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Compulsory licensing

Compulsory licensing (CL) – or the threat of using one – has achieved significant price reductions of essential medicines both in developed and developing countries, thus ensuring adequate supply to patients. However, the use of this legal provision remains highly political and a lot of uncertainties or misconceptions circulate about it. The present factsheet aims at providing key information regarding what compulsory licensing is and how to use it.

What does the international legal framework says:

Compulsory licenses correspond to a legal provision of the international trade rules, described by the WTO's agreement on intellectual property (Trade-Related Aspects of Intellectual Property Rights, TRIPS) in its article 31¹ ("Other Use without Authorization of the Right Holder") and mentioned in the Paris convention for the Protection of Industrial Property from 1883.

Just like patents, compulsory licenses can apply to any «invention» and be used in any field of technology. A compulsory license gives the possibility to a State, sovereign on its territory, to **authorize a third party or a state entity to use** –meaning to make, use, offer for sale, sell, import or export– **a patent without the authorization or the patent holder**. To put it simply, it lifts the monopoly rights that the national authority (usually a patent office or office of industrial property, see factsheet n°X)² has allocated to a patent holder when it granted the patent. Thus, a generic version of a patented medicine can be produced, imported or exported under compulsory license.

Compulsory licensing is often referred to as one of the "flexibilities" of the TRIPS agreement as it introduces the possibility to limit or override exclusive rights. It was brought to the public attention in the context of international debates and conflicts at WTO over access to medicines. Countries from the global South obtained the adoption of a declaration called **Declaration on the TRIPS agreement and public health** also referred to as the *Doha declaration* that stated that "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted"³ Contrary to what is sometimes said, there is no limitation of the use of compulsory licenses to situations of emergency or epidemic.

1. Text available here: [http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm].

2. In some cases, as in Europe or in East Africa, a regional patent office was established by a regional agreement.

3. Text available here: [http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm].

These licenses are called «compulsory» precisely because it is an obligation imposed by the national authorities, contrary to **voluntary licenses** that are granted by the patent owner to other companies to authorize a third party to use the product or process that the patent(s) cover(s) (TRIPS, article 28(2)). However, **royalties** have to be set and paid to the patent owner to compensate for the use of the patent.⁴

As the TRIPS agreement limits the use of CLs «predominantly» for domestic use (article 31.f) (which can be understood as 51% of the production needs to be for domestic use), the WTO Members came up to an agreement on August 30, 2003 to amend TRIPS in order to allow the issuance of CLs for export when countries do not have to possibility to manufacture medicines for themselves⁵.

What does national laws say:

Although compulsory licensing is defined in TRIPS, to be implemented it had to be specifically mentioned in the national law (or regional in the case where countries have signed a regional agreement governing patents). It is usually in the law on patents, on industrial property or on intellectual property). TRIPS provides a general framing but leaves a lot of room to individual WTO Member States. Thus, the crafting of the law and regulations that specify the details about how it should be implemented lies in the hands of national legislators. As a consequence, there are significant differences in the compulsory licensing provisions from one country to the other. Some laws are more flexible than others, some on the contrary are more restrictive than WTO's standards (this happened especially when the law was designed under the pressure or with the advise of the industry or of foreign trade partners from wealthy countries).

Depending on the language, the national legal tradition or even the purpose of the license, different names are used in national laws to refer to compulsory licenses: non voluntary license, non contractual license, license for government use, license to the public sector, crown use provision, licence d'office, etc.

Based on TRIPS there are basically two different categories of license of such licenses. What is commonly called «compulsory license», also referred to as a «non-voluntary license», is the use of patents without authorization of the right holder and can only be granted where the patent holder has refused (or did not respond to the request), over a reasonable period of time, to grant a voluntary license on reasonable terms. Another type of compulsory use of a license authorized by TRIPS is the use by governments for their own purposes: it is usually referred as public non-commercial use, or government use (or crown use). In such situation, as in other circumstances set by TRIPS⁶, the requirement for prior negotiations is waived.

