GUIDE FOR THE APPLICATION AND GRANTING OF COMPULSORY LICENCES AND AUTHORIZATION OF GOVERNMENT USE OF PHARMACEUTICAL PATENTS

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# Table of contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgements</td>
<td>i</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Compulsory licences</td>
<td>5</td>
</tr>
<tr>
<td>Government use</td>
<td>21</td>
</tr>
<tr>
<td>Annex I</td>
<td>23</td>
</tr>
<tr>
<td>Annex II</td>
<td>25</td>
</tr>
</tbody>
</table>
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(a) facilitate and promote coherence in the perspectives on intellectual property rights in the context of medicines procurement;
(b) develop, where appropriate, common approaches and strategies on these issues; and
(c) develop legal tools and instruments for use in the procurement process.

This paper is an attempt to foster a common approach in the use of TRIPS flexibilities in medicines procurement. Since the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001, it is acknowledged that countries are permitted to take measures, such as compulsory licensing and government use of patents, to ensure that patents do not constitute a barrier to access to affordable medicines. This paper aims to provide technical advice to governments, as well as procurement and nongovernmental organizations (NGOs), on the modalities for the application of compulsory licences and government use authorization. The paper focuses on the use of compulsory licences and government use authorization in the context of the purchase and import of patent-protected pharmaceutical products. It also addresses the special situation of least developed countries, as provided for in paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, which allows least developed countries a transition period until 2016, during which they need not provide for, nor enforce patents and exclusive marketing rights in relation to pharmaceutical products.

It should however, be pointed out that this paper can only provide general recommendations in the process of applying for a compulsory licence or the authorization of government use of patents. The concrete application of these recommendations will necessarily be subject to the provisions of the applicable national law.

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Guide for the application and granting of compulsory licences and authorization of government use of pharmaceutical patents

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Introduction

Patents - as well as other intellectual property rights - confer exclusive rights. This means that the title-holder may exclude competition in the manufacture and sale of the protected products and, therefore, control the production and distribution of such products and their prices.

The existence of patents on products or processes\(^1\) may prevent in some cases the acquisition of pharmaceutical products at low prices\(^2\) or in sufficient quantities, such as when the products are offered at prices that are not affordable to patients or government purchasing agencies, or the patent owner has no capacity to timely deliver the needed products. In these cases, patent owners may exercise their exclusive rights and prevent supplies from alternative sources.

Like other rights, however, patent rights are not absolute. There are situations in which their exercise can be limited to protect public interests. Such situations may arise, in particular, in the area of public health, when access to needed pharmaceutical products must be ensured. "Compulsory licences" and "government use for non-commercial purposes" (hereinafter referred to as "government use") are mechanisms provided for in most laws worldwide to limit the exercise of exclusive patent rights - under the circumstances specified in the respective laws - which can specifically be used to address public health needs.

For the purposes of this document:

"Compulsory licence"\(^3\) is an authorization given by a national authority to a natural or legal person for the exploitation, without the consent of the title-holder, of the subject matter protected by a patent in order to attain certain public policy objectives.

"Government use"\(^4\) is an act by the government authorizing a government department to exploit by itself or through a contractor a patented invention without the consent of the title-holder.

The right of States to limit the use of patents through compulsory licences has been recognized since the end of the 19th century. They were incorporated into the Paris Convention for the Protection of Industrial Property (Paris Convention) in 1925, and thereafter in most national laws. Compulsory licences and government use have become regular features in patent laws all over the world\(^5\).

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\(^1\) In some countries, patents on the therapeutic indication or use of products are also allowed by the national law.

\(^2\) Of course, there are other factors that affect prices of pharmaceutical products. See, e.g. WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs, available at http://www.wto.org/english/tratop_e/TRIPs_e/tr_hosbjor_e.htm.

\(^3\) Often also called a "non-voluntary licence".

\(^4\) Also called "Crown use" under British and Commonwealth legislation.

\(^5\) See, e.g. Corea C. Intellectual property rights and the use of compulsory licenses: options for developing countries. Trade-Related Agenda, Development and Equity, Working Papers. Geneva, South Centre, 1999; Reichman J. and Hasenzahl C. Non-voluntary Licensing of Patented
The right to use such mechanisms was recognized in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994.

The concerns of developing countries about the possible impact of patents in the pharmaceutical sector led the WTO to adopt, in November 2001, the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration confirmed, inter alia, that the granting of compulsory licences (and government use) was one of the clearly admitted flexibilities under the TRIPS Agreement, and that WTO Members were free to determine the reasons for the granting of such licences (see Box).

### Doha Declaration on the TRIPS Agreement and Public Health:
**Sub-paragraph 5 (b)**

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.

Compulsory licences and government use can be utilized in relation to any of the rights conferred by a patent, including the manufacture, importation or exportation (subject to the limitation imposed in Article 31(f) of the TRIPS Agreement) of patent-protected products, and with regard to all kinds of products, including medicines, vaccines and diagnostic kits.

The present Guide aims to provide practical advice to governments, purchasing and funding entities and NGOs about the modalities for the application of compulsory licences and the utilization of government use provisions. It focuses on the utilization of such mechanisms for the purchase and importation of patent-protected pharmaceutical products. It contains two sections: in the first section, the application for and granting of a compulsory licence is dealt with; and the second section considers the case of government use, subject to the general

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* Article 31 of the TRIPS Agreement, however, does not refer to “compulsory licences” but to “other use without authorization of the right holder”. This provision applies to both compulsory licences and government use.


