

Compulsory Licensing in Eighteen Middle-Income Countries



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Author:

Gaelle Krikorian

Edited by:

Sergiy Kondratyuk, Detrich Peeler, Tracy Swan

Graphic Design:

Anthea Duce

Contributors:

Riany Ambunsuri, Felipe Carvalho, Mari Chokheli, Marisabel Colorado, Maria Lorena Di Giano, Do Dang Dong, Marwa El Harrar, Evghenii Alexandrovici Goloşceapov, Sergey Golovin, Anastasiia Homeniuk, Chalerm Sak Kittitrakul, Sergiy Kondratyuk, Alma De Leon, Edward Low, Ferry Norila, Shiba Phurailatpam, Umesh Sharma Hidangmayum, Maria Shibaeva, Mykyta Trofymenko, Aditya Wardhana.

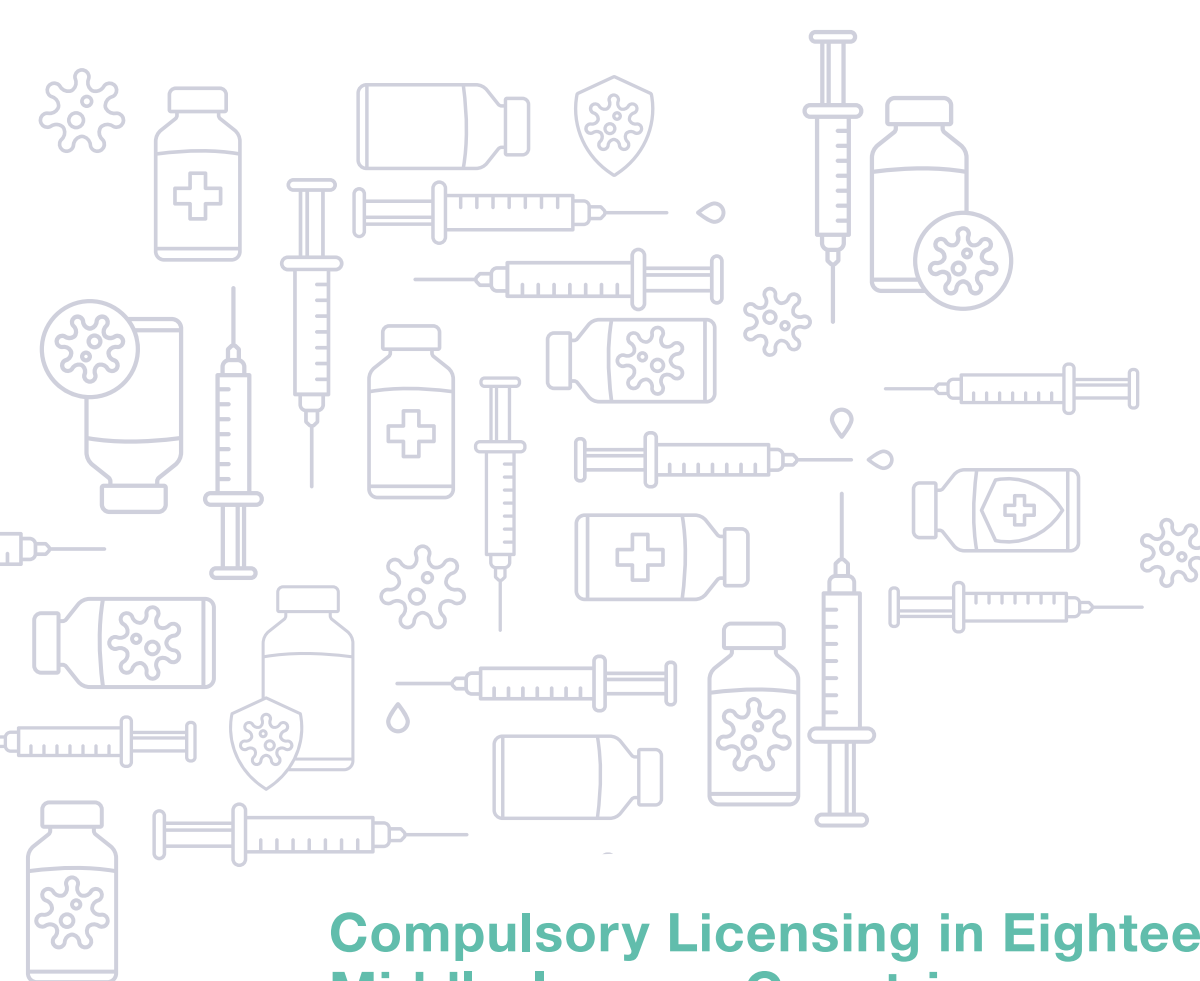
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About

[Make Medicines Affordable](#) (MMA) consortium works to bring down the prices of HIV, TB, Hepatitis C, and COVID-19 medicines by removing intellectual property and other access barriers. The MMA consortium is led by civil society organizations from over 20 countries. They include patients, lawyers, health experts and activists, all choosing, instead, to challenge the IP measures that benefit profit but not people.

The [International Treatment Preparedness Coalition](#) (ITPC) is a global coalition of PLHIV and community activists working to achieve universal access to optimal HIV, HCV and TB treatment of those in need. Formed in 2003 by a group of 125 HIV activists from 65 countries at a meeting in Cape Town, ITPC actively advocates for treatment access in eight regions across the globe. ITPC believes that the fight for treatment remains one of the most significant global social justice issues. ITPC is an issue-based coalition. ITPC actively advocates for treatment access through three strategic focus areas:

- [#MakeMedicinesAffordable](#)
- [#WatchWhatMatters](#)
- [#BuildResilientCommunities](#)



Compulsory Licensing in Eighteen Middle-Income Countries

Introduction and Summary

This study provides an analysis of provisions related to compulsory licensing (CL); it was created to assess their utility and potential impact on access to health products in **18** middle-income countries (MIC).¹ This study was based on the work of community-based activists.

This study presents a selection of the most significant provisions, by country, in the following three areas:

1. The type of legal mechanisms that exist for granting CL;
2. The scope and grounds provided to issue CLs;
3. The conditions required to request, issue and implement CLs.

This study also provides a **summary of ideal provisions to include in laws and regulations, and problematic trends in CL legislation and procedures.**

This study is to **identify provisions that facilitate the use of CL/ GUL**, especially those that result in increased access to health products, and **provisions that narrow the possibility of its use.**²

The use of CL varied by country; for more detailed information on the medical products and dates by country, see Annex 1.

¹ Argentina, Belarus, Brazil, Ecuador, El Salvador, Georgia, Guatemala, Honduras, India, Indonesia, Kazakhstan, Kyrgyzstan, Malaysia, Morocco, Russia, Thailand, Vietnam and Zimbabwe.

² Results in the tables reflect the legal landscape when the study was conducted (2021-2022); they may have changed since then, due to the adoption of new laws and regulations, or the amendment of existing ones.

Table 1.
CL Implementation, by Country

| Number of countries that have not granted a CL | Number of countries that have granted a single CL | Number of countries that have granted two CL | Number of countries that have granted three CL | Number of countries that have granted four CL | Number of countries that have granted seven CL | Number of countries that have granted nine CL |
|--|---|--|--|---|--|---|
| 6 | 5 | 2 | 2 | 1 | 1 | 1 |

In six of these 18 countries CLs have never been granted. In five countries, one CL has been granted; in two countries two CLs have been granted; two countries have granted three CLs; one country has granted four CLs; one country seven, and in one nine CLs have been issued to date (see Annex 1 for more detailed information).

1. Decision-Making Mechanisms for Issuing CL/GUL

The TRIPS Agreement does not set requirements on state authority for granting CLs or GUL, leaving it up to countries to define whether a judicial or administrative body can authorize the use of a patent by a third party without authorization of the right holder. **The mechanisms for implementing compulsory licenses vary** by country, according to its laws and regulations.

