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Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents

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SOUTH CENTRE

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GUIDE FOR THE GRANTING OF COMPULSORY LICENSES AND GOVERNMENT USE OF PHARMACEUTICAL PATENTS

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SOUTH CENTRE

In August 1995 the South Centre was established as a permanent inter-governmental organization of developing countries. In pursuing its objectives of promoting South solidarity, South-South cooperation, and coordinated participation by developing countries in international forums, the South Centre has full intellectual independence. It prepares, publishes and distributes information, strategic analyses and recommendations on international economic, social and political matters of concern to the South.

NOTE

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FOREWORD

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides for a set of "flexibilities" that the WTO Members can utilize to protect or achieve public interests, such as public health. Compulsory licenses and government use for non-commercial purposes (government use), are part of these flexibilities. These are legal instruments widely recognized in the laws of both developed and developing countries, that can be used to address a variety of situations, such as insufficient supply or excessive prices of products, national emergencies, etc. They can be, in particular, necessary to implement public policies aiming at ensuring the production or procurement of medicines and other health technologies in situations of global health crises, as it is the case with COVID-19.

Such situations require that health products (including medicines, vaccines, diagnostic kits, equipment and protective devices) be made available to **all** countries at the **same time**. To this end, any inventions or know-how and other technologies protected by intellectual property rights, need to be treated as global public goods so that they can be manufactured by multiple producers, thereby expanding the capacity to distribute them globally with the necessary quality and quantity. While there are other measures that governments may use under the TRIPS Agreement, such as the security exception of article 73(b) of that Agreement, compulsory licensing and government use are important components in the toolkit at their disposal.

This guide was originally written, at the request of the WHO Secretariat, in response to the mandate given by the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (Resolution WHA 61.21, 2008) which requested WHO to "(…) *strengthen education and training in the application and management of intellectual property from a public health perspective, taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health".*[1] The South Centre received permission from WHO to reproduce this guide.

In the current situation, the South Centre considered important to update and revise this guide to assist countries in the utilization of compulsory licenses and government use to address the current international emergency and beyond it, when needed. The South Centre has and will continue to use this guide in technical assistance and the trainings it regularly provides to policy makers in developing countries to improve access to medicines and other health products.[2]

While access to technologies voluntarily offered by right holders may contribute to address global health crises, such as the one created by COVID-19, not all those enjoying exclusive rights may be ready to take such step in a manner that all countries can provide prevention and treatment to their populations. As Martin Luther King famously noted, it is a historical fact that privileges and prerogatives "are seldom given up voluntarily".[3] If such is the case, and right holders pursue commercial strategies based on such exclusive rights in a situation of global emergency, governments can use tools legitimately available under international law, as described in this guide.

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[1] WHA 61.21" Global Strategy and plan of action on public health innovation and intellectual property https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf.
[2] See https://ipaccessmeds.southcentre.int/.
[3] Martin Luther King Letter from a Birmingham Jail, 1963.

ABSTRACT

Like other rights, patent rights are not absolute. There are situations in which their exercise can be limited to protect public interests. Such situations may arise, for instance, when access to needed pharmaceutical products must be ensured. Compulsory licenses and government use for non-commercial purposes are tools, provided for under most laws worldwide, that can specifically be used to address public health needs. This document is intended to provide legal guidance for the effective use of such tools, consistently with the international law.

Al igual que otros derechos, los derechos de patente no son absolutos. Hay situaciones en las que su ejercicio puede limitarse para proteger los intereses públicos. Esas situaciones pueden surgir, por ejemplo, cuando debe garantizarse el acceso a los productos farmacéuticos necesarios. Las licencias obligatorias y el uso gubernamental con fines no comerciales son instrumentos, previstos en la mayoría de las leyes de todo el mundo, que pueden utilizarse específicamente para atender las necesidades de salud pública. El presente documento tiene por objeto proporcionar orientación jurídica para el uso eficaz de esos instrumentos, de conformidad con el derecho internacional.