* Article 31(f): “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”.

* The expression “patent-protected products” includes patents on products as such, as well as products directly obtained by a patented process. See Article 28.1(b) of the TRIPS Agreement.

* As a result, this Guide does not consider aspects that would be particularly important for the use of such mechanisms for the production of pharmaceutical products.
conditions established by domestic legislation. The special requirements that may arise in cases where a compulsory licence is granted in the *importing country* in accordance with the waivers approved by the Decision of 30 August 2003 (which address situations of lack of or insufficient manufacturing capacity in pharmaceuticals)\(^\text{12}\) are mentioned in the text, wherever appropriate.

It is important to note that *the concrete application and grant will necessarily be subject to the provisions of the applicable national law*. Therefore, knowledge and understanding of the national law and regulations will be unavoidable in order to efficiently undertake the proceedings for obtaining and putting into practice such authorizations.

As already mentioned, the first section deals with compulsory licences and the second with government use. This sequence has been chosen only for presentation purposes: it does not mean that governments or agencies wishing to purchase medicines should consider granting a compulsory licence as the first option. As explained below, government use may in many cases be the simplest and fastest way of purchasing patented medicines, notably because it can be decided by the government ex officio without the need for a third party's request and, if issued for a public non-commercial purpose, without prior negotiation with the patent holder.

\(^{12}\) Article 31bis of the TRIPS Agreement incorporates the WTO Decision of 30 August 2003 (WT/L/540, available at [www.wto.org](http://www.wto.org)). This article is not yet in force, pending acceptance by WTO Members.
Guide for the application and granting of compulsory licences and authorization of government use of pharmaceutical patents
Compulsory licences

Establishing the need to apply for a compulsory licence

The essential precondition for the application of a compulsory licence is that the required product (or the process for its manufacture) is patented and the purchasing party is seeking to obtain the product from a source different from the patent owner, his licensees or other authorized parties. This will occur, for instance, when the potential supplier is a generic company that has not obtained a licence, in the importing country, to use the relevant patent(s).

If the product is not patent-protected in the country where the importation will take place, there is no limitation (stemming from the patent law) to import the required medicine.

Notes:
1. The need to apply for a compulsory licence would normally arise when there are relevant patents in force on the products to be purchased. In some situations, there may be no patents on the products themselves but on the process for their manufacture. In accordance with the TRIPS Agreement, the protection conferred on a process extends to the product directly obtained with it (Article 28.1(b)). This means that, even if a product patent does not exist in the importing country, a process patent may be used to prevent the importation of a product directly obtained abroad with the same process. It is a matter of proof whether a given product has been directly obtained with the patented process. Article 34 of the Agreement provides, under certain circumstances, the reversal of the burden of proof in cases of infringement of a process patent.
2. In countries where patents on second pharmaceutical indications are admitted, a compulsory licence may also be necessary if the intended use of the product is covered by the patent.
3. If the product to be purchased has been commercialized by the patent owner or his licensee(s) in a foreign country, a compulsory licence is not needed if the national legislation admits "parallel imports", that is, if it considers that the rights of the patent owner have been exhausted with the sale of the product in a foreign country. Depending also on the national law (of the importing country), parallel imports may also take place when the supplier is authorized to commercialize or distribute the product under a compulsory licence in the exporting country.
4. It should be noted that patents are territorial, that is, they are only valid in the specific countries where they have been applied for and granted. Therefore, there is no need to apply for a compulsory licence if the patent is not in force in the country of importation, irrespective of the existence of such patent in other countries.

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13 Often patents are hybrid, that is, they include claims on both products and processes (and, where allowed, therapeutic uses of the product).
15 While there are opposing views on the consistency of this possibility with the TRIPS Agreement, such imports may in some cases be important to secure the supply of low-priced pharmaceutical products.
5. Irrespective of whether or not patents are in force in the relevant country, compliance with health regulations (such as those requiring the marketing approval of medicines) would normally be necessary for the importation and distribution of pharmaceutical products. The facilities provided by the WHO Prequalification Project, established in 2001, can be used by countries and procurement agencies to acquire products that have been tested and found to meet high quality standards and speed up access to required products.\(^\text{16}\)

Special situation of least developed countries

Least developed countries (LDCs) need not implement the obligations under the TRIPS Agreement relating to patents (and data protection) for pharmaceutical products until 2016, by virtue of Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health.\(^\text{17}\) This means that LDCs that make use of this transitional period, need neither grant nor enforce (if granted) pharmaceutical patents and, therefore, the purchase and importation of such products can be made without compulsory licences.

LDCs interested in the support of international and other organizations in the purchase of pharmaceutical products, may possibly be required by these organizations to state that, in accordance with paragraph 7 of the Doha Declaration and the Decision of the Council for TRIPS of 27 June 2002, they do not grant or enforce patents on such products. WHO and UNICEF have collaborated in the drafting of a "Paragraph 7 Model Letter" (see Annex II) which LDCs may consider using in order to confirm that pharmaceutical patents are not recognized or enforceable in their country. The letter may be signed by any competent authority, as appropriate according to domestic legislation.

Determining the patent status of required products

Although it would seem simple to determine when a compulsory licence is needed, because there is patent protection, and which patents would be involved, this is not often the case. It may be difficult to establish the patent status of pharmaceutical products in developing countries. In these cases, and where prior negotiation with the patent holder is not required, an application for a compulsory licence could be made with regard to all patents that may be infringed by the importation and use of the required product(s). Although this approach has not been discussed at the WTO, some countries have already applied it.