Table 2.
Mechanisms for Granting CL, by Country
(for detailed information, see Annex 2 and Annex 3)

| Country | Mechanism for granting CL through administrative decision | Mechanism for granting CL through executive action | Mechanism for granting CL through the court | Comments |
|-----------|---|--|---|---|
| Argentina | Yes; CLs are issued through the patent office or another governmental body; there is no judicial route for granting CLs | YES; grounds may be limited | | |
| Belarus | NO | | YES | There is no explicit mention of any other mechanisms for issuing CLs or GULs in this country. |
| Brazil | | YES; grounds may be limited | YES | |
| Ecuador | | YES; grounds may be limited | NO | |

| Country | Mechanism for granting CL through administrative decision | Mechanism for granting CL through executive action | Mechanism for granting CL through the court | Comments |
|-------------|--|--|--|---|
| El Salvador | NO | | YES | There is no explicit mention of any other mechanisms for issuing CLs or GULs in this country. |
| Georgia | | YES; grounds may be limited | NO | |
| Guatemala | | YES; grounds may be limited | NO | |
| Honduras | | YES; grounds may be limited | NO | |
| India | | YES; grounds may be limited | This option is explicitly mentioned in the law; however, courts in India have wide-ranging powers and can choose to exercise them by granting CLs. They can also issue guidance for granting a CL. | |
| Indonesia | Yes; CLs are only issued <u>through</u> the patent office; there is no judicial route for granting CLs | YES; grounds may be limited | NO | |
| Kazakhstan | NO | | YES | There is no explicit mention of any other mechanisms for issuing CLs or GULs in this country. |
| Kyrgyzstan | | YES; grounds may be limited | YES | |
| Malaysia | Yes; CLs are issued <u>through</u> the patent office or another governmental body; there is no judicial route for granting CLs | YES; grounds may be limited | NO | |
| Morocco | | YES; a CL can be issued for only for health- and defense-related matters | YES | There is no explicit mention of any other mechanisms for issuing CLs or GULs in this country. |

| Country | Mechanism for granting CL through administrative decision | Mechanism for granting CL through executive action | Mechanism for granting CL through the court | Comments |
|----------|---|--|---|----------|
| Russia | Granted only by government request | YES; grounds may be limited | YES | |
| Vietnam | | YES; grounds may be limited | NO | |
| Thailand | Yes; CLs are issued through the patent office or another governmental body; there is no judicial route for granting CLs | YES; grounds may be limited | NO | |
| Zimbabwe | | YES; only in the case of abuse or insufficient use of the patent. ³ | YES | |

Only a small number of countries **have no mechanisms for granting CLs by administrative decisions**. In our sample, only Belarus, El Salvador and Kazakhstan lacked this mechanism. In these countries, CLs must be granted by a court decision; there is no explicit mention of any other decision-making mechanisms for issuing CLs or GULs.

Most countries have a non-judicial option to grant a CL through executive action. In some countries, **CLs that are granted through administrative act can only be for government use**, and, in the case of Russia, only through a request from the government. In the case of Argentina, Indonesia, Malaysia, and Thailand, the only option for **granting** is through the patent office or another governmental body; there is no judicial route to grant CLs in these countries. In Argentina, only the patent office can grant a CL. In some countries **no option for granting CLs through the courts**. In India, the option to grant a CL is explicitly mentioned in the law; however, courts in India have wide-ranging powers and can choose to exercise them by granting CLs. They can also issue guidance for granting a CL.

The best scenario is the ability to grant CLs through **executive authorities and the courts** (Brazil, India, Kyrgyzstan, Morocco, Russia, and Zimbabwe).

In countries that only have a judicial process, the interpretation of the law sometimes leaves room to maneuver. In Belarus, government officials noted that during exchanges with access advocates, mechanisms they have used in the past are similar to CLs (a type of special import permit).⁴ In such cases, it would be of interest to explore ways to either clarify the interpretation of the law and the sustainability of the option, or to discuss minor amendments to the law that would allow governmental bodies to use CL.

³ It is interesting to note that in Zimbabwe (Art 31.6.f) it is explicitly mentioned that “for the purpose of determining whether there has been any abuse of the monopoly rights under a patent, due regard shall be had to the fact that patents are granted not only to encourage invention but also to secure that inventions shall so far as possible be worked on a commercial scale in Zimbabwe without undue delay.

⁴ According to some sources, the legal basis was weak or absent, the importation of generics took place while the company was not present on the Belarus market.

In Kazakhstan, article 12 of the patent law⁵ provides an exception to patent rights that can serve as an indirect basis for other type of CLs or GUL (in addition to the compulsory license allowed under article 11 of the Kazakh patent law that is for non-working of a patent). It allows government use, even if the text does not mention government use *per se*,⁶ and it can be used by generics manufacturers and suppliers as a defense in courts against patent infringement lawsuit:



Article 12.

*Actions that are **not recognized as a violation of the exclusive rights** of the patent owner.*

The following shall not be recognized as a violation of the exclusive rights of a patent owner: (...)

*3) use of such means in **case of emergencies (natural disasters, catastrophes, major accidents) with immediate notification of the patent owner and payment of proportional compensation to the patent owner;***

In Belarus, a similar provision is described in article 10, but with a broader, non-exhaustive, list of situations:



Article 10.

*Acts not recognized as infringing the exclusive right of the patent owner are not recognized as a violation of the exclusive right of the patent owner: (...) use of an invention, utility model, industrial design under **extraordinary circumstances (natural disasters, catastrophes, accidents, epidemics, epizootics, etc.)** with notifying the patent holder of such use as soon as possible and paying him proportionate compensation;⁷*

In Kyrgyzstan, article 12 of the law clearly provides for government use with the same sort of language, except that it explicitly mentions “the Government of the Kyrgyz Republic” is in the text, making it clear that government use is allowed:



Article 12. Duties of the Patent Owner and Compulsory Licenses

*In extraordinary circumstances (natural disasters, catastrophes, major accidents, epidemics), and in the interests of national security, the **Government of the Kyrgyz Republic** has the right to grant a compulsory license to the owner of the patent with payment of proportionate remuneration; the scope and duration of the use of the patented industrial property subject matter shall be limited to the purposes for which it was authorized. Disputes arising from such use shall be resolved by the court;⁸*

In Belarus⁹ and Kazakhstan, there is a provision that provides an exception from patent rights, by authorizing the one-time use of patented medicines in pharmacies (extemporaneous preparation of medicines).¹⁰

⁵ <https://wipolex.wipo.int/en/legislation/details/19341>

⁶ The government can use this provision for government use purposes. A sub-legislation is only required (by decree of the cabinet of ministers) on definition and procedure of payment of proportionate compensation.

⁷ https://www.ncip.by/upload/doc/2020/izob_mobel_obraz/1.pdf

⁸ <https://wipolex.wipo.int/en/legislation/details/18916>

⁹ In Kazakhstan it is in article 12. 5 of the patent law; in Belarus article 10.

¹⁰ See WIPO note on: https://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_5.pdf



Article 10.

*Acts not recognized as infringing the exclusive right of the patent owner are not recognized as a violation of the exclusive right of the patent owner: (...) **one-time production of medicines in pharmacies** according to a doctor's prescription using a patented invention;*

In cases where the treatment is given as a one-time prescription (such as vaccines) pharmacy in hospitals may use of the patented product. In the Netherlands, a similar type of exception allows compounding (an old practice of preparing medicines for individual patients), which was used recently to allow hospitals to produce intravenous treatment that companies were selling at high prices to treat certain cancers in on-site laboratories.¹¹



Recommendation:

The TRIPS Agreement leaves it to each country to decide how to implement article 31 and exercise the use of compulsory licensing. The best option for any country is to have as many mechanisms and channels as possible for the use of this flexibility in its law. Having both a judicial option and an administrative route to authorize the use of a patent by a third party is the best scenario. It allows for quick decisions by administrative authorities, if they have the will to do so, and it can also allow third parties, such as civil society organizations or generics producers, to file CL requests. This can force the authority to look into a situation, if the government is not acting or taking the appropriate measures.

2. Scope and Grounds for Granting CL/GUL

2.1 Grounds:

The TRIPS Agreement leaves WTO member states free to decide the grounds on which they will issue compulsory licenses, as long as the text of their own law allows it. As the Doha declaration clarified in 2001: "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted".

In some countries, the only grounds for compulsory licenses (aside from government use) is the **lack or absence of working the patent** – what is called "non-use" in some countries, or a "working requirement" in others.¹² For instance, in Morocco, where CL (that are not a government use type of CL) can only be granted if the patent has not been used, or if the product's marketing does not fulfil the needs or if the patent holder has abandoned the market.¹³

¹¹ <https://www.reuters.com/article/us-netherlands-pharmaceuticals-insight-idUSKCN1QP0M4>

¹² In line with the Paris Convention article 4: "A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons."

¹³ In French: <https://wipo.lex.wipo.int/en/text/583308>.



Article 60.

On expiry of a period of three years from the grant of a patent or four years from the filing date of an application and subject to the conditions laid down in Articles 61 and 62 below, any public or private legal person may be granted a compulsory license under the patent provided that, at the time of the request and failing legitimate reasons, neither the owner of the patent nor his successor in title:

- (a) **has begun to work** or has made real and effective preparations for working the invention that is the subject matter of the patent on the **territory of the Kingdom of Morocco**;
- (b) **has marketed the product** that is the subject matter of the patent in a quantity sufficient to satisfy the needs of the Moroccan market; or
- (c) if **working or marketing of the patent in Morocco has been abandoned** for more than three years.



Article 73.