Tout comme d'autres droits, les droits de brevet ne sont pas absolus. Il existe des situations dans lesquelles leur exercice peut être limité pour protéger des intérêts publics. De telles situations peuvent se présenter, par exemple, lorsque l'accès aux produits pharmaceutiques indispensables doit être garanti. Les licences obligatoires et l'utilisation par les pouvoirs publics à des fins non commerciales sont des outils, prévus par la plupart des lois dans le monde, qui peuvent être utilisés spécifiquement pour répondre aux besoins de santé publique. Le présent document vise à fournir des conseils juridiques pour l'utilisation efficace de ces outils, conformément au droit international.

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ABBREVIATIONS AND ACRONYMS

ANDS	Abbreviated New Drug Submission
ARIPO	African Regional Industrial Property Organization
CLs	compulsory licenses
COVID-19	Coronavirus disease 2019
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Commission
EMR	Exclusive Marketing Rights
EPA	Environmental Protection Agency
EPO	European Patent Office
EU	European Union
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FTAs	Free Trade Agreements
GATT	General Agreement on Tariffs and Trade
IIPI	International Intellectual Property Institute
IPRs	intellectual property rights
LDCs	least developed countries
MFN	most-favored-nation
NAFTA	North American Free Trade Agreement
NDS	New Drug Submission
OAPI	Organisation Africaine de la Propriété Intellectuelle
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT	Agreement on Technical Barriers to Trade
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

INTRODUCTION

Patents – as well as other intellectual property rights – confer exclusive rights. This means that the titleholder 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] generally prevents 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.[3] 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 licenses" 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 license"[4] 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"[5] is an act by the government authorizing a government department to exploit by itself or through a contractor, public or private, a patented invention without the consent of the title-holder.

The right of States to limit the use of patents through compulsory licenses has been recognized since the end of the nineteenth 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 licenses and government use have become regular features in patent laws all over the world.[6] The right to use such mechanisms was recognized in the World Trade

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[1] In some countries, patents on the therapeutic *indication* or *use* of products are also allowed by the national law. Some countries such as India, Argentina, Ecuador, Egypt do not allow for the patenting of second indications or use. See Ducimetière, Clara "Second medical use patents – Legal treatment and public health issues", Research Paper No. 101, South Centre, December 2019. Available from https://www.southcentre.int/category/publications/research-papers/.

[2] Of course, there are other factors that affect prices of pharmaceutical products. See, e.g. WHO International price comparison of pharmaceuticals 2016. Available from https://apps.who.int/medicinedocs/en/m/abstract/Js23166en/, or WHO/HAI "Measuring medicine prices, availability, affordability and price components", 2008 available from https://www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf.

[3] This may namely occur in situations of health emergencies, like in the case of the COVID-19 pandemic.

[4] Often also called a "non-voluntary license".

[5] Also called "Crown use" under British and Commonwealth legislation.

[6] See, e.g. Correa 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 Inventions: historical perspective, legal framework under TRIPS and an Overview of the Practice in Canada and the USA.* UNCTAD-ICTSD Issue Paper No. 5, Geneva, 2003; WIPO, Compilation of provisions on compulsory licenses and government use by country, SCP/30/3, 2019. Available from https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-appendix1.pdf.

Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994.[7]

The concerns of developing countries about the possible impact of patents in the pharmaceutical sector led WTO to adopt, in November 2001, the Doha Declaration on the TRIPS Agreement and Public Health.[8] The Declaration confirmed, *inter alia*, that the granting of compulsory licenses was one of the clearly admitted flexibilities under the TRIPS Agreement,[9] and that WTO Members were free to determine the reasons for the granting of such licenses (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 licenses and the freedom to determine the grounds upon which such licenses are granted.

Compulsory licenses 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)[10] of patent-protected products,[11] and with regard to all kinds of products, including medicines (and their active ingredients), vaccines and diagnostic kits. A significant number of countries, including developed countries (such as Germany, Italy, USA) have granted compulsory licenses or government use relating to pharmaceutical patents.[12]