Notes:

1. There are various reasons why the identification of patents may be difficult. Pharmaceutical companies tend to apply for (and generally obtain) more than one patent for the same product.\(^\text{18}\) Even for products that have been on the market for a long time, it is possible to find a multiplicity of patents on variations thereof, such as different salts, sodium, etc.

\(^{16}\) For more information about this Project, see www.who.int.


ethers, polymorphs, etc., or new therapeutic indications. Although in some countries (e.g. India) legislation has been adopted to limit the patenting of such variants (often called “evergreening” patents) the possibility of finding more than one patent for a given product is considerable.

2. Sometimes patent information available at the patent offices is incomplete or difficult to access (particularly where computerized records do not exist).

3. Moreover, data contained in published abstracts of patent applications or grants, often do not provide sufficient information to identify the drug they refer to, especially when they do not include the International Nonproprietary Names for Pharmaceutical Substances (INN).

4. It should be noted that when patents on specific formulations exist, but the active ingredients are off-patent, there will be no need to apply for a compulsory licence if a different formulation can be purchased.

5. If the existence of a patent relevant for a given product has been identified, a question that may be raised is whether such a patent was validly granted or not. In some cases, patents are granted without fulfilling the patentability requirements (novelty, inventive step or non-obviousness and industrial applicability or utility) and may be invalidated upon request. However, a process for the invalidation of a patent may take several years, unless a faster post-grant examination by an administrative authority (such as the patent office) is permitted under national law.

6. In applying for a compulsory licence for a particular patent, the applicant might be deemed as implicitly endorsing its validity. When there are doubts in this respect, a reservation could be made by the applicant regarding a possible challenge of the validity of the patent, if needed.

7. In some cases, there may be pending patent applications with regard to products to be purchased. In these cases, it would not be necessary to apply for a compulsory licence (nor possible in fact since no patent exists yet). It should be noted, however, that according to some laws the applicant may exercise the rights ordinarily conferred on a patent owner after the publication of the application\(^\text{19}\), while under other laws the patentee may, after the grant of the patent, claim for a compensation with regard to acts conducted by a third party before the grant.

8. One of the reasons, admitted in most national laws, for the invalidation of a patent is the lack of payment of maintenance fees (that is, fees that must be paid by the patent owner to keep a patent in force). In many countries, patents automatically lapse if such fees have not been paid\(^\text{20}\). A quick investigation with the national patent office is therefore recommended, to establish if the maintenance fees have been paid for the identified patents and, therefore, whether or not they remain in force.

9. It is also of note that under many laws a third party can file an opposition to or make observations on a patent application, indicating reasons why the patent should not be granted.

**Searching patent data**

The key issue for the purpose of applying for a compulsory licence is to determine, as mentioned, the existence of valid and enforceable patents in the importing country.

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\(^{19}\) See, e.g. Section 46 of the Patent Act of Philippines - *Rights Conferred by a Patent Application After Publication*: "The applicant shall have all the rights of a patentee under Section 76 against any person who, without his authorization, exercised any of the rights conferred under Section 71 of this Act in relation to the invention claimed in the published patent application, as if a patent had been granted for that invention".

\(^{20}\) In some countries, however, national laws allow for a grace period; if payment of the fee takes place within that period, the validity of a patent may be restored.
The most straightforward way to determine whether a relevant and valid patent exists and whether a compulsory licence is needed, is to consult the patent office about existing patents on a given product. Patent offices may take, however, from a few weeks to several months to undertake the search and, in many cases, the results may not be conclusive due to the lack of appropriate records.

The fact that a patent on a given product or process has been applied for or granted in another jurisdiction (e.g. by the US Patent and Trade Mark Office or the European Patent Office) may provide an indication that an equivalent patent may be found in the potential country of importation. However, patents are territorial in nature, and there should be no automatic assumption that a patent applied for or granted in a foreign country has been applied for or granted domestically.

Notes:
1. There are several databases that can be accessed in order to search data on patents in particular jurisdictions, such as esp@cenet for the European Patent Office, http://www.uspto.gov for US patents, and many web pages of other national patent offices. There are also a number of private databases that can be accessed, normally for a fee.
2. The Patent Cooperation Treaty (PCT) allows for “international applications” for patents in which the countries (which must be PCT members) where the applicant intends to file a patent are designated. The PCT offers an Online File Inspection System that permits interested parties to search more than one million international patent applications (http://www.wipo.int/pctdb/en/search-adv.jsp).
3. Information regarding the patent status of medicines in developing countries is often neither readily accessible nor available in an easily-understood form. In the interest of facilitating the availability of up-to-date and accurate information on the patent status of essential medicines in developing countries, WHO, in conjunction with Médecins Sans Frontières (MSF) and UNAIDS, has published a patent table which lists the patent status of a number of essential medicines, including antiretrovirals, in selected developing countries\(^21\). WHO is undertaking work to expand the patent table, so as to increase the number of medicines and the list of countries.

Establishing whether the acts to be performed are subject to patent rights

Another important consideration to establish the need for a compulsory licence is whether or not the intended acts will constitute an infringement of a patent, if it exists. Most patent laws provide exceptions to the patentee’s exclusive rights with regard to certain acts, such as

- research or experimentation
- acts done for private use and with non-commercial purpose
- submission of information (and samples) to obtain the marketing approval of a pharmaceutical product before the expiry of the patent\(^22\).