If the formal notice referred to in Article 71 above remains without effect within a period of one year starting with the day of receipt of notification and if the **lack of working or insufficient quality or quantity** of the working undertaken **seriously prejudices economic development and the public interest**, the patents that are the subject matter of the formal notice may be worked ex officio. (...)

In Kazakhstan, **non-use is one of just a few grounds** for issuing CLs and it applies to **patents that have not been continuously used**. In Belarus, “non-use” or “insufficient use” are **the only options for issuing a CL**.¹⁴



Article 11 of Patent Law of Republic of Kazakhstan:

The exclusive right to use the industrial property subject matter and the conditions for the grant of a compulsory non-exclusive license.

4. **In the case of non-use** by the patentee of the subject matter of industrial property and its refusal to conclude a licensing agreement on reasonable commercial terms within ninety calendar days from the date of the request, any person may apply to the court for a compulsory non-exclusive license where the industrial property subject matter **has not been continuously used** after the first publication of information on the grant of a protected industrial property document for any period of three years preceding the date of filing of the application.

Most countries include non-use grounds for issuing a CL (Ecuador, Honduras, Indonesia, India, Malaysia, Russia, Thailand, Vietnam, and Zimbabwe,); however, **a few countries do not** have this provision, such as El Salvador, Georgia, and Guatemala.

Some countries **specifically require local working** (working in the territory) in order to be considered that a patent is being worked. Interestingly, in Zimbabwe, **importation is considered as potentially inhibiting the working** of the invention in the country and thus justifying the use of a CL:¹⁵



Article 31. (b)

If the **working of the invention within Zimbabwe** on a commercial scale is **being prevented or hindered by the importation** of the patented article (...)

¹⁴ https://www.ncip.by/upload/doc/2020/lzob_mobel_obraz/1.pdf

¹⁵ <https://wipo.lex.wipo.int/en/text/215241>

India does include the absence of working in the territory as grounds for CL in its law. However, India's High Court has clarified in an appeal that a patent holder can justify relying on exports as working the patent if they can demonstrate satisfactorily why they do not manufacture the product locally. The Moroccan law mentions that if the exploitation and marketing is abandoned for more than three years, a CL can be granted (article 60.c). It is interesting that marketing is mentioned in the article and the absence of marketing is highlighted as a ground for CL.

Many countries do not include the **absence of working specifically in the territory** as a ground for compulsory license in their law (Belarus, Indonesia, Kazakhstan, Kyrgyzstan, Malaysia, Thailand, Vietnam, etc.). In such cases, importation is considered to be working the patent.

In Argentina, the law **limits the excuses that the patent holders can present for not exploiting a patent:**¹⁶



Article 43.

*As a force majeure, in addition to those legally recognized as such, objective technical difficulties, such as delay in obtaining registration in public bodies for marketing authorization, beyond the will of the patent owner, **make the exploitation of the invention impossible**. The lack of economic resources or the lack of economic viability of exploitation alone **will not constitute justifiable circumstances**.*



Recommendation:

The lack of working a patent is an important concept that came out of the Paris Convention.¹⁷ Countries can interpret TRIPS in a way that considers the lack of local working as grounds for a compulsory license, as has been done in India. Section 83 of the Indian Patents Act states:

Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely,—

- (a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;*
- (b) that they are not granted merely to enable patentees to enjoy a monopoly for the*
- (c) importation of the patented article.*

Sub-section (b) of Section 83 clarifies that patents are not granted simply to allow patentees to exclusively import the patented product into the country, whereas Sub-section (a) states that patents must be worked in India to the extent reasonably practicable.

¹⁶ In Spanish: <https://wipo.lex.wipo.int/en/text/475857>

¹⁷ Article 5A(2) of the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) provides that a compulsory license may be issued in case of failure to work a patent. The Paris Convention allow to interpret the term 'working' as requiring local manufacture of a patented product. Article 27:1 of the TRIPS agreement provides that patent must be made available without discrimination regarding the place where the product is produced. So, there is a tension between Article 27.1 of TRIPS and Article 5A(2) of the Paris Convention. However, the compulsory licensing mechanism under the article 31 of TRIPS can be used to impose a local working requirement under domestic patent law provided that it does not give rise to unjustifiable discrimination, as it was done in India.

In Belarus, El Salvador, Guatemala, Malaysia, Morocco, and Zimbabwe, there is specific **mention of supply** (insufficient supply or security of supply). The Belarus law (art. 38) states that:



Article 38.

*In case of **non-use or insufficient use** by the patentee of an invention, utility model, industrial design **within three years from the date** of publication of information about the patent, **leading to insufficient supply of relevant goods**, works or services on the market, any natural or legal person willing and ready to use the invention, utility model, industrial design, in case the patent owner refuses to conclude a license agreement on terms consistent with established practice, may apply to the court with an application for granting him a compulsory simple (non-exclusive) license.¹⁸*

This is a useful feature, if insufficient supply is not just an additional condition for the lack of working but if it in and of itself serves as a sufficient ground to justify a compulsory license.

India does include the issue of supply (demand not met), and also applies it explicitly to export:¹⁹



Article 84. 7. (iii) a market for export of the patented article manufactured in India is not being supplied or developed;

Remedying anti-competitive practices is important ground to issue a CL. Increasingly, health advocates consider this as a remedy for excessive prices. However, in some countries (Belarus, El Salvador, Honduras, Indonesia, Morocco, Russia, and Thailand), the patent law does not mention it. Its historical absence in the law does not necessarily mean that anti-competitive practices cannot be used to justify a CL in the country in future. In Russia, for instance, use of CLs to remedy anti-competitive practices is mentioned for semi-conductors. In Honduras, it is also mentioned specifically for semi-conductors (art. 67) in the CL section, but the revocation that can remedy the abuse of the patent is mentioned as a remedy when a CL fails to solve the problem:



Article 44.

The patent may be revoked by the Industrial Property Registry, requested by any interested person or competent authority, when the rights conferred by the patent are abused, with the purpose of controlling, restricting or suppressing activities. industrial or commercial. in such a way that it unduly affects the national economy, and provided that the granting of a compulsory license had not been based to stop the situation created by that abuse.

*The revocation request may not be submitted **before two (2) years have elapsed from the date of granting of the first compulsory license**. This license shall be applicable to the provisions of Article 71 of this Law, as appropriate.*

The following situations, among others, shall be considered as abuses of the patent:

1. Due to the **unjustified or abusive conditions imposed for the granting of a license** or a sub-license, the establishment or development of new companies or industrial or commercial activities in the country is unduly prevented or affected.
2. Products protected by the patent are offered in the country at an unjustifiably high price **as a consequence of an abuse of the rights conferred by the patent**; Y,
3. The patent is used to unjustifiably request, restrict control of any industrial or commercial activity related to products or procedures that are not covered by the patent.

¹⁸ https://www.ncip.by/upload/doc/2020/lzob_mobel_obraz/1.pdf

¹⁹ <https://wipo.int/wipo.int/en/text/580625>

In Brazil, a patent can expire after a CL has been granted if the CL is not sufficient to solve abuse or disuse:²⁰



Article 80. *The patent will expire, ex officio or at the request of any person with legitimate interest, if, after 2 (two) years after the granting of the first compulsory license, this period **has not been sufficient to prevent or remedy the abuse or disuse**, unless justified.*



Recommendation:

Remedy to anti-competitive practices is indicated as ground for CLs in several analyzed countries - Argentina, Brazil, Ecuador, Guatemala. This remedy is gaining traction because the excessive prices of patented pharmaceuticals is increasingly considered by competition authorities to be anti-competitive, is an additional reason for countries to include it in their laws.

Unlimited export is possible under TRIPS when CLs are granted based on competition grounds. The option exists in the Indian law,²¹ as well as in Argentina, Ecuador, Kyrgyzstan and Vietnam. In Kyrgyzstan, the Regulation on Conditions and Procedures for the Granting of Compulsory Licenses (...) (approved by Decision No. 862 of December 24, 1998, and amended up to the Decision No. 715 of October 30, 2017, of the Government of the Kyrgyz Republic) states:²²



*(...) 7. The court **may not apply** the conditions provided for in paragraph 4 and subparagraph (e) of this Regulation in deciding whether to grant a compulsory license to correct practices which, upon the **decision of the court or the antimonopoly body, may not apply the conditions provided for in paragraph 4 and subparagraph (e) of this Regulation**. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. The court shall have the right to refuse the cancellation of the authorization if it is probable that the conditions that led to such authorization may arise again.*

Some countries do not have a clause allowing this – and must rely on the art. 31(k) provision of TRIPS.



Recommendation:

Granting a CL on competition grounds without limitation on exports is a feature that can be useful in the context of public health and should be included in all patent laws.