National law prescribes specifically **how compulsory licenses can be granted**: whether it is through an administrative decision – often a decree by a Minister or the head of a national institution –, or through a court decision. Although the WTO leaves member states free to decide of the reasons why they issue compulsory licensing, in many countries national laws list the grounds for compulsory licensing: insufficient/non-working ground (the patent holder fails to use their patent or use it insufficiently); anti-competitive practices by the patent holder; the existence of dependent or secondary patent (an invention cannot be exploited without infringing another patent); national emergency/urgency; the case of “non-commercial use” or “government use” for public policy objectives or public interest.

National law also sets the conditions required to request or obtain a compulsory license: who can ask for it (ex: anybody), when it is possible to ask for it (ex: as soon as a patent is issued/4 years after a patent is issued/ etc.), after an effort was made to obtain the authorization from the right holder, or not, etc.

4. See the guidelines about the payment of royalties published by the World Health Organization [http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf].

5. For more information, see for instance: [<https://www.ip-watch.org/2017/01/30/wto-members-celebrate-treaty-amendment-medicines-access-look-ahead>].

6. According to Article 31.b of the TRIPS Agreement, for “national emergencies”, “other circumstances of extreme urgency” or “public non-commercial use” (or “government use”) or anti-competitive practices, there is no need to request first a voluntary licence from the patent holder.

Implementation: to launch a request for compulsory licensing step by step

STEP 1. Identify the patent(s) covering a medicine. First, you need to find out if the medicine is covered by a valid patent, or by several valid patents. In order to do that you can make a search by yourselves (see factsheet n°X) and/or ask the patent office. Experts in the activist community can also help you with this phase.

If there is one or several valid patent covering the medicine, you need to see if it is/they are in the way of generic access? Some patents may cover the process to manufacture the medicines, a therapeutic indication or a method of administration (depending on what the national law allows, see factsheet n°X), but not cover the active ingredient *per se* and not prevent the production or importation of generic versions of the medicines.

You also need to check whether each existing patent is really valid. To do so you have to check the status of the patent: was it properly granted (or is it still under examination)? In some case a patent can be revoked. To be valid the fees need to be paid by the patent owner every year. These information can be transmitted by the patent office – increasingly patent offices put online database on their website that allow you to do searches.

You do not need to identify all the patents that cover the medicine (in some case there maybe dozens). But as long as you were able to identify one valid patent that prevents the use of generic, compulsory licensing is the only way to lift the monopoly. Practically when the compulsory license is granted the administrative order or the court decision can mention that it applies to all the patents covering the medicine, without naming each of them.

STEP 2. Check what the national law on patent says. As there are differences between countries, you need to check exactly what the national laws and regulations say. It may be necessary to talk with a local lawyer to analyses in detail what the law says. Each word counts. You will need to understand which institution can grant a compulsory license, how the conditions are set. If you want to introduce an official request for the government or court of issue a compulsory license you need to see exactly who is allowed to do that. Depending on the country, the law is different: in some case it is anybody, in other cases it is only the parties who will then be able to use the patent (for instance, import, produce or market the medicines). Where the government issues a CL in cases of national emergency, extreme urgency or public non-commercial use, it is usually a government department like the Ministry of Health that initiates the process. However civil society groups can play an important role in such cases by bringing high priced patented medicines to the notice of the government or filing petitions or request for CLs. For instance in Malaysia, people living with HIV and hepatitis C presented a petition for a CL on sofosbuvir to the Minister of Health in 2015. Two years later a CL on sofosbuvir was issued by the government.

STEP 3. Check what the national regulation on pharmaceutical products and marketing authorization says about generic drugs.

In some countries and if you want to rely on importation, you need to be particularly attentive to the rules that apply to products that are not manufactured locally. Indeed, these procedures may be long and delay the marketing of a generic drug for several years. Experts in the activist community can also help you with this aspect.

If there is a problem with a specific medicine in your country, before requesting a compulsory license it is important to check if **generic versions of the medicine are already produced somewhere in the world and at what price they are sold.** Here also patient groups or NGO experts from other countries may be able to help and provide information.