Note:


\(^{22}\) This exception is generally known as "early working", regulatory review or "Bolar exception".
Except if admissible as parallel imports, the importation of a large number of products would fall under the exclusive rights conferred by a patent. Before applying for a compulsory licence, however, the national law should be checked to determine whether the importation of products made for non-profit could be deemed an act exempted from patent rights.

Articulating the grounds for compulsory licences

As mentioned, most patent laws in the world provide for the granting of compulsory licences (and government use). However, the grounds under which such licences may be conferred vary from country to country. The Doha Declaration confirmed the right of WTO Members to determine such grounds. They may include, for instance, some or all of the following:

- national emergency or situation of extreme urgency
- dependency of patents
- licences to remedy anti-competitive practices
- lack of or insufficient working of the patent
- refusal to deal
- public interest
- public health.

Not only may the grounds for granting a compulsory licence vary, but also the way in which such grounds are applied. For instance, the lack of or insufficient working is deemed to refer, in some jurisdictions (e.g. Brazil) to the industrial exploitation of the patent in the national territory, while in others working may be justified merely through importation.

As a result of these variations, before applying for a compulsory licence the specific grounds that may support its grant under the applicable national law should be carefully examined.

Notes:
1. The grounds invoked for granting a compulsory licence should normally be indicated in the application. In some cases, more than one ground may apply.
2. In some countries, the situations of "emergency" may need to be formally declared by a competent authority, while in others its existence can be determined by the authority granting the compulsory licence.

Compulsory licence solely for importation

The text of the TRIPS Agreement is open with respect to the rights that can be exercised by the beneficiary of a compulsory licence. It may be granted only for importation.

WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector that have notified their intention to use the mechanism

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23 The interpretation of Article 27.1 of the TRIPS Agreement in this regard is, however, controversial. See, e.g. the WTO document Brazil - Measures Affecting Patent Protection, WT/DS 1991 and 4.
24 Some national laws seem to require local production of the protected product but, as mentioned, this is not required by the TRIPS Agreement.
established by Article 31bis of the TRIPS Agreement, are bound to notify the Council for TRIPS of the following:

(i) the names and expected quantities of the product(s) needed;
(ii) confirmation that the importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to the Annex to Article 31bis of the Agreement; and
(iii) confirmation that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of the Agreement and the provisions of its Annex.

Notes:
1. The possibility of granting compulsory licences solely for importation has been confirmed beyond any doubt by paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health and the subsequent WTO Decision of 30 August 2003, incorporated on 6 December 2005 into the TRIPS Agreement as Article 31bis.
2. It is important to note that, in the case of application of Article 31bis of the TRIPS Agreement, the "expected quantities of the product(s) needed" have to be indicated in the notification to the Council for TRIPS, but this is not a requirement for the granting of the compulsory licence itself.

Applying for a compulsory licence

Who can apply?
In principle, any interested party may request the granting of a compulsory licence. However, some national laws impose specific requirements on applicants, such as proof of technical or economic capacity to utilize the licence.

Compulsory licences for the production or importation of pharmaceuticals may be applied for by commercial entities, as well as by any other natural or legal person that complies with the requirements established by the national law. NGOs and international organizations may apply for such licences, if allowed under their respective bylaws or statutes, subject to the applicable national law.

Notes:
1. A compulsory licence may be applied for by any natural or legal person with an interest in the execution of the licence.
2. International organizations that are active in the purchasing and distribution of pharmaceutical products may apply for a compulsory licence. They may also act on behalf of the government or other parties. As mentioned below, they may act as contractors or agents of governments in the case of government use.

26 As noted, this amendment is still subject to acceptance by Members in accordance with WTO rules.
27 See the section on government use below.
When can a compulsory licence be applied for?
In many cases, such as when UN and other purchasing agencies intervene, the acquisition of pharmaceutical products is done through bidding procedures. In these cases an apparent dilemma may be faced by potential suppliers: an offer for sale may be deemed a patent infringement, although it would be extremely costly and cumbersome, and in the last instance a wasteful exercise, to apply for a compulsory licence just to make an offer that may be accepted or not.

This problem may be addressed by including in all offers under bidding procedures a disclaimer indicating that the offer is conditional and subject to the granting of a compulsory licence, if the offer were accepted by the purchasing party. Such a disclaimer would make clear that the supplier does not intend to supply a patent-protected product unless the respective authorization is given.

How should the application be made?
The procedures to obtain a compulsory licence are governed by national laws. The application must comply with the required formalities and procedures. Important issues to consider include:

- which is the competent authority to grant a compulsory licence?
- requirements about domicile
- documentation about the applicant
- justification of the application
- proof of economic or technical capacity, where required
- identification of products(s) and of the patents involved, if known
- identification of the title-holder(s)
- unsuccessful prior request, where necessary, to the patent owner for a voluntary licence on reasonable commercial terms
- scope and duration of the compulsory licence.

Which is the competent authority to grant a compulsory licence?
A compulsory licence must be granted by a national authority with legal competence to that effect. The institutional models vary considerably in this regard.

In most countries, compulsory licences are granted by a department of the executive branch. There are cases, however, where such competence lies with judicial courts.

In the case of a grant by the executive branch, there may be one or more offices or departments involved. Thus, in some cases, the grant is made by the patent office. Often, however, other departments need to be consulted or intervene, such as the departments of health or trade.

