Compulsory licensing is a mechanism aiming at exploiting a current patent further to the authorization of the relevant national authorities but without its holder’s consent. This authorization or license can be given to a third party, a state agency or a party acting on the state’s behalf (in these latter cases, it is called “government use”).

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What may compulsory licensing bring?

The purpose of the compulsory licensing (CL) depends on the ground it is issued on (see next section). Yet, we can identify the following objectives:

Compulsory licensing as a corrective tool for the market.

In such cases, CL is granted to tackle anti-competitive practices by the patent holder and enhance competition in a given market. Examples of such a use of CL would be Italy’s 2005 and 2006 CL on Imipenem Cilastatina and Sumatriptan Succinate (pharmaceutical sector) or the European Commission’s 2007 mandatory licensing of Microsoft Corp. ’s interoperability information (computer and software sector).

Compulsory licensing as remedy to sub-optimal supply or exploitation of an invention.

In this case, the CL is issued in order to provide the national market (or – in very specific cases - a foreign market) with the level of supply of a given product it needs. Examples of such a use of CL would be US patients’ 2010 request to the authorities for a CL on Fabrazyme (the request was eventually denied); or Canada’s export of ARV to Rwanda under CL (so-called “Paragraph 6 System” explained below) in 2009.

NB: A compulsory license does not “break” the patent it applies to. The patent holder retains certain rights (see below).
Compulsory licensing as a price reduction tool.
This has been a very mediatized use of CL for pharmaceutical products in the last 20 years. Under such a CL (or the threat of one), countries seek to ensure a lower price for a given product to their population.
Examples of such a use of CL would be Brazil’s 2007 CL for efavirenz (ARV drug) or Canada and US’s threat to issue one for anthrax medicines in 2001 (resulted in a discount from the companies involved).

Compulsory licensing as an industrial policy tools.
It is suggested that certain countries have extensively used CL and other flexibilities as an indirect way to support the development of a national industry.

How compulsory licenses can be issued?

BASIC REQUIREMENTS IN INTERNATIONAL LAW
International agreements provide basic requirements for a CL to be issued. Yet, they also recognized the full competence of state in defining when and how, CL can be granted.

The main grounds for requesting or issuing compulsory licenses are:
> the patent holder fails to exploit their patent or exploit it insufficiently (insufficient/non-working ground)
> the patent holder is involved in anti-competitive practice relevant to the patent of interest.
> public interest or national emergency/urgency
> dependent or secondary patent
> “non-commercial use” or “government use” for public policy objectives or public interest

For example, Spanish law on Patent recognizes non-working or insufficient working by the patent holder; export imperative (to countries that cannot satisfy their national demand); dependent patent; and public interest (in health or defense) as ground for the granting of a CL.

Usually, the party seeking a CL is expected to try negotiating a voluntary license with the patent holder before turning to a compulsory license. However, this step can be skipped in certain cases (see next section).

In any cases, issuing a CL does not ban the patent holder or its products from a market: they can still be marketed alongside those produced under CL. The patent holder is also entitled to, as the TRIPS agreement provides - a “fair” remuneration against the issuing of a CL.

Finally, CL is primarily designed to satisfy the needs of the national market and does not originally aim to be exported. An exception (called the Paragraph 6 System) was introduced in the Doha Declaration and endorse in 2003 by the General Council in order to address the needs of countries that do not have any or sufficient manufacturing capacities to fully exploit compulsory licensing. A specific procedure applies to this system.

However, over 30 countries (including Spain) have already announced they wouldn’t import medicines under Paragraph 6 System – although some of them (such as EU countries or Canada) have agreed to the possibility of exporting to a country with no or insufficient manufacturing capacity under system (see CE Regulation no 816/2006).

Outside of the “Paragraph 6 System”, importing/exporting a product manufactured under CL is much more complex. First of all, the CL itself may specify the scope of the CL and whether the product might be exported. For example, Italy’s 2007 CL on Finasteride (a pharmaceutical active ingredient) allowed exports whereas Ecuador’s 2010 CL on ARV allowed import but limited the use of produced/imported ARVs to national needs.