Most laws mention national security or emergencies as grounds for CLs. In our sample, all countries except Belarus and Indonesia have this provision. In Belarus (and, similarly, in Kazakhstan), the law includes extraordinary circumstances as grounds for granting a CL, which may be used in cases where the government considers that national security is at stake (but this may also be contested).²³

²⁰ <https://wipolex.wipo.int/en/text/461539>

²¹ In India, exportation can also take place when the product is needed in other countries and not provided by the patent owner (art 84.7.a.iii).

²² <https://wipolex.wipo.int/en/legislation/details/18916>

²³ https://www.ncip.by/upload/doc/2020/izob_mobel_obraz/1.pdf



Article 10. Are not recognized as a violation of the exclusive right of the patent owner: (...) use of an invention, utility model, industrial design under extraordinary circumstances (natural disasters, catastrophes, accidents, epidemics, epizootics, etc.) with notifying the patent holder of such use as soon as possible and paying him proportionate compensation;

In Indonesia, on the other hand, no such provision exists.



Recommendation:

National security and emergencies are basic features that should be included in all laws.

In some countries, the law mentions non-commercial use among possible grounds for CLs., and in particular for government use of patented products, which is the case in Guatemala, India, Kyrgyzstan, Thailand and Vietnam. Unfortunately, many countries do not have this provision, including Belarus, El Salvador, Georgia, Morocco, and Zimbabwe. In many countries, it appears that non-commercial use is grounds for CLs only in the case of semi-conductors, as in Honduras, Indonesia, Kazakhstan, Malaysia and Russia.



Recommendation:

Non-commercial use is an important concept that does not apply to health products in many countries' laws, which should be modified accordingly to include it.

Government use of patented products does not exist in all laws, despite that it is an important tool for managing patent rights. It exists in Argentina, Georgia, Guatemala, Honduras, India, Indonesia, Kyrgyzstan, Malaysia, Morocco, Russia, Thailand, Vietnam, and Zimbabwe. In Malaysia, for example, the Patents Act 1983 (Act No. 291, as amended in Act No. A1264)²⁴ states:



84. Rights of Government.

(1) Notwithstanding anything contained in this Act

(a) where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy **as determined by the Government**, so requires; or

(b) where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive, the Minister may decide that, even without the agreement of the owner of the patent, a **Government agency or a third person designated by the Minister may exploit a patented invention.**

(2) The owner of the patent shall be notified of the decision of the Minister as soon as is reasonably practicable.

Some countries do not have this provision in their law. In our sample this is the case in Belarus, El Salvador, and Kazakhstan.

In Kazakhstan (as well as Belarus and Ukraine), where the law had allowed government use and has since been amended, Article 12 of the patent law²⁵ could still offer an option to implement a CL:

²⁴ <https://wipolex.wipo.int/en/text/584060>

²⁵ <https://wipolex.wipo.int/en/text/539462>



Article 12.

Actions that are not recognized as a violation of the exclusive rights of the patent owner

The following shall not be recognized as a violation of the exclusive rights of a patent owner:

- 3) use of such means in case of emergencies (natural disasters, catastrophes, major accidents) with immediate notification of the patent owner and payment of proportional compensation to the patent owner;

However, the Ministry of Justice in Kazakhstan does not believe that this is possible, since the government is not explicitly mentioned as having the authority to issue CLs or to use inventions without the consent of the patent holder. To fix this, the law should be amended to give relevant state authorities the ability to use this exception.



Recommendation:

Government use licensing should be included in all patent laws.

Public interest is not necessarily mentioned as potential grounds in many CL provisions. It is, however, present in Brazil, Ecuador, Guatemala, Honduras, India, Indonesia, Malaysia, and Morocco. In Kazakhstan it applies only to semi-conductors.

Public health appears in the law in Argentina, Georgia, Guatemala, Honduras, India, Kazakhstan, Kyrgyzstan, Malaysia, Morocco, Russia, and Vietnam. In Morocco, a specific provision of Law No. 17-97 on the Protection of Industrial Property²⁶ is dedicated to **public health and medicines**:



Article 67.

Where the **interests of public health** demand, patents granted for medicines, for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be worked ex officio in the event of such medicines being made available to the public in **insufficient quantity or quality** or at an **abnormally high price**. Ex officio working shall be ordered by administrative act at the request of the office responsible for public health.

In Kyrgyzstan, **epidemics** were added to the law:²⁷



Decision of the Government of the Kyrgyz Republic No. 652 of September 21, 2015, on Amendments to Certain Decisions of the Government of the Kyrgyz Republic (as amended by the Decision of Government of the Kyrgyz Republic No. 523 of October 3, 2016)

3. Introduce in the Decision of the Government of the Kyrgyz Republic "On approval of the Regulation on the conditions and procedure for the provision of a compulsory license for an industrial property object and its use" No. 862 of December 24, 1998, the following amendments and additions:

in the Regulations on the conditions and procedure for granting a compulsory license for an industrial property object and its use approved by the above-mentioned decision:

- Subclause "b" of Clause 2 after the word "major accidents" **add the word "epidemic"**;

²⁶ <https://wipo.lex.wipo.int/en/legislation/details/19767>

²⁷ In Russian: <https://wipo.lex.wipo.int/en/text/513612>

Pharmaceuticals are often not mentioned in the law (Belarus, Kazakhstan, Kyrgyzstan etc.), but it does appear in some countries, as in the case of Indonesia, Morocco, Thailand, Vietnam, and Zimbabwe.

In Zimbabwe, the Patents Act (2002)²⁸ states that:



32. Inventions relating to food or certain other commodities

- (1) *Subject to subsection (15) of section thirty-one and without prejudice to the other foregoing provisions of this Act, where a patent is in force in respect of—*
- (a) *a substance capable of being used as food or **medicine** or in the production of food or **medicine**; or*
 - (b) *a process for producing a substance referred to in paragraph (a); or*
 - (c) *any invention capable of being used as or as part of a surgical or curative device or in protection of the environment.*

In Indonesia, access to pharmaceuticals is listed as grounds for the issuance of a CL in the patent law;²⁹ imports and exports are also mentioned:



Article 93.

- (1) *The minister may grant a compulsory license to produce **pharmaceutical products** that are patented in Indonesia for the treatment of diseases in humans.*
- (2) *The Minister may grant a compulsory license for the **import of the procurement of pharmaceutical products** that are patented in Indonesia but cannot yet be produced in Indonesia for the treatment of human diseases.*
- (3) *The Minister may grant a compulsory license to **export pharmaceutical products** that are patented and produced in Indonesia for the treatment of human diseases based on requests from developing or underdeveloped countries.*

Reasonable price appears as grounds for a CL in the law in Honduras, India, Malaysia, Morocco, and Thailand: Malaysia and Thailand mention products sold at '**unreasonably high prices**.' In Honduras, revocation can be triggered by '**unjustifiably high prices**' as a consequence of an abuse of rights, although price is not mentioned in the CL section. In India, price is listed as one of the grounds for a CL in article 84:³⁰



84. Compulsory licenses.—

- (1) *At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:—*
- (...) « (b) *that the patented invention is not available to the public at a **reasonably affordable price** »*

According to this article, in paragraph 7, high prices can be understood as an unreasonable term:



- (7) *For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—*
- (a) *if, by reason of the refusal of the patentee to grant a license or licenses on reasonable terms,— (...)*
 - (ii) *the demand for the patented article has not been met to an adequate extent **or on reasonable terms**; or (...)*

²⁸ <https://wipo.lex.wipo.int/en/text/215241>

²⁹ <https://wipo.lex.wipo.int/en/legislation/details/16392>

³⁰ <https://wipo.lex.wipo.int/en/text/580625>



Recommendation:

Public interest is important ground to have spelled out in national laws. More specific grounds such as public health, access to pharmaceutical products, and prices of medicines, can also facilitate swift decisions to issue a CL by health authorities in the country, or facilitate processes to lead to a CL decision. Nonetheless, it is important to note that countries like France and Morocco, which have such provisions, have thus far never used them, despite circumstances that would justify it.

Many countries do not include technology transfer or the development of local industry in their law as grounds for CLs (Belarus, Kazakhstan, and Kyrgyzstan). However, the patent law of India³¹ does:



Section 83. (c) *that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to **the transfer and dissemination of technology**, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;” and “(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or **adversely affect the international transfer of technology**;*³²

The Indian Patent Act³³ also has a provision concerning technological development of local industry as grounds for a CL:



Section 83. (d) *that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for **socio-economic and technological development** of India;*

Similarly, in Malaysia, the Patents Act³⁴ states:



84. Rights of Government. (a) *where there is national emergency or where the public interest, in particular, national security, nutrition, health or the **development of other vital sectors of the national economy** as determined by the Government, so requires;*

In Morocco, there is an option in the Law on the Protection of Industrial Property³⁵ to issue a CL in order to satisfy the needs of the national economy.