Notes:
1. The institutional setting for the granting of a compulsory licence must be properly examined. In some cases, the intervention of the Ministry of Health is required, when the compulsory licence is grounded on public health considerations.
2. In administrative procedures the services of legal professionals are not generally required, and a certain degree of informality is admitted. If judicial courts intervene, however, the support of an attorney will normally be required.

28 See Article 28.1 of the TRIPS Agreement, which includes "offering for sale" as one of the acts that can be prevented by the patent owner.
Domicile or establishment
Unless otherwise determined by the national law, a compulsory licence can be requested by an applicant with or without domicile or establishment in the country where the compulsory licence is sought. However, the national law may require the designation of an address for service or the appointment of an agent to act before the administration or court.

Identification of the applicant
Under most legal systems, the applicant, if not a natural person, will have to submit copies of the statutes or bylaws. In addition, the person acting as an agent of the applicant will have to demonstrate his capacity to do so.

Note:
It should be recalled that, according to the TRIPS Agreement, a compulsory licence is non-assignable (that is, it cannot be used by a person other than the applicant). It can only be assigned with that part of the enterprise or goodwill which enjoys such use (Article 31(e) of the TRIPS Agreement).

Justification of the application
The application for a compulsory licence should, to the extent possible,

- indicate the specific legal provisions on which its grant is sought
- provide a brief justification of the reasons for the request.

The justification needs to show the extent to which the application falls under the applicable provisions of the law. It should also briefly explain the motivation for the granting of the licence. These elements in the application may help the competent national authority to speed up the granting procedures.

Notes:
1. Since compulsory licences are a legitimate means to achieve public policy objectives, governments should act according to the prescriptions of the national law, in conformity with the standards set out by the TRIPS Agreement.
2. The granting of a compulsory licence should be seen as an ordinary administrative or judicial act, and be considered only in the light of the relevant legal requirements. However, the issue is politically sensitive. Although not a party in the procedures, governments of the companies eventually affected by a compulsory licence may involve themselves in discussions and other actions regarding the licence. In a rule-based system, the granting government should decide on the basis of the applicable legal requirements and the merits of the case.

Proof of economic or technical capacity, where required
Some national laws require that the applicants for compulsory licences demonstrate a technical or economic capacity to execute the compulsory licences they have applied for. The evidence to be provided will vary depending on whether the purpose of the licence is to manufacture or to import the protected product. While in the former case the availability of manufacturing facilities (owned or not by the applicant) may have to be shown, in the latter it may be sufficient to indicate that the applicant is a legally established entity with a credible capacity to finance and undertake the acquisition and distribution of the relevant products.
Identification of products(s) and of the patents involved, if known

As discussed above\(^{29}\), it is frequently difficult to identify the patent or patents in force in a given country with regard to certain products. This should not be a deterrent for the application for and granting of a compulsory licence, as the proper identification of the product (by its generic name) would be sufficient to establish the scope of the licence.

A compulsory licence may be applied for with regard to the whole subject matter covered by a patent (e.g. all forms of administration of a drug) or be limited to a sub-set of modalities in which the patented product may be presented (e.g. oral formulations). This will depend on the evaluation of the applicant in the light of the health needs to be addressed.

Identification of title-holder(s)

An application for a compulsory licence should ideally identify the owners of all the relevant patents. The lack of a precise identification of such patents, however, should not be a deterrent for the application for, and granting of, the compulsory licence.

Notes:

1. In the absence of identification of the title-holders, the prior request for a voluntary licence (where applicable, as discussed below) may not take place. Negotiation (where provided for under national laws) between the applicant and the title-holder(s) on a mutually agreeable remuneration for the use of the patent, may not be possible either.
2. If the title-holders are not identified at the time of the granting of the compulsory licence and when payments of the remuneration are due (see below), the compulsory licensee may have to deposit (judicially or otherwise) the corresponding amounts. Payment may be calculated on the basis of the product supplied under the compulsory licence\(^{30}\).

Prior request for a voluntary licence

In conformity with Article 31(b) of the TRIPS Agreement, in some cases there is a need to request a voluntary licence from the patent owner before a compulsory licence is applied for. Wherever this requirement applies, the applicant may need to prove that: (a) the patent owner has refused to grant a voluntary licence on reasonable commercial terms within a reasonable period, or (b) the patent owner has not replied to such a request after the expiry of a reasonable period.

The request to the patent owner for a voluntary licence may include:

- identification of the product(s)
- purpose of the licence (e.g. manufacture, importation, non-profit distribution)
- designation under which the product(s) will be distributed
- remuneration to be paid
- duration of the licence (for instance, until the expiry of the relevant patent(s)).

\(^{29}\) See page 6.

\(^{30}\) For methods that may be used to determine the remuneration to be paid, see Love J. Remuneration guidelines for non-voluntary use of a patent on medical technologies. Health Economics and Drugs Series No 18. Geneva, World Health Organization, 2005 (WHO/TCM/2005.1), 83-85.
The evaluation of whether a voluntary licence has been requested or offered on reasonable commercial terms will lie with the competent authority for the granting of the compulsory licence. Any decision in this regard should be taken in line with commercial practice while taking into account the public health objectives that could be attained with the compulsory licence. The critical criterion will generally be the level of offered remuneration, which may be determined according to the methods described below.

Some national laws establish the period within which the patent owner is bound to indicate its acceptance or refusal to grant a voluntary licence on reasonable commercial terms.

It is important to note that the prior negotiation of a voluntary licence is not required, in accordance with the TRIPS Agreement (and, most probably, the applicable national law), when a compulsory licence is applied for in order to:

- address a national emergency or other circumstances of extreme urgency
- remedy anti-competitive practices.