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[7] Article 31 of the TRIPS Agreement, however, does not refer to "compulsory licenses" but to "other use without authorization of the right holder". This provision applies to both compulsory licenses and government use.
[8] WT/MIN(01)/DEC/W/2, 14 November 2001, available from www.wto.org.
[9] On TRIPS flexibilities, see Velásquez G., Boulet P. *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement*. Health Economics and Drugs Series No. 7, Revised. Geneva, World Health Organization, 1999 (WHO/DAP/98.9); Musungu S, Oh C. *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* Study commissioned by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). 2006. Available from www.who.int/intellectualproperty/studies/en/index.html.; Velasquez, G., Correa, C., and Ido Pinto V.H., *Intellectual Property, Human Rights and Access to Medicines, A Selected and Annotated Bibliography Third Edition* (2020); Correa, C. M., "Patent Examination and Legal Fictions: How Rights Are Created on Feet of Clay", Research Paper 58, South Centre, December 2014. Available from https://www.southcentre.int/research-paper-58-december-2014/; Correa, C. M., "Implementing Pro-Competitive Criteria for the Examination of Pharmaceutical Patents", Research Paper 64, South Centre, February 2016. Available from https://www.southcentre.int/research-paper-64-february-2016/; Available from https://www.southcentre.int/research-paper-68-june-2016/; Correa, C. M., Velásquez, G., "Access to Medicines: Experiences with Compulsory Licenses and Government Use – The case of Hepatitis C", Research Paper 85, South Centre, April 2019. Available from https://www.southcentre.int/research-paper-85-april-2019/; Vawda, Yousuf A., "Compulsory Licensing Jurisprudence in South Africa: Do We Have Our Priorities Right?" Research Paper 90, South Centre, December 2018. Available from https://www.southcentre.int/research-paper-90-december-2018/; Vawda, Yousuf A., & Shozi, B., "Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa", Research Paper 103, South Centre, February 2020. Available from https://www.southcentre.int/research-paper-103-february-2020/; Gurgula, O., "The 'obvious to try' method of addressing strategic patenting: How developing countries can utilise patent law to facilitate access to medicines", Policy Brief 59, South Centre, April 2019. Available from https://www.southcentre.int/policy-brief-59-april-2019/.
[10] Article 31(f): "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use". See, however, below the waiver allowed under article 31*bis* of the TRIPS Agreement.
[11] 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.
[12] Correa, C., "Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries", T.R.A.D.E. Series Working Paper 5, South Centre, October 1999. Available from

The present Guide[13] aims to provide practical advice to governments, purchasing and funding entities, international organizations and non-governmental organizations (NGOs) about the modalities for the application of compulsory licenses and the utilization of government use provisions. It focuses on the utilization of such mechanisms for the purchase of locally produced or imported patent-protected pharmaceutical products. It contains two sections: in the first section, the application for and granting of a compulsory license is dealt with; the second section considers the case of government use, subject to the general conditions established by domestic legislation. The special requirements that may arise in cases where a compulsory license is granted in the **importing country** in accordance with the waivers approved by the Decision of 30 August 2003, finally ratified by WTO Members on 23 January 2017, as incorporated into Article 31*bis* of the TRIPS Agreement (which address situations of lack of or insufficient manufacturing capacity in pharmaceuticals)[14] are mentioned in the text, wherever appropriate.

It is important to note that **the concrete application and grant of a compulsory license or government use 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 licenses 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 acquire medicines should consider granting a compulsory license as the first option. As explained below, government use may in many cases be the simplest and fastest way for acquiring 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.

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https://www.dropbox.com/sh/wg8txyimpyu0tvp/AADJKywzs_5Yqzuhxo-Vm7Cja/T.R.A.D.E.%20Working%20Papers/EN?dl=0&preview=WP+5.pdf&subfolder_nav_tracking=1;
Correa, C. M., Velásquez, G., "Access to Medicines: Experiences with Compulsory Licenses and Government Use – The case of Hepatitis C", Research Paper 85, South Centre, April 2019. Available from https://www.southcentre.int/research-paper-85-april-2019/;
South Centre, "Compulsory Licenses and Government Use of Patented Medicines: Precedents Relevant To Address Covid-19". Available from https://ipaccessmeds.southcentre.int/covid-19-pandemic/.

[13] This Guide was originally published by the World Health Organization and in Correa, C., *Public Health Perspective on Intellectual Property and Access to Medicines: A Compilation of Studies Prepared for WHO*, South Centre, 2016. This document presents a revised and updated version of the Guide.