Article 71.

*The competent administration may issue formal notice to the owners of patents other than those referred to in Article 67 above to work them **in such a manner as to satisfy the needs of the national economy**.*

³¹ <https://wipo.lex.wipo.int/en/text/580625>

³² <https://wipo.lex.wipo.int/en/text/580625>

³³ <https://wipo.lex.wipo.int/en/text/580625>

³⁴ <https://wipo.lex.wipo.int/en/text/584060>

³⁵ <https://wipo.lex.wipo.int/en/text/583308>

In Zimbabwe,³⁶ conditions set by a patentee limiting trade or contrary to public policy (such as limitations in purchase, hire contracts for consumers or businesses) may be additional grounds for CL.



Article 31: Compulsory license in case of abuse or insufficient use of patent rights.

6.(e) if any trade or industry in Zimbabwe or any person or class of persons engaged therein is being prejudiced by **unfair conditions attached by the patentee**, whether before or after the appointed day, to the purchase, hire, license or use of the patented article or to the using or working of the patented process; (...)

6.(f) if any condition, which under section forty-four is null and void as **being in restraint of trade and contrary to public policy, has been inserted in any contract** made in relation to the sale or lease of or any license to use or work any article or process protected by the patent:



Recommendation:

Technology transfer and development of local industry in CL provisions of national laws only appear in a handful of countries. All countries should include in their law the lack of technology transfer as a ground to grant CL.

Most countries include a basic feature in their law for **dependent patents** to be used without infringing on the original patent as grounds for a CL; in Belarus, Guatemala, Honduras, India, Russia, and Zimbabwe, reciprocity is mentioned. This option does not seem to exist in the law in El Salvador.

In Argentina, a provision of note in the chapter on Uses Without the Authorization of the Patent Owner, which is found in the Law on Patents For Inventions and Utility Models,³⁷ offers the possibility for extending a CL to **related patents** necessary to manufacture the product; this can be useful, as it is often difficult to identify every patent covering a technology.



Article 47:

(d) The authorization shall **extend to patents relating to manufacturing components and processes** that permit their exploitation;

³⁶ <https://wipo.lex.wipo.int/en/text/215241>

³⁷ <https://wipo.lex.wipo.int/en/legislation/details/21176>

2.2 Limitations:

Many countries do not take full advantage of the flexibility that the TRIPS agreement provides to determine the grounds for issuing CLs; some countries have severe limitations. In Russia, non-use is the only grounds for regular CLs, and national defense and security are the only grounds for government use. As we have seen, some countries do not include remedies to anti-competitive behavior among the grounds for issuing a CL, or the possibility of issuing CLs for non-commercial use, or for the public interest; such grounds are absent in the Georgian patent law, for example. In some cases, the use of CLs is also limited by additional conditions, for instance, in El Salvador, where the grounds to use CLs are limited to emergency and national security. The El Salvador law on intellectual property³⁸ includes an additional condition that such CLs should satisfy the “basic needs of the population”:



Article 133. *When there are declared causes of emergency or national security and as long as they persist, a compulsory license for patent exploitation may be granted provided that this concession is necessary to satisfy the basic needs of the population.*

Some countries have no provisions for government use in their laws; and in countries that do have such provisions, its use is limited. As mentioned above, in Russia, national security and defense are the only grounds for government use. In some countries, to trigger the use of CLs or GU, an emergency or national security issue must be declared by a competent authority (President, Minister, etc.). In Brazil, for instance, the law³⁹ states that a national emergency or public interest needs to be declared by the public power:



Decree No. 4,830, of September 4, 2003

Article 2: *Compulsory patent license may be granted, in the event of national emergency or public interest, in the latter case only for non-commercial public use, **provided that so declared by the Public Power**, when it is found that the titleholder patent, either directly or through a licensee, does not meet these needs.*

Some countries limit the use of CLs to the domestic market only. In El Salvador, for instance, the law⁴⁰ states:



Article 4. 134.

*(d) Compulsory license shall be granted in order to **supply the internal market**.*

Most countries, following article 31.f, specify that CLs are mainly for internal markets (Georgia, Guatemala, Honduras, Malaysia, Thailand). The Georgian law, for example, states “first of all, to meet the needs of the Georgian market”. Several countries have the TRIPS Agreement article 31(k) exception to this rule; for instance, in case of anti-competitive behavior (Vietnam, Ecuador, Argentina, Kyrgyzstan, etc.). In India, the law mentions that CLs can be used for the export market (See above Art 84.7(iii)), and Article 92A provides an exception specifically for the exportation of pharmaceuticals without limitation. This is the implementation of the TRIPS agreement amendment that entered into force on 23 January 2017 which allows exporting countries to grant compulsory licenses to generic suppliers for the purpose of manufacturing and exporting needed medicines to countries lacking production capacity.

³⁸ <https://wipolex.wipo.int/en/text/455849> (in Spanish)

³⁹ <https://wipolex.wipo.int/en/text/461539>

⁴⁰ <https://wipolex.wipo.int/en/text/455849> (in Spanish)

In our sample, Kazakhstan and Ecuador have also adopted such an exception:



Article 319. (...) 3. *The compulsory license shall be granted primarily to supply the domestic market, except in the case of the **export of pharmaceutical products** in accordance with the World Trade Organization Decision of 30 August 2003 (...).*⁴¹

Most countries, however, do not include this option in their law (as of time of this study).

In Malaysia, the law states that CLs may not extend to imports and therefore can be limited to local production (which is not the case for government use):



52. Scope of compulsory license.

Upon the granting of the compulsory license to the applicant the Board shall fix

- (a) the scope of the license specifying in particular for what period the license is granted and to which of the acts referred to in paragraph (a) of subsection (1), and sub- section (3), of section 36 [Rights of owner of patents] the license extends except that it **may not extend to the act of importation**;*
- (b) the time limit within which the beneficiary of the compulsory license shall begin to work the patented invention in Malaysia; and*
- (c) the amount and conditions of the royalty due from the beneficiary of the compulsory license to the owner of the patent.*⁴²

In Ecuador, the granting of CLs for lack of use is limited mainly to production:



Article 310. *Grant of compulsory license for lack of use. - Within three years from the grant of the patent or four years from the application of the patent, whichever is the greater, the competent national intellectual rights authority, at the request of any interested party, shall grant a compulsory license **mainly for the industrial production** of the product subject to the patent or the full use of the patented process only if at the time of its application the patent has not been exploited, or if it has been suspended for more than one year.*⁴³

Very few countries have provisions to limit damages and remedies to infringement, as allowed by article 44 of the TRIPS agreement,⁴⁴ which opens the door to CLs (a well-developed practice in the US):



Article 44. Injunctions

- 1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.*

⁴¹ <https://wipo.lex.wipo.int/en/text/439410>

⁴² <https://wipo.lex.wipo.int/en/text/584060>

⁴³ <https://wipo.lex.wipo.int/en/text/439410>

⁴⁴ https://www.wto.org/english/docs_e/legal_e/trips_e.htm#art5

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically **addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder** are complied with, Members **may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31**. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

Interestingly, in India, article 111 of the patent law puts limitations on damage claims when a person is not considered to have been aware of, or has had reasonable grounds for knowing that a product was covered by a patent.



Article 111.

*Restriction on power of court to grant damages or account of profits for infringement.— (1) In a suit for infringement of patent, damages or an account of profits shall not be granted against the defendant who proves that at the date of the infringement he **was not aware and had no reasonable grounds for believing that the patent existed**.*⁴⁵

India's law also specifically mentions that a CL can be issued after the act of using the patent has taken place:



Article 100.

*(4) The authorisation by the Central Government in respect of an invention may be given under this section, either before or after the patent is granted and either **before or after the acts in respect of which such authorisation is given or done**, and may be given to any person whether or not he is authorised directly or indirectly by the applicant or the patentee to make, use, exercise or vend the invention or import the machine, apparatus or other article or medicine or drug covered by such patent.*⁴⁶



Recommendation:

Article 44 and the limitation of remedies is an important provision that is often overlooked or absent in patent laws. Activists and governments should consider its inclusion and use.

In most cases, the TRIPS agreement requires that a negotiation be attempted with the patent holder before issuing a CL (although exceptions exist: national emergencies, other circumstances of extreme urgency, public non-commercial use, or in order to remedy competition violations). In Ecuador, as in many countries, the law states that the lack of an agreement with the patent holder is grounds for a CL:



Article 318. Compulsory leave due to lack of agreement.