However, in these cases the right holder shall be notified as soon as reasonably practicable about the granting of a compulsory licence.

Notes:
1. A request to obtain a voluntary licence should always be made in a written form, ensuring that the reception of the request by the addressee can be proven, if necessary.
2. In the case of government use for non-commercial purposes, there is no need to previously request a voluntary licence justification of the application (see section on government use below).

Scope and duration of a compulsory licence
Depending on national law, the act granting a compulsory licence may be conceived in broad terms and allow for the exercise of the rights of making, using, offering for sale, selling, or importing for these purposes the covered product(s) for the full term of the patent. It may also limit the licence to some of such rights or to a period shorter than the life of the patent, or to some claims or fields of use of the patent.

Beneficiaries of a compulsory licence can also export, provided that they predominantly supply the domestic market of the country where the licence has been granted (Article 31(f) of the TRIPS Agreement). This limitation, however, does not apply in cases where the compulsory licence is granted to remedy anti-competitive practices (Article 31(k) of the TRIPS Agreement).

31 See paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health, which states: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".
32 In Argentina, for instance, the period to accept or refuse a request for a voluntary licence is 150 days (Law 24.481, as amended by Law 24.572, Article 42).
33 This limitation may be waived in accordance with the system adopted by the afore-mentioned Decision of 30 August 2003, pending the acceptance of the proposed new Article 31bis of the TRIPS Agreement.
In filing an application for a compulsory licence, the applicant may either request it without any limitation with regard to the scope of use of the patent or duration of the licence, or deliberately limit the application to certain acts and duration.

In cases, for instance, where the only intended purpose of the compulsory licence is to import and distribute medicines, this can be explicitly stated in the application. It is likely that the broader the potential scope of a compulsory licence, the stronger will be the opposition of the patent owner (and of the host country's government).

With regard to duration, it is advisable to request the compulsory licence for the full remaining period of the patent, in order to avoid having to request extensions or start procedures anew for the granting of a licence.

Notes:
1. It should be recalled that, in all cases, a compulsory licence shall be non-exclusive (Article 31(d) of the TRIPS Agreement), that is, the patent owner or other licensees (voluntary or compulsory) may compete with the beneficiary of the compulsory licence.
2. It should also be borne in mind that, according to some national laws, a compulsory licence may be revoked if not utilized within a certain period.
3. Moreover, a compulsory licence is liable, subject to adequate protection of the legitimate interests of the compulsory licensee, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent national authority shall have the authority to review, upon motivated request, the continued existence of these circumstances (Article 31(g) of the TRIPS Agreement) and can, hence, determine in certain cases the termination of the licence.
4. Compulsory licences create an exception to patent rights. The applicant should not be required to specify the value or quantity of the product(s) to be produced or imported, or the time or other conditions under which production or importation may occur.

Summary

Some of the aspects of the previous analysis on the application for a compulsory licence are schematically presented in Figure 1.

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34 It is to be noted, however, that the Decision of 30 August 2003 requires the exporting country and the supplier to provide certain information about the products to be exported. See, e.g. Correa C. Implementation of the WHO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Op.cit.
Figure 1.

Filing a request for a compulsory licence

Procedures for granting a compulsory licence

The procedures for processing an application for a compulsory licence are exclusively determined by the applicable national legislation. They are subject, however, to the general obligations relating to the procedures for the enforcement, acquisition and maintenance of intellectual property rights set out in Parts III and IV of the TRIPS Agreement. Such procedures shall be "fair and equitable".

In accordance with some national laws, once an application for a compulsory licence is filed, the competent authority should notify the patent owner and seek an agreement with the applicant about the level of remuneration to be paid. Since the requested licence is compulsory, the patent owner - who is not a party to such procedures - should not be allowed to make other submissions that interfere with the procedures.

In some cases, decisions about the granting of compulsory licences should be made within periods specifically provided for by the national law or regulations. If such periods are not provided for, the general administrative (or judicial) procedural rules will apply. In any case, it is of note that Article 41.2 of the TRIPS Agreement requires that "Procedures concerning the enforcement of intellectual property rights shall ... not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays". Although conceived to protect right-holders, the same treatment should be accorded, in a non-discriminatory way, to all parties in procedures involving intellectual property rights.

Degree of discretion left to grant or refuse a licence

When the requirements for the granting of a compulsory licence have been complied with, the competent authority should grant it. While some laws clearly mandate the granting of a licence in such circumstances, in other cases the laws

35 See Articles 62.4 and 41.2 of the TRIPS Agreement.
36 See, e.g. Section 21.04 of Canadian Bill C-9 ("An Act to amend the Patent Act and the Food and Drugs Act") which implements the WTO Decision of 30 August 2003.
leave more room for the exercise of discretion by said authority. While the TRIPS Agreement is merely permissive, from a public health perspective, such discretion may be deemed limited by the State's obligation to protect public health and respect patients' human right to have access to affordable medicines.\(^3^7\)

**Validity of the act granting a compulsory licence**

The administrative (or judicial) act granting a compulsory licence should generally contain:

- legal background and justification for the granting of a compulsory licence
- identification of the product(s) and of the patents involved, if known
- remuneration to be paid to the patent owner
- scope (e.g. production, importation) and duration of the licence.