[14] Article 31*bis* of the TRIPS Agreement incorporates the WTO Decision of 30 August 2003 (WT/L/540, available from www.wto.org). And finally ratified by WTO Members on 23 January 2017**.** Available from https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf.

COMPULSORY LICENSES

Establishing the Need to Apply for a Compulsory License

The essential precondition for the application of a compulsory license is that the required product (or the process for its manufacture) is patented and a party is seeking to produce or 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 producer or supplier is a generic company that has not obtained a license to use the relevant patent(s).

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

Notes:

1. *The need to apply for a compulsory license 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.*[15] *According to 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, a process patent may be used to prevent the production, or 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 license 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 license 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.*[16] *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 license in the exporting country.*[17]
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 license if the patent is not in force in the country concerned, irrespective of the existence of such patent in other countries.*
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 commercialization or importation of pharmaceutical products. The facilities provided by the WHO Prequalification Project, established in 2001, can be used by countries and procurement agencies to acquire*

[15] Often patents are hybrid, that is, they include claims on both products and processes (and, where allowed, therapeutic uses of the product).

[16] On parallel imports see, e.g. Correa C. "The TRIPS Agreement: how much room for maneuver?" *Journal of Human Development*, UNDP, CARFAX Publishing, 2001, vol. 2, no. 1;
Calboli I., & Lee E., (editors), *Research Handbook on Intellectual Property Exhaustion and Parallel Imports*, Edward Elgar, 2016.

[17] 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.

products that have been tested and found to meet high quality standards so at to speed up access to required products.[18]

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 2033,[19] based on the extensions of the transitional period granted under article 66.1 of the TRIPS Agreement. This means that LDCs need neither to grant nor enforce pharmaceutical patents (if granted) and, therefore, the production, purchase and importation of such products can be made without compulsory licenses.

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 the extension of the transitional period, they do not grant or enforce patents on such products. Such statement 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 license 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 license 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 in 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.*[20] *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, ethers, polymorphs, etc., or new therapeutic indications. Although in some countries (e.g. India, Argentina, Egypt) legislation, guidelines or examination practices have 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 in patent offices is incomplete or difficult to access (particularly if computerized records do not exist).*
3. *Moreover, published titles or abstracts of patent applications or grants often do not provide sufficient information to identify the drug they refer to, especially when they*

[18] For more information about this Project, see www.who.int.

[19] In 2015 the WTO TRIPS Council extended until January 2033 the period during which the provisions of the TRIPS Agreement do not apply to pharmaceutical products in LDCs. See Decision of the Council for TRIPS of 6 November 2015 "Extension of The Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products". Available from https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm.

[20] See. for instance, I-MAK, "Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices", 2018. Available from https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.
According to a WIPO report, the antiretroviral "Ritonavir" has more than 800 patents. See "Patent Landscape Report on Ritonavir", available from https://www.wipo.int/publications/en/details.jsp?id=230&plang=EN.

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 license if a different formulation can be produced or 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 judicial 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 license 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 license (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,*[21] *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.*[22] *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 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 license is to determine, as mentioned, the existence of valid and enforceable patents in the country concerned.

The most straightforward way to determine whether a relevant and valid patent exists and whether a compulsory license is needed, is to consult the patent office about existing patents on a given product. Patent offices may however take 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 Trademark Office or the European Patent Office) may provide an indication that an equivalent patent may be found. However, as noted, patents are

[21] 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".

[22] 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.

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. MedsPaL, the Medicines Patent Pool's patents and licenses database provides information on the intellectual property status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in low- and middle-income countries.*[23] *There are also a number of private databases that can be accessed, usually for a fee.*

2. *The Patent Cooperation Treaty (PCT) allows for "international applications" for patents where the applicant may indicate the countries (that must be PCT members) where he intends to file a patent. The PCT offers an Online File Inspection System that permits interested parties to search for international patent applications (http://www.wipo.int/pctdb/en/search-adv.jsp).*

Establishing Whether the Acts to Be Performed are Subject to Patent Rights

Another important consideration to establish the need for a compulsory license 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.[24]

Note:
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 license, 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 Licenses

As mentioned, most patent laws in the world provide for the granting of compulsory licenses (and government use). However, the grounds under which such licenses 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 (as is the case with pandemic outbreaks)
- dependency of patents;
- licenses to remedy anti-competitive practices;

[23] See https://medicinespatentpool.org/resources/medspal/.
[24] This exception is generally known as "early working", regulatory review or "Bolar exception". See Correa, C. M., "The Bolar Exception: Legislative Models and Drafting Options", Research Paper 66, South Centre, March 2016. Available from https://www.southcentre.int/research-paper-66-march-2016/.