*Granting of compulsory license due to lack of agreement.-For the case provided for in Article 276, the competent national authority in the field of intellectual rights, at the request of the legitimate interested party, shall grant a compulsory license mainly for the industrial production of the product which is the subject of the patent or the full use of the patented process, **if the terms and conditions of a voluntary license have not been agreed upon at the time of the request**.*⁴⁷

⁴⁵ <https://wipolex.wipo.int/en/text/580625>

⁴⁶ <https://wipolex.wipo.int/en/text/580625>

⁴⁷ <https://wipolex.wipo.int/en/legislation/details/16990>

The same type of language exists in the law in Zimbabwe,⁴⁸ but the **existence of unfair conditions of licenses by the patentee** are grounds as well:



Article 31. Compulsory license in case of abuse or insufficient use of patent rights.

6.(e) if any trade or industry in Zimbabwe or any person or class of persons engaged therein is being prejudiced by unfair conditions attached by the patentee, whether before or after the appointed day, to the purchase, hire, license or use of the patented article or to the using or working of the patented process; (...)

Similarly, India also provides grounds for the patent controller to order compulsory licenses in response to **conditions imposed by the patentee**.



Article 88.

(1) Where the Controller is satisfied on an application made under section 84 that the manufacture, use or sale of materials not protected by the patent is prejudiced by reason of **conditions imposed by the patentee upon the grant of licenses under the patent, or upon the purchase, hire or use of the patented article or process**, he may, subject to the provisions of that section, order the **grant of licenses** under the patent to such customers of the applicant as he thinks fit as well as to the applicant.⁴⁹

It is interesting to note that in Honduras, revocation of a patent can be triggered by the same types of arguments.⁵⁰

India also has an interesting article related to **coercive package licensing**, that may be used in the case of restrictive voluntary licenses (VLs):



Article 84.

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied— (...) (c) if the patentee imposes a condition upon the grant of licenses under the patent to provide **exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing**;⁵¹



Recommendation:

An order to issue a license to sanction prejudicial, unjustified or abusive conditions of licenses voluntarily granted by the patentee can, in some cases, be an avenue to counter the negative impact or significant limitations in place through VLs.

Such licenses were granted in 2003 against GlaxoSmithKline and Boehringer Ingelheim in South Africa as a result of the decision by the Competition Commission, which found that they had violated the Competition Act and abused their dominant positions in the anti-retroviral market.⁵²

⁴⁸ <https://wipolex.wipo.int/en/text/215241>

⁴⁹ <https://wipolex.wipo.int/en/text/580625>

⁵⁰ See article 44.1 about « unjustified or abusive conditions imposed for the granting of a license or a sub-license».

⁵¹ <https://wipolex.wipo.int/en/text/580625>

⁵² <http://www.cptech.org/ip/health/sa/cc12102003.html>

3. Conditions for the Implementation of CLs

In Brazil, the COVID-19 pandemic triggered a review of the provisions of the Patent Statute (9.279/1996) on compulsory licensing of patents in case of national emergency or in the public interest. On 6 May 2021, the Brazilian Senate approved bill 12/2021, which amends the Brazilian Patent Statute and creates a **two-step compulsory licensing process**. In July 2021, the House of Representatives approved the bill with amendments. According to the amendment, as the first step of the process, the Brazilian Executive Branch publishes a list of patents or patent applications related to essential products and processes necessary to manufacture them within 30 days of the date of state of emergency declaration. The second step occurs after publication of the list; the Executive Branch has 30 days, which can be extended, to analyze the inventions and utility models covered by the patents and patent applications listed. Compulsory licenses should then be granted, ex officio, for a specified period and on a non-exclusive basis, and the patent owners shall receive remuneration corresponding to 1.5% of the net sale price of the product covered by the patent.



Recommendation:

The capacity of countries to fast-track granting of CLs can be particularly useful in an emergency situation or to avoid a crisis. The fact that CLs apply to patent applications (before they are granted) can prevent unfair monopolies that block access to medical technologies. However, the requirement to list patents can be problematic, as it is often difficult to identify every patent granted (or filed) that may cover a technology – except if a repository of the correspondence between patents and technologies exists, and is systematically filed by entities requesting patents.

Some countries allow the **request and granting of CLs even before the patent is granted** – as long as the patent has been filed. For instance, Guatemala, Honduras, India, Zimbabwe and, more recently, Brazil, allow for CLs on pending patent applications. For instance, the Industrial Property Law, Decree No. 57 of 18/09/2000 in Guatemala,⁵³ states:



Article 134.

For reasons of public interest and in particular for reasons of national emergency, public health, national security or non-commercial public use, or to remedy any anticompetitive practice, after hearing the interested party, the Registry may, at the request of the authority or an interested person, have at any time:

- a) That the invention object of **a patent or of a pending patent application** is used or industrially or commercially exploited by a state entity or by one or more persons of public or private law designated for that purpose; (...)*

However, many countries do not have this option and can only issue CLs on granted patents (Belarus, Ecuador, Georgia, Indonesia, Kazakhstan, Kyrgyzstan, Malaysia, Morocco, Russia, Thailand, etc.).

⁵³ <https://wipo.lex.wipo.int/en/text/236914> (In Spanish).

In many laws, only certain people or entities can request a CL – as compared to countries where anyone can request (Guatemala, Kazakhstan, Zimbabwe). Depending on the law, it may be an ability to “exploit” (Ecuador, Honduras), by a “qualified person” (Morocco), with “legitimate interest” (Brazil, Ecuador), a person “willing or ready to use” (Belarus, Kyrgyzstan), with “the technical and economic capacity to carry out the efficient exploitation” (Argentina, Brazil), and that “submits evidence” of “the ability to fully implement the patent” and “has the facilities” to do so (Indonesia), or “the ability of the applicant to work the invention to the public advantage” (India). These limitations **may prevent many people, including health advocates or NGOs, from filing CL requests.** Vietnam, however, allows for a larger number of entities and people to make CL requests to include “organizations or individuals that are capable, obliged or have a need to use patents,” which could include patients, and potentially patient representatives.

Some laws state that CLs can only be granted if the patentee does not prove that the non-use or insufficient use has legitimate or valid reasons (Belarus, Kazakhstan, Kyrgyzstan); meaning if the patentee provides a valid justification, the CL will not be issued. In addition, in Kyrgyzstan, the person requesting the CL has the necessity to prove that the “real” need in relevant products.⁵⁴

Despite the possibility provided by the TRIPS agreement, some countries **do not have the option of waiving prior negotiations** with the patent holder in case of government use (Belarus, Kazakhstan), which is a substantial limitation and can slow down or even stall a process of getting CL.

Some laws reference royalties as remuneration (Argentina, Brazil, Ecuador, El Salvador, Guatemala, India, Kazakhstan, Kyrgyzstan), others as compensation (Georgia, Russia, Vietnam).

In India, the provision on royalty payments mentions spending on R&D by the patentee and the price of the product.



Article 90. Terms and conditions of compulsory licenses. —

(1) In settling the terms and conditions of a license under section 84, the Controller shall endeavour to secure—

- (i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, **is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;** (...)*
- (iii) that the patented articles are **made available to the public at reasonably affordable prices;***

In practical terms, it may be difficult for the Controller to know how much the actual amount the patentee spent on what they spend on R&D. This can be an area where the Indian government, as well as governments in other countries, can push to require transparency, and even to consider sanctions when they cannot obtain this information. It also reinforces the importance of having independent studies assessing both public and private investments in R&D on essential medicines, which might be useful information for a government to assess R&D costs on medicines for which a CL will be issued.

⁵⁴ <https://cbd.minjust.gov.kg/6153> (In Russian).

Vietnam has an interesting (and rare among the 18 surveyed countries) provision on **inventions financed or created in part with public resources**:



Article 133.- Rights to use inventions on behalf of the State⁵⁵

1. Ministries and ministerial-level agencies shall have the right to, on behalf of the State, use or permit other organizations or individuals to use inventions in domains under their respective management for public and non-commercial purposes, national defense, security, disease prevention and treatment and nutrition for the people, and to meet other urgent social needs without having to obtain permission of invention owners or their licensees under exclusive contracts (hereinafter referred to as holders of exclusive right to use inventions) according to Articles 145 and 146 of this Law.
2. The use of inventions mentioned in Clause 1 of this Article shall be limited within the scope of and under the conditions for licensing provided for in Clause 1, Article 146 of this Law, except where such inventions are **created by using material-technical facilities and funds from the state budget**.⁵⁶

Such a provision is similar to the March-in rights that exist in the US.⁵⁷

Another interesting provision exists in Brazil, where the law mentions the **possible legal obligation to facilitate technology transfer** in case of a CL.



Decree N° 4,830, of September 4, 2003. Art 5.

§ 1 The act of granting the compulsory license may also establish the obligation of the holder to transmit the necessary and sufficient information for effective reproduction of the protected object and the other technical aspects applicable to the case in question, observing, in the negative, the provisions at the art. 24 and Title I, Chapter VI of Law n 9279, 1996.