Like any other administrative (or judicial) act, the validity of an act conferring a compulsory licence may be subject to challenges by the patent owner or other interested parties, in accordance with the general rules applicable to administrative or judicial procedures. The TRIPS Agreement specifically provides that "the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member" (Article 31(i)).

An appeal questioning the validity of the act granting the compulsory licence may delay for a long time the execution of the licence and frustrate the purpose for which it has been sought. Some laws have attempted to avoid this possibility and only allow for an appeal against the grant of a compulsory licence that does not suspend its effects,\(^3^8\) that is, the appeal would not impede the immediate execution of the licence, at the option of the compulsory licensee.

**Note:**

*The compulsory licence does not need to specify a determined quantity or value of the product to be produced or imported, including in the case where a licence is granted in an eligible importing country under the mechanism of the Decision of 30 August 2003 (proposed Article 31bis of the TRIPS Agreement), where applicable.*

**Remuneration**

A key aspect in the granting of a compulsory licence is the determination of the remuneration to be paid to the patent owner, and the modalities of payment. Governments have considerable discretion in defining the level and mode of payment, subject to the general rule that the remuneration is adequate in the circumstances of each case, taking into account the economic value of the authorization in conformity with Article 31(h) of the TRIPS Agreement. The level of remuneration, however, should be reasonable and not frustrate the purpose of a compulsory licence that is intended to address a public health need, such as ensuring access to pharmaceutical products at the lowest possible price.

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\(^3^7\) The International Covenant on Economic, Social and Cultural Rights recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" (Article 12.1). In General Comment No. 14 on Article 12, the Committee on Economic, Social and Cultural Rights enumerates basic obligations that include the provision of essential biomedical innovations, General Comment E/C.12/2000/4, 11 August 2000.

\(^3^8\) The TRIPS Agreement does not regulate the effects of judicial or administrative appeals.
According to the already quoted "Remuneration guidelines for non-voluntary use of a patent on medical technologies", the following are some of the methods of calculation that may be reasonably applied to determine the level of remuneration:

a) The 1998 Japan Patent Office (JPO) Guidelines (applicable to government-owned patents) allow for normal royalties of 2 to 4% of the price of the generic product, and can be increased or decreased by as much as 2%, for a range of 0 to 6%.

b) The 2001 United Nations Development Programme (UNDP) Human Development Report proposed a base royalty rate of 4% of the price of the generic product. This can be increased or decreased by 2%, depending upon such factors as the degree to which a medicine is particularly innovative or the role of governments in paying for research and development.

c) The 2005 Canadian Government royalty guidelines for compulsory licensing of patents for export to countries that lack the capacity to manufacture medicines, in accordance with the WTO Decision of 30 August 2003, establish a sliding scale of 0.02 to 4% of the price of the generic product, based upon the country rank in the UN Human Development Index. For most developing countries, the royalty rate is less than 3%. For most countries in Africa, the rate is less than 1%.

d) The Tiered Royalty Method is different from the 2001/UNDP, 1998/JPO or 2005/Canadian methods in that the royalty rate is not based upon the price of the generic product. Instead, the royalty is based upon the price of the patented product in the high-income country. The base royalty is 4% of the high-income country price, which is then adjusted to account for relative income per capita or, for countries facing a particularly high burden of disease, relative income per person with the disease.

In addition to establishing the level of remuneration, the act granting a compulsory licence should specify how the payment will be made, notably:

- time of payment
- base for the calculation of royalties (the net sales value should normally be considered)
- currency of payment
- bank account where the payment will be deposited.

The patent owner can appeal a decision granting a compulsory licence with regard to the remuneration to be paid by the applicant."}

Note:
The methods and guidelines summarized above may also be used by a would-be applicant to calculate a reasonable remuneration to be offered where prior negotiation with the patent owner is required.

39 Article 31(j) of the TRIPS Agreement: "any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member".

18
Waiver of the obligation to pay remuneration

In the case of a compulsory licence granted under the Decision of 30 August 2003 (or, if accepted, the proposed Article 31bis of the TRIPS Agreement) the obligation to pay a remuneration is waived in the importing country when adequate remuneration pursuant to Article 31(h) is paid in the exporting country.

Data exclusivity

Article 39.3 of the TRIPS Agreement requires protection of undisclosed test data against unfair commercial use. It does not mandate the granting of exclusive rights; on the contrary, it is firmly based on the discipline of unfair competition, which neither confers property nor exclusive rights, but protects against dishonest commercial practices as defined under national laws. Under this interpretation, generic competition - which pushes prices down and increases access to medicines - is not unduly delayed when the products are off-patent and, hence, freely available for manufacturing and sale.

In some countries, such as the United States, countries of the European Union and Japan, as well as those that have signed free trade agreements (FTAs) with the United States, test data relating to pharmaceutical products may be subject to exclusive rights (data exclusivity). This may mean that, unless clinical trials are repeated, a third party may not be able to obtain marketing approval for a product without the authorization of the originator of the data.

In countries where data exclusivity is enforced, the very purpose of granting a compulsory licence may be frustrated until the period of data exclusivity ends (generally after five years counted from the date of approval of the product), since the beneficiary would not be able to commercialize the product under the licence without the respective marketing approval. In order to avoid this situation, an application for a compulsory licence should include, where necessary, a petition for a waiver of any restrictions that may stem from data exclusivity.

40 See Article 39.1 of the TRIPS Agreement. For an analysis of this subject, see Correa C. Protection of data submitted for the registration of pharmaceuticals: implementing the standards of the TRIPS Agreement. Geneva, South Centre, 2004.