You may also want to consider whether **local production is an option.** However you have to bear in mind that it takes at least a few years for local manufacturers to be ready to launch the production of a new product. They would need to do reverse engineering of the medicine or to gain access to the know-how needed from somewhere (through a license contract with another producer, for example). This would most probably require that they

adapt their production line to the specificity of the drug and the associated regulation (with some drugs good manufacturing practices are very demanding). This could be a long process, but it may be worth starting it while working on importing the medicine at first (this is, for instance, what Thailand and Indonesia have done – import while local government producers gear up to produce).

During the whole process, dialogue with MOH or other ministries can ease or facilitate the action, waive regulatory requirements or profile public health interest in the public space in cases of attacks by industry lobbyists in the media or political forum.

Some examples of compulsory licensing granted recently

- In September 2017, the Malaysian government approved the use of Rights of Government under Patent Act 1983 (Act 291) to exploit the patented invention of sofosbuvir tablet 400mg to treat people with hepatitis C. Find out more here: [<http://www.apnplus.org/?p=1272>].
- In July 2014, a presidential decree granted a licence to the Ecuadorian Intellectual Property Institute (IEPI) to appoint local companies to produce several cancer medicines (sunitinib, certolizumab, etoricoxib, mycophenolate sodium). CLs had already been granted in the

country in 2009 and 2013 on HIV medicines. Find out more here: [<https://www.ip-watch.org/2014/09/12/guest-post-nine-mandatory-licenses-allow-greater-access-to-medicines-in-ecuador/>] and [<https://www.ihs.com/country-industry-forecasting.html?ID=1065991764>].

■ In March 2012, in India, the Controller of the Indian Patents Office granted a compulsory licence to NatcoPharma to manufacture and sell Bayer AG's patented anti-cancer drug sorafenibtosylate (Nexavar®) to treat kidney and liver cancer patients. Find out more here: [<https://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/>].

■ In septembre 2012, a government use licence was issued in Indonesia by the President on seven antiretroviral drugs (efavirenz, abacavir, ddI, lopinavir/ritonavir, tenofovir, the combinaisons tenofovir+emtricitabine et tenofovir+emtricitabine/efavirenz) and an hepatitis B medicines, for the Ministry of Health to appoint local companies to manufacture the medicines. CLs had already been granted in the country in 2004 and 2007. Find out more here: [http://www.scielo.org.co/scielo.php?pid=S0121-40042012000300002&script=sci_arttext&lng=en].

■ Between 2006 and 2008, the Department of Disease Control, under the ministry of public health of Thailand issued several compulsory licenses. In November 2006, a compulsory license was granted for the antiretroviral (ARV) drug, efavirenz (EFV). In January 2007, two licenses were granted for the second-line ARV combination of lopinavir/ritonavir (LPV/r) and for clopidogrel, an antiplatelet agent used in the treatment of coronary artery disease. In January 2008, four licenses were granted for cancer drugs, letrozole, docetaxel, erlotinib, and imatinib, which are used in the treatment of breast and lung cancers, gastrointestinal stromal tumor and leukaemia. To see what a compulsory license can look like, check here: [http://www.cptech.org/ip/health/c/thailand/thai-cl-kaleta_en.pdf] or here: [http://thailaws.com/law/t_laws/tlaw10807.pdf]. Find out more here: [<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3180369/>].

FIND OUT MORE (SOURCES AND RESOURCES)

- Khor M. (2009, second edition), "Patents, compulsory licences and access to medicines: some recent examples", available at [www.twn.my/title2/IPR/pdf/ipr10.pdf].
- Love J. (2014), "KEI's comments on Special 301", March 7, 2014 (Annex B), available at [<http://www.keionline.org/node/1976>].
- Ministry of Public Health and National Health Security Office (NHSO) of Thailand (2007), *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three patented Essential Drugs in Thailand*, available at [<http://apps.who.int/medicinedocs/documents/s18718en/s18718en.pdf>].