In India, the patent law⁵⁸ also includes a provision that can allow the acquisition of an invention by the government for agreed-upon compensation.



Article 102. Acquisition of inventions and patents by the Central Government. —

- (1) The Central Government may, if satisfied that it is necessary that an invention which is the subject of an application for a patent or a patent **should be acquired** from the applicant or the patentee for a public purpose, publish a notification to that effect in the Official Gazette, and thereupon the invention or patent and all rights in respect of the invention or **patent shall, by force of this section, stand transferred to and be vested in the Central Government**.
- (2) Notice of the acquisition shall be given to the applicant, and, where a patent has been granted, to the patentee and other persons, if any, appearing in the register as having an interest in the patent.
- (3) The Central Government shall pay to the applicant, or, as the case may be, the patentee and other persons appearing on the register as having an interest in the patent **such compensation as may be agreed upon between the Central Government and the applicant, or the patentee and other persons; or, as may, in default of agreement, be determined by the High Court on a reference under section 103 to be just having regard to the expenditure incurred in connection with the invention and, in the case of a patent, the term thereof, the period during which and the manner in which it has already been worked (including the profits made during such period by the patentee or by his licensee whether exclusive or otherwise) and other relevant factors**.

⁵⁵ <https://wipo.lex.wipo.int/en/text/274445>

⁵⁶ Clause 1, Article 1 of the law on intellectual property in Viet Nam concerns the conditions of limitation on the right to use inventions licensed under compulsory decisions (non-exclusivity of the license, limited scope and duration, no possibility to transfer, payment of a compensation).

⁵⁷ See, for instance, <https://www.policymed.com/2022/06/attention-on-march-in-rights-what-are-they-and-why-are-they-relevant.html>

⁵⁸ <https://wipo.lex.wipo.int/en/text/580625>

In India, **a broad definition of pharmaceutical products** is provided in the provision on exports of patent pharmaceuticals, which would facilitate and improve the efficiency of this provision the CL for export can thus apply not only to finished products but for instance to active ingredients or intermediary products.



Article 92A. Compulsory license for export of patented pharmaceutical products in certain exceptional circumstances. —

- (1) *Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.*
- (2) *The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory license solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.*
- (3) *The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.*

*Explanation. — For the purposes of this section, ‘pharmaceutical products’ means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.*⁵⁹

Finally, where laws systematically allow, in several countries it specifies that the appeal does **not have a suspensive effect on the CL** (Argentina, Brazil, Ecuador, etc.) and thus will not prevent the granting of a CL to be effective even if an appeal is introduced.

Conclusion

This study highlights the diversity of patent laws in different MIC, all of which are WTO member states, reflecting the freedom provided by the WTO, and the variation in interpretation of the TRIPS Agreement.

It is evident that many – if not all – countries do not take full advantage of all of the available flexibilities to create an optimal legal environment for maximizing access to health products.

The analysis provided in this report and the tables in Annex 3 are a pool of useful provisions that can inspire activists and policymakers on ways to amend and improve the legal landscape in their countries, and develop better processes for implementing CLs.

⁵⁹ <https://wipolex.wipo.int/en/text/580625>

Annex 1:

Countries Included in This Study

| Country | World Bank Income Classification | | Issued CL(s) | | | |
|-------------|----------------------------------|---------------------------|---|--------|--|--|
| | Upper Middle-Income (UMI) | Lower Middle-Income (LMI) | No/Yes | Number | Disease Area(s) | Year(s) |
| Argentina | UMI | | No | | | |
| Belarus | UMI | | Yes | 1 | HIV | 2005 (according to Medicines and Law database but not confirmed) |
| Brazil | UMI | | Yes | 1 | HIV | 2007 |
| Ecuador | UMI | | Yes | 9 | HIV, Cancer, Rheumatoid Arthritis, Kidney Transplant | 2010, 2012, 2013 (x3), 2014 (x4) |
| El Salvador | | LMI | No | | | |
| Georgia | UMI | | Yes | 1 | HIV | 2006 (not confirmed) |
| Guatemala | UMI | | Yes | 1 | HIV | 2005 |
| Honduras | | LMI | Yes | 3 | HIV | 2005, 2008 (x2) |
| India | | LMI | Yes | 1 | Cancer | 2012 |
| Indonesia | | LMI | Yes | 3 | HIV, HIV/HBV | 2004, 2007, 2012 |
| Kazakhstan | UMI | | No (process was engaged, but stopped due to lack of political will after voluntary licensing was granted) | | | |
| Kyrgyzstan | | LMI | No | | | |
| Malaysia | UMI | | Yes | 2 | HIV, Hepatitis C | 2003, 2017 |
| Morocco | | LMI | No | | | |
| Russia | UMI | | Yes | 2 | Leprosy/TB, COVID-19 | 2018, 2021 |
| Thailand | UMI | | Yes | 7 | HIV, Cancer, Cardiovascular Disease | 2006, 2007 (x2), 2008 (x4) |
| Vietnam | | LMI | No | | | |
| Zimbabwe | | LMI | Yes | 4 | HIV | 2002, 2003, 2004, 2005 |

Annex 2:

National Laws, Decrees and Regulations from 18 Countries Used for This Report

| Country | Texts Consulted |
|-------------|--|
| Argentina | <ul style="list-style-type: none"> • Law No. 24.481 of March 30, 1995, on Patents and Utility Models (as amended up to Decree No. 27/2018 of January 10, 2018) • Decree No. 260/1996 of March 20, 1996, on Approval of the Consolidated Text of Law No. 24.481 on Patents and Utility Models and its Regulation (as amended up to Decree No. 403/2019 of June 5, 2019) (AR193) • Decree No. 403/2019 of June 5, 2019, on Amendments to Decree No. 260/1996 of March 20, 1996 (AR197) • Regulation of the Law No. 24.481, on Patents and Utility Models (AR040) 1996 • Law No. 24.572 of September 28, 1995, amending Law No. 24.481 of March 30, 1995, on Patents and Utility Models (AR041) |
| Belarus | <ul style="list-style-type: none"> • Law of Republic of Belarus 'On patents for inventions, utility models, industrial designs' 16 December 2002 № 160-3 As amended on 18 December 2019. • Study 2015 Best Practices of Implementation of Public Health Related Flexible Provisions of the WTO TRIPS Agreement in Belarus, Georgia, Moldova and Ukraine and Steps Forward for Advocacy. • Study access to drugs 2020: Access to Treatment of HIV-Infection and Hepatitis C in Belarus in 2019-2020. |
| Brazil | <ul style="list-style-type: none"> • Law No. 9.279 of May 14, 1996 (Law on Industrial Property, as amended up to Law No. 10.196 of February 14, 2001) BR283 • Decree No. 4.830 of September 4, 2003 (Compulsory Licenses in Cases of National Emergency and Public Interest) |
| Ecuador | <ul style="list-style-type: none"> • Constitution 2018 EC035 • Decision 486 of the Andean Community • Law on Generic Medicines for Human Use (as amended up to October 13, 2011) (EC092) • Organic Code on the Social Economy of Knowledge, Creativity and Innovation EC075 • Regulation on Management of Knowledge (issued by Agreement No. SENESCYT-2020-077 of the National Secretary of Higher Education, Science, Technology and Innovation) (EC143) Art 67 etc. • Regulation on the Functioning and Exercise of the Competencies of the Collegial Body for Intellectual Rights of the National Service of Intellectual Rights (issued by Resolution No. 002-2018-DG-NT-SENADI, and amended on September 7, 2018) (EC136) (Art. 4. 52) • Regulation on the Organic Code on the Social Economy of Knowledge, Creativity and Innovation (issued by Executive Decree No. 1435, and amended up to April 18, 2018) (EC133) Art 39 |
| El Salvador | <ul style="list-style-type: none"> • Ley de propiedad intelectual (as amended up to Legislative Decree No. 604 of February 15, 2017) |
| Georgia | <ul style="list-style-type: none"> • Law of Georgia No. 1791 of February 5, 1999, on Patents (as amended up to Law No. 3235 of July 20, 2018) • Law of Georgia on Medicines and Pharmaceutical Activities • Report Analytical Report National Intellectual Property Landscapes and Their Impact on Access to Medicines 100% Life ITPC |
| Guatemala | <ul style="list-style-type: none"> • Decreto n. 57-2000 y sus reformas. Última modificación en 2013. • Estudio de Barreras Legales en Guatemala (mayo 2016) • ITPC LATCA_estudio comparativo de las leyes nacionales de propiedad industrial |
| Honduras | <ul style="list-style-type: none"> • Código Civil (aprobada por Decreto N° 76-1906) (2017) • Código Procesal Civil (aprobada por Decreto N° 211-2006) • Honduras IP Decreto 12-99 (2000) • Honduras Reglamento de la Ley de Propiedad (aprobado par Resolución C.D.-IP N° 003-2010) 2011 |