41 Note that there are diverging views on the interpretation of Article 39.3 among WTO Members. Thus, the USA and the European Union have argued that it obliges to confer exclusive rights. See, e.g., WTO documents IP/C/W/296 and IP/C/M/31.

42 Such a waiver is explicitly provided for in Article 18 of the Regulation (EC) 816/2006 adopted by the European Parliament on "compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems". This Regulation implements the WTO Decision of 30 August 2003 in the European Union.
Government use

In the case of government use, similar steps and conditions to those described above for compulsory licences apply. The main difference between compulsory licences and government use is that the former is conferred, upon request, to a third party, while the latter permits the use of a patent by the government itself or by a contractor or agent appointed by it.

There is no need for a formal request to the government, as it can act ex officio to address identified public health needs. Government use may be utilized, for instance, for distribution of medicines in dispensaries, hospitals and other medical institutions owned by or on behalf of the Government.

Government use may have distinct advantages vis-à-vis compulsory licences in cases where the purchase of pharmaceutical products is made with non-commercial purposes, since:

- the government can act ex officio
- a contractor or agent can be appointed
- there is no need to engage in previous negotiations with the title-holder, thereby speeding up the process
- national laws can limit the remedies available against government use to payment of remuneration in accordance with subparagraph (h) of Article 31 of the TRIPS Agreement, that is, no injunctions may be admitted.\(^4\)

Who can authorize the use of a patent?

Depending on national laws, government use can be decided in a decentralized form by different departments or government bodies, or by a particular authority designated by law. Certainty about competence to give the authorization may avoid possible challenges to the validity of the act.

Content of an administrative act authorizing government use

The use of a patent by the government requires an administrative act indicating, at least:

- department or government body that authorizes the government use
- legal background
- justification of the need to use the patent(s)
- identification of product(s)
- identification of the patents involved and of the title-holders, if known
- remuneration to be paid to the patent owner
- scope and duration of the intended use
- persons or entities authorized to act as contractor or on behalf of the government.

\(^4\) See Article 44.2 of the TRIPS Agreement.
Note:  
An administrative act authorizing government use of a patent does not need to specify a determined quantity or value of the product to be produced or imported thereunder.

Who can use the patent(s)?

The TRIPS Agreement (Article 31(b)) suggests that, in cases of government use, the relevant patent(s) may be used by a contractor, as is common practice, for instance, in the United States . Moreover, actual use of the patent(s) may be made by a natural or legal person on behalf of the government authorizing the use.

Notes:
1. Any natural or legal person designated by the government may act on its behalf to execute an authorization of government use.
2. In particular, UN agencies, such as WHO and UNICEF, and NGOs, may act on behalf of the government in the purchase and distribution of pharmaceutical products.
3. The fact that a commercial entity is involved as a contractor or acts on behalf of the government does not prevent government use from being qualified as "non-commercial", to the extent that the patented invention is used for a public purpose.

Notification of the patent owner

As in the case of compulsory licences, the government may authorize the use of any patents relating to a particular product. As mentioned above, a patent search to establish which patents are relevant may take a long time and face practical difficulties.

In accordance with Article 31(b) of the TRIPS Agreement, "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". This provision suggests that the patent owner can be notified before or after the use of the patent has commenced, and that this notification should take place when the right holder has been identified through a patent search or by other means.

Notes:
1. Patents may be assigned and they often are. Patent laws require that any assignment be registered in order to be valid. Therefore, it would not be sufficient to check the original title of a patent to determine who the right holder is, but the complete files relating to the patent must be examined.
2. The notification of patent owners does not mean that they may become a party to whatever procedures have been initiated. As in the case of compulsory licences, they would have the right to appeal against the authorization to use a patent on grounds of validity of the authorization or the remuneration determined for its use.

See Reichman J. op. cit.
WORLD TRADE ORGANIZATION

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

   In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(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.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.
CERTIFICATION OF NON-RECOGNITION AND NON-ENFORCEABILITY OF PATENTS AND DATA PROTECTION IN RESPECT OF PHARMACEUTICAL PRODUCTS

Whereas

Further to Paragraph 7 of the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference on 14 November 2001 (WT/MIN(01)/DEC/W/2), the WTO Council for TRIPS decided on 27 June 2002 (IP/C/25) that least developed country Members of the WTO need not enforce patents and data protection with respect to pharmaceutical products at least until 1 January 2016.

The 30 August 2003 Decision by the WTO General Council on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) acknowledged that the system established by the Decision is without prejudice to the exemption granted to least developed country Members pursuant to Article 66.1 of the TRIPS Agreement.

The [insert title of government official] hereby confirms that:

(a) patents and data protection with respect to pharmaceutical products shall not be recognized or deemed enforceable within and with respect to [insert country name] at least until 1 January 2016;

(b) importation, manufacturing, use, sale, and offering for sale of pharmaceutical products is authorized notwithstanding any patents which may have been granted or data protection rules which may be applicable with respect to those products; and

(c) patents and data protection rights may not be enforced by holders thereof within and with respect to [insert country name] with regard to any actions by the government or third parties undertaken during the period extending at least until 1 January 2016.

45 There is no guidance from WTO regarding the certification of the non-recognition or enforceability of patents and data protection pursuant to paragraph 7 of the Declaration on the TRIPS Agreement and Public Health. This Annex provides a model for such certification, on the understanding that the legal situation in each country should be assessed in the light of its domestic legislation and constitution.