- lack of or insufficient working of the patent;
- excessive pricing;
- refusal to deal;
- public interest;
- public health.

Not only may the grounds for granting a compulsory license 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.[25]

As a result of these variations, before applying for a compulsory license 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 license 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 license.*

Compulsory License 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 license. It may be granted only for importation.[26]

WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector that have notified their intention to use the mechanism established by Article 31*bis* of the TRIPS Agreement,[27] are bound to notify the Council for TRIPS 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 31*bis* 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 license in accordance with Articles 31 and 31*bis* of the Agreement and the provisions of its Annex.

Notes:

1. *The possibility of granting compulsory licenses solely for importation has been confirmed beyond any doubt by paragraph 6 of the Doha Declaration on the TRIPS*

[25] 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 199/1 and 4.
[26] Some national laws seem to require local production of the protected product but, as mentioned, this is not required by the TRIPS Agreement.
[27] 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*, 2004. Available from https://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf. On the conditions to be complied with under this provision, see Correa, C., "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?", Policy Brief 57, South Centre, January 2019. Available from https://www.southcentre.int/policy-brief-57-january-2019/.

Agreement and Public Health and the subsequent WTO Decision of 30 August 2003,[28] *later incorporated as Article 31bis of said Agreement.*[29]

2. *It is important to note that, in the case of the 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 license itself.*

Applying for a Compulsory License

Who can apply?

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

Compulsory licenses 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 licenses, if allowed under their respective bylaws or statutes, subject to the applicable national law.

Notes:

1. *A compulsory license may be applied for by any natural or legal person with an interest in the execution of the license.*
2. *International organizations that are active in the purchasing and distribution of pharmaceutical products may apply for a compulsory license. They may also act on behalf of a government or other parties. As mentioned below, they may act as contractors or agents of Governments in the case of government use.*[30]

When can a compulsory license 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,[31] although it would be extremely costly and cumbersome, and in the last instance a wasteful exercise, to apply for a compulsory license 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 license, 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.

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[28] See WT/L/540, available at www.wto.org and Correa C. *Implementation of the WHO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*. Health Economics and Drugs Series No. 16. Geneva, World Health Organization, 2004 (WHO/EDM/PAR/2004.4).

[29] As noted, this amendment is still subject to acceptance by Members in accordance with WTO rules.

[30] See the section on government use below.

[31] 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.

How should the application be made?

The procedures to obtain a compulsory license 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 license?
- 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 license on reasonable commercial terms;
- scope and duration of the compulsory license.

Which is the competent authority to grant a compulsory license?

A compulsory license 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 licenses 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 license must be properly examined. In some cases, the intervention of the Ministry of Health is required, when the compulsory license 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.*

Domicile or establishment

Unless otherwise determined by the national law, a compulsory license can be requested by an applicant with or without domicile or establishment in the country where the compulsory license 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 license 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 license 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 license. These elements in the application may help the competent national authority to speed up the granting procedures.

Notes:

1. *Since compulsory licenses 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 license should be seen as an ordinary administrative or judicial act, and be considered only in the light of the relevant legal requirements. It is not an "extraordinary" or "exceptional" act. However, the issue is often politically sensitive.*[32] *Although not a party in the procedures, governments of the companies eventually affected by a compulsory license may involve themselves in discussions and other actions regarding the license. 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 licenses demonstrate a technical or economic capacity to execute the compulsory licenses they have applied for. The evidence to be provided will vary depending on whether the purpose of the license 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, 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 license, as the proper identification of the product (by its generic name) would be sufficient to establish the scope of the license.