Exporting and marketing a compulsory-licensed product in a country without such a license may also considered as patent infringement and subject to litigations. As a result, outside of the Paragraph 6 System, the use of parallel import and exhaustion rule to export or import CL products may still be limited by patent rights.

1) A second invention/patent considered as major technical advance, cannot be exploited without infringing another patent. In such case, the owner of the first (blocking) patent is entitled to a cross-license to the secondary patent.
THE STEPS TO BE TAKEN TO GRANT A CL ARE DEFINED BY NATIONAL LAW (PROVIDED THAT THE REQUIREMENTS ABOVE ARE RESPECTED) AND ALSO DEPEND ON THE GROUND ON WHICH THE CL IS BASED. THUS, EACH COUNTRY DEFINES:

1) The grounds to base a CL request upon (see above)

2) The requirements that have to be met and demonstrated by the party requesting or issuing the CL.

This may vary according to the ground used. For example, the TRIPS agreement provides that in case of “anti-competitive practice”, “national emergency” or “extreme urgency”, or “government use”, the mandatory negotiations of a voluntary license before requesting a CL may be skipped.

3) The competent authority to review the case and grant a CL as well as the procedure to be followed.

A CL may be issued by the national patent control authorities (as in India in 2012 for a cancer drug and Ecuador in 2010 for ARVs); the market regulation and surveillance authorities (as in Italy in 2005), the government or some of its ministries (as in Thailand in 2006 for ARVs), or by a court of law or an adjudicating body (as in Germany for a Fabry’s Disease drug in 2011/12). In any case, the patent holder is entitled to a legal review of its case.

In the case of Spain, CL based on public interest or export imperative can only be issued by a royal decree, further to a government decision. CL based on public interest must be granted according to the proposal of the Ministry of the Industry jointly with any other relevant Ministries (health, defense...). CL for national defense purposes also have specific rules.

4) The conditions of implementation (remuneration of patent holder, appeal mechanisms, definition of a breach the license…) and the scope (geographical, duration, quantity produced…) of CL may have to follow requirements defined by law but may also be defined on a case-by-case basis.

BASED THESE LEGAL REQUIREMENTS, THE COMPETENT AUTHORITY WOULD DEFINE FOR EACH CL GRANTED:

- the patent(s) covered (with associated extensions if needed) and the patent holder;
- the beneficiary/ies of the CL – unless the CL is non-exclusive (i.e. allow any relevant parties in the country to exploit the CL);
- the scope of the CL (duration, quantity of product covered, country/ies covered and (im)possibility of export/import…).
- the condition of implementation (beyond those included in the law).

2) These “flexibilities” have also been used to provide markets with further supply of lower-priced medicines.
3) CL based on the other grounds follows a different procedure under the authority of the Spanish patent office.
BRINGING GENERIC TO THE MARKET WITH COMPULSORY LICENSING

As mentioned earlier, CL can contribute to address certain issues created by the patent system. However, issuing a CL may not guarantee a quick introduction of affordable medicines into a market.

Firstly, a product produced under compulsory license may not be exempted from other regulatory procedures needed for its effective marketing (market authorization, conformity and quality assessments, ...) – thus delaying its introduction into the targeted market.

For examples, the 3-year-long procedure to have Canadian ARV exported to Rwanda under the Paragraph 6 System was mainly due to factors and procedures unrelated to the system itself. Likewise, when American patients requested a CL on Fabrazyme to deal with a national shortage in 2010, their request was denied by the NIH partly because CL wouldn’t overcome all the barriers (such as data exclusivity clause) that would be preventing a CL generic to be available on the American market. The NIH argued that even if a CL was granted and a drug produced under CL, existing barriers to have this drug allowed on the market wouldn’t be overcome by this CL (thus preventing the product to be distributed).

Thus, efforts to obtain or grant a compulsory license for a given medicine have to include careful consideration and planning in order to shorten and/or couple these other procedures with those of the CL and so, ensure that the targeted product is made available as soon as possible.

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