| Country | Texts Consulted |
|------------|---|
| India | <ul style="list-style-type: none"> Patents Act, 1970 (Act No. 39 of 1970, as amended up to the Patents (Amendment) Act, 2005) (2017) https://wipo.lex.wipo.int/en/legislation/details/20694 Patents (Amendment) Act, 2005 (Act No. 15 of 2005) (IN018) Patents (Amendment) Act, 1999 (IN030) The Patents (Amendment) Ordinance, 1994 (IN001) |
| Indonesia | <ul style="list-style-type: none"> Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents Regulation No. 8 of 2016 on Requirements and Procedures for Recordal of IP License Agreements Omnibus law passed in 2020, one of the clauses mentioning law no.13 on patents (discussions postponed) |
| Kazakhstan | <ul style="list-style-type: none"> Law on Patents of the Republic of Kazakhstan No. 427-I of July 16, 1999 (as amended up to Law No. 268-VI of October 28, 2019) Kh and Russian Law of the Republic of Kazakhstan No. 365-V of October 27, 2015, on Amendments to Certain Laws of the Republic of Kazakhstan with regard to the Accession to the World Trade Organization(KZ047) Law of the Republic of Kazakhstan No. 537-IV of January 12, 2012, on Amendments to Certain Laws Relating to Intellectual Property(KZ035) Entrepreneurial Code of the Republic of Kazakhstan No. 375-V of October 29, 2015 (as amended up to Law No. 262-VI of July 3, 2019) (Kh) Code of the Republic of Kazakhstan No. 193-IV of September 18, 2009, on People's Health and Healthcare System (as amended up to Law No. 272-VI of November 25, 2019) (Kh) Law of the Republic of Kazakhstan No. 304 of March 18, 2002, on Bodies of Justice (as amended up to Law No. 241-VI of April 2, 2019) (Kh) |
| Kyrgyzstan | <ul style="list-style-type: none"> Law of the Kyrgyz Republic No. 8 of January 14, 1998, on Patents (as amended up to Law No. 55 of May 26, 2018) Decision of the Government of the Kyrgyz Republic No. 715 of October 30, 2017, on Amendments to the Decision of the Government of the Kyrgyz Republic of No. 862 of December 24, 1998, on Approval of the Regulation on Conditions and Procedures for the Granting of Compulsory Licenses for the Use of Industrial Property Rights and Traditional Knowledge(KG286) Regulation on Conditions and Procedures for the Granting of Compulsory Licenses for the Use of Industrial Property Rights, Traditional Knowledge and Selective Breeding Achievements (approved by Decision No. 862 of December 24, 1998, and amended up to the Decision No. 715 of October 30, 2017, of the Government of the Kyrgyz Republic)(KG265) Decision of the Government of the Kyrgyz Republic No. 652 of September 21, 2015, on Amendments to Certain Decisions of the Government of the Kyrgyz Republic (as amended by the Decision of Government of the Kyrgyz Republic No. 523 of October 3, 2016)(KG242) Decision of the Government of the Kyrgyz Republic No. 862 of December 24, 1998, on Approval of the Regulation on Conditions and Procedures for the Granting of Compulsory Licenses for the Use of Industrial Property Rights, Traditional Knowledge and Selective Breeding Achievements (as amended up to Decision No. 715 of October 30, 2017)(KG285) Study ITPC Ru: Analysis of procurement of antiretroviral drugs and drugs for the treatment of viral hepatitis C in the Kyrgyz Republic in 2019 |
| Malaysia | <ul style="list-style-type: none"> Patents (Amendment) Regulations 2011, MY073 (Fees for CLs (and other stuff)) Patents (Amendment) Act 2006 (Act A1264) Patents (Amendment) Regulations 2006 Patents (Amendment) Regulations 1995(MY070) (Form and element of procedure) Patents (Amendment) Act 2000 (Act A1088)(MY008) but from 2000!!? Patents (Amendment) Act 1993 (Act A863)(MY023) one deletion of something related to CL 1993 Patents (Amendment) Act 1986 (Act A648)(MY024) board 1986 Patent Act 1983 (Art 291) Press Statement Minister of Health 20th September 2017 Gilead tussles with Malaysia over licensing its hepatitis C treatment - STAT |

| Country | Texts Consulted |
|----------|--|
| Morocco | <ul style="list-style-type: none"> • Maroc-Decret n° 2-00-368 du 7 juin 2004 • Circulaire relative à procédure d'autorisation d'importation de médicaments et de dispositifs médicaux à titre de dons • 17-04-Code du Médicament-Maroc • Law No. 17-97 on the Protection of Industrial Property incorporates all the amendments made by the following Amendment Laws: Law No. 31-05, which was adopted on February 14, 2006, and entered into force on March 2, 2006; and Law No. 23-13, which was adopted on November 21, 2014, and entered into force on December 18, 2014. |
| Russia | <ul style="list-style-type: none"> • Civil Code of the Russian Federation (Parts One to Four) • Law "On Circulation of Medicines" • ITPC ru study 2021 |
| Thailand | <ul style="list-style-type: none"> • Patent Act B.E. 2522 (1979), amended en 1999 |
| Vietnam | <ul style="list-style-type: none"> • Law No. 50/2005/QH11 of November 29, 2005, on Intellectual Property • Circular No. 05/2010/TT-BYT of March 1, 2010, on Guiding the Confidential Protection of Trial Data in Drug Registration(VN077) • Circular No. 01/2007/TT-BKHCH of February 14, 2007, guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, detailing and guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property(VN010) • Decree No. 103/2006/ND-CP of September 22, 2006, detailing and guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property(VN008) |
| Zimbabwe | <ul style="list-style-type: none"> • Patents Act (Chapter 26:03, as amended up to Act No. 14/2002) • Declaration of emergency 2002 |

Annex 3:

Grounds for CL: Summary of the main findings per country

| Main findings per country | Ecuador | Brazil | Argentina | Guatemala | Honduras | El Salvador | Belarus | Kyrgyzstan | Kazakhstan | Georgia | Russia | Morocco | Zimbabwe | India | Vietnam | Thailand | Malaysia | Indonesia |
|---------------------------|---------|--------|-----------|-----------|----------|-------------|---------|------------|------------|---------|--------|---------|----------|-------|---------|----------|----------|-----------|
| Admin route | | | | | | | | | | | | | | | | | | |
| Judicial proc | | | | | | | | | | | | | | | | | | |
| Non-use | | | | | | | | | | | | | | | | | | |
| Local work | | | | | | | | | | | | | | | | | | |
| Supply | | | | | | | | | | | | | | | | | | |
| Competition | | | | | | | | | | | | | | | | | | |
| Urgency | | | | | | | | | | | | | | | | | | |
| Nat. security | | | | | | | | | | | | | | | | | | |
| Non-com use | | | | | | | | | | | | | | | | | | |
| Gov. use | | | | | | | | | | | | | | | | | | |
| Public int | | | | | | | | | | | | | | | | | | |
| Health | | | | | | | | | | | | | | | | | | |
| Pharmaceu | | | | | | | | | | | | | | | | | | |
| Tech. trans | | | | | | | | | | | | | | | | | | |
| Industry dev | | | | | | | | | | | | | | | | | | |
| Export meds | | | | | | | | | | | | | | | | | | |
| Infringement | | | | | | | | | | | | | | | | | | |
| Dep. patents | | | | | | | | | | | | | | | | | | |

Key

| | |
|-----------------------|--|
| Admin route: | Administrative decision |
| Judicial pro: | Decision to grant CL through court |
| Non-use: | Lack of use of the patent as a ground |
| Local work: | Absence of local work as a ground |
| Supply: | Insufficient supply as a ground |
| Competition: | Remedy to anticompetitive practices is a ground |
| Urgency: | Extreme urgency, national emergency, calamity or catastrophe is mentioned as a ground. |
| Nat. security: | National security is mentioned as a ground |
| Non-com use: | Public non-commercial use is mentioned as a ground |
| Gov. use: | Government use is an option |
| Public int: | Public interest is a grounded |
| Health: | Health is mentioned as a ground |
| Pharmaceu: | Grounds related to pharmaceuticals/health products |
| Tech. trans: | Technology transfer is a ground |
| Industry dev: | Building of local industry as purposes of CL |
| Export meds: | The option of CL for export is specifically mentioned |
| Infringement: | CL as a remedy by a court in a case of infringement/limited liability |
| Dep. patents: | Use of dependent patents is allowed |

See the Excel files at <https://makemedicinesaffordable.org/resources/>



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