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[32] See UN Secretary General High Level Panel on Access to medicines box 7 page 24: Obstacles to the use of TRIPS Flexibilities : A letter from the Permanent Mission of Colombia to the United Nations, as well as letters from civil society groups addressed to the co-chairs of the High-Level Panel, brought to light developments in Colombia. In early 2016, the Ministry of Health of Columbia adopted resolution 2475, declaring that access to imatinib, a medicine that appears on the WHO Essential Medicines List, was of "public interest" for the treatment of leukemia. The resolution was a pathway for the issuance of a compulsory license. The letters chronicle attempts by various domestic and foreign parties to dissuade the Colombian government from issuing a compulsory license as provided for by the TRIPS Agreement and the Doha Declaration. Available from https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf.

A compulsory license 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 license should ideally identify the owners of all the relevant patents. As noted, the lack of a precise identification of such patents, however, should not be a deterrent for the application for, and granting of, the compulsory license.

Notes:

1. *In the absence of identification of the title-holders, the prior request for a voluntary license (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 license 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 license.*[33]

Prior request for a voluntary license

In conformity with Article 31(b) of the TRIPS Agreement, in some cases there is a need to request a voluntary license from the patent owner before a compulsory license is applied for. Wherever this requirement applies, the applicant may need to prove that: (a) the patent owner has refused to grant a voluntary license 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 license may include:

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

The evaluation of whether a voluntary license has been requested or offered on reasonable commercial terms will lie with the competent authority for the granting of the compulsory license. 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 license.[34] The critical criterion will generally be the level of offered remuneration, which may be determined according to the methods described below.

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[33] 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.

[34] 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".

Some national laws establish the period within which the patent owner is bound to indicate its acceptance or refusal to grant a voluntary license on reasonable commercial terms.[35]

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

- address a national emergency or other circumstances of extreme urgency (as in cases of pandemic outbreaks)
- 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 license.

Notes:

1. *A request to obtain a voluntary license 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 license (see section on government use below).*

Scope and duration of a compulsory license

Depending on the national law, the act granting a compulsory license 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 license 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 license can also export, provided that they predominantly supply the domestic market of the country where the license has been granted (Article 31(f) of the TRIPS Agreement).[36] This limitation, however, does not apply in cases where the compulsory license is granted to remedy anti-competitive practices (Article 31(k) of the TRIPS Agreement).

In filing an application for a compulsory license, the applicant may either request it without any limitation with regard to the scope of use of the patent or duration of the license, or deliberately limit the application to certain acts and duration.

In cases, for instance, where the only intended purpose of the compulsory license 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 license, the stronger will be the opposition of the patent owner (and of its host country's government).

With regard to duration, it is advisable to request the compulsory license 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 license.

[35] In Argentina, for instance, the period to accept or refuse a request for a voluntary license is 150 days (Law 24.481, as amended by Law 24.572, Article 42).

[36] This limitation may be waived in accordance with the system adopted by the afore-mentioned Decision of 30 August 2003, now the new Article 31*bis* of the TRIPS Agreement.

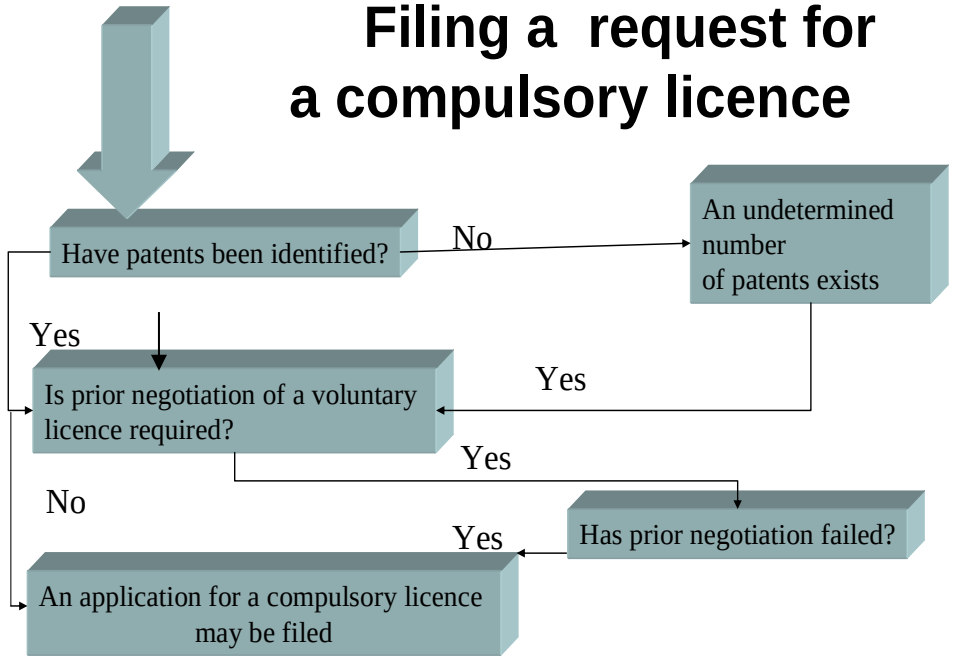
Notes:

1. *It should be recalled that, in all cases, a compulsory license 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 license.*
2. *It should also be borne in mind that, according to some national laws, a compulsory license may be revoked if not utilized within a certain period.*
3. *Moreover, a compulsory license 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 license.*
4. *Compulsory licenses 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.*[37]

Summary

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

Figure 1



[37] It is to be noted, however, that the Decision of 30 August 2003, now Article 31*bis*, 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, 2004*, available from https://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf.

Procedures for Granting a Compulsory License

The procedures for processing an application for a compulsory license 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".[38]

In accordance with some national laws, once an application for a compulsory license 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 license 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 licenses 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 license

When the requirements for the granting of a compulsory license have been complied with, the competent authority should grant it. While some laws clearly mandate the granting of a license in such circumstances,[39] in other cases the laws 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.[40]

Validity of the act granting a compulsory license

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

- legal background and justification for the granting of a compulsory license;
- 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 license.

Like any other administrative (or judicial) act, the validity of an act conferring a compulsory license 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)).

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[38] See Articles 62.4 and 41.2 of the TRIPS Agreement.

[39] 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 implemented the WTO Decision of 30 August 2003.

[40] 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.

An appeal questioning the validity of the act granting the compulsory license may delay for a long time the execution of the license 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 license that does not suspend its effects,[41] that is, the appeal would not impede the immediate execution of the license, at the option of the compulsory licensee.

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

Remuneration

A key aspect in the granting of a compulsory license 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 license that is intended to address a public health need, such as ensuring access to pharmaceutical products at the lowest possible price.

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 2-4 per cent of the price of the generic product, and can be increased or decreased by as much as 2 per cent for a range of 0-6 per cent.
b) The 2001 United Nations Development Programme (UNDP) Human Development Report proposed a base royalty rate of 4 per cent of the price of the generic product. This can be increased or decreased by 2 per cent, 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 per cent 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 per cent. For most countries in Africa, the rate is less than 1 per cent.
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 per cent 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 license should specify how the payment will be made, notably:

[41] The TRIPS Agreement does not regulate the effects of judicial or administrative appeals.

- 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 license with regard to the remuneration to be paid by the applicant.[42]

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.

Waiver of the obligation to pay remuneration

In the case of a compulsory license granted under Article 31*bis* of the TRIPS Agreement, the obligation to pay a remuneration is waived in the importing country when adequate remuneration pursuant to Article 31(h) has been 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,[43] which neither confers property nor exclusive rights,[44] 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 license 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 license without the respective marketing approval. In order to avoid this situation, an application for a compulsory license should include, where necessary, a petition for a waiver of any restrictions that may stem from data exclusivity.[45]

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[42] 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".
[43] 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. Available from https://www.southcentre.int/book-by-the-south-centre-2002/.
[44] 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.
[45] 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 licenses apply. The main difference between compulsory licenses and government use is that the former are conferred – upon request – to a third party, while the latter permits the use of a patent by the government itself or by a contractor (public or private) or agent appointed by it.

There is no need for a formal request by 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 licenses in cases where the production or purchase of pharmaceutical products is made for 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.[46]

Who Can Authorize the Use of a Patent?

Depending on national laws, government use can be decided in a decentralized manner 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.

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.

[46] See Article 44.2 of the TRIPS Agreement.

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[47]. 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 licenses, 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 indicates 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 licenses, 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.*

[47] See Reichman J. op. cit.

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