “parallel imports” (see separate heading) are also not generics.

Developing countries’ transition periods

GENERAL

Developing countries and economies in transition from central planning did not have to apply most provisions of the TRIPS Agreement until 1 January 2000. The provisions they did have to apply deal with non-discrimination. *Article 65.2 and 65.3*

Least-developed countries have at least until 1 January 2006 – this may be extended. *Article 66.1* For pharmaceutical patents this is now extended to 2016 under the Doha Declaration on TRIPS and Public Health.

(Developed countries had until 1 January 1996, one year after the TRIPS Agreement took effect. *Article 65.1)*

Most **new members** who joined after the WTO was created in 1995 have agreed to apply the TRIPS Agreement as soon as they joined. *Determined by each new member’s terms of accession*

PHARMACEUTICALS AND AGRICULTURAL CHEMICALS

Some developing countries are delaying patent protection for pharmaceutical products (and agricultural chemicals) until 1 January 2005.

This is allowed under provisions that say a developing country that did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (on 1 January 1995), has up to 10 years to introduce the protection. *Article 65.4*

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

They must 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 – *Article 70.8*. This is sometimes called the “**mailbox**” provision (a metaphorical “mailbox” is

The TRIPS Agreement

Article 65 *Transitional Arrangements*

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.
2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.
3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.
4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.
5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66 *Least-Developed Country Members*

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

[...]

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 allows the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, it must – 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 is taken, whichever is shorter. *Article 70.9*

Which developing countries are using the extra transition period under Article 65.4? The answer is not entirely straightforward. To the best of the WTO’s knowledge six countries currently use this: Cuba, Egypt, India, Pakistan, Qatar and United Arab Emirates. (See also least-developed countries, above.)

The TRIPS Agreement

Article 70

Protection of Existing Subject Matter

[...]

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

- (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
- (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
- (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

For more information

The WTO website’s gateway to TRIPS:

http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

TRIPS, pharmaceuticals and public health:

http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

The Doha Declaration on TRIPS and Public Health:

http://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm

The 30 August 2003 decision on importing and exporting under compulsory licence:

http://www.wto.org/english/news_e/pres03_e/pr350_e.htm