

# Country experiences in using TRIPS safeguards: Part I

The document is a brief overview of countries' experiences in using the safeguards available in the TRIPS Agreement to protect public health and access to medicines. It is written in response to requests to share such experiences. Part I of this note highlights examples of compulsory licensing and application of strict patentability criteria. Part II highlights examples of the use of competition law and TRIPS safeguards specific to least developed countries (LDCs).

## Compulsory licensing in developing countries

While the TRIPS Agreement contains several safeguards, probably the most important one is compulsory licensing. A compulsory licence (CL) is a licence granted by the government to allow the use of a patented invention without the permission of the patent holder. Virtually all patent laws contain provisions for compulsory licensing, which is allowed under TRIPS. A CL allows the production, import, sale and use of generic products before expiry of the patent. A special case of compulsory licensing is "government use" (GU) or a CL for public non-commercial use, i.e. when a government itself uses, or authorizes a third party to use, a patented invention for government purposes, without the permission of the patent holder. A CL predominantly or exclusively for export is also recognized under Article 31*bis* of the TRIPS Agreement.

Since the coming into force of the TRIPS Agreement in 1995, several developing countries have issued CLs in order to increase access to medicines.<sup>a</sup>

<sup>a</sup> The examples listed in this briefing note do not represent a complete or comprehensive list.

## Malaysia

On 20 September 2017, Malaysia issued a CL for the 400 mg sofosbuvir tablet to treat hepatitis C. The Minister of Health, Malaysia stated that with approximately 500 000 patients in Malaysia, hepatitis C was a major public health concern. Therefore, the Cabinet approved the use of Rights of Government under Patent Act 1983 (Act 291) by exploiting the patented invention of sofosbuvir tablet 400 mg. The decision to initiate the Rights of Government was made after unsuccessful attempts at price negotiations by the Ministry of Health (MoH) with the patent holder. The implementation of the Rights of Government for the 400 mg sofosbuvir tablet is for use in government facilities only (MoH and Armed Forces hospitals). In the initial phase, it will be offered in only 12 MoH hospitals.<sup>1</sup>

The country had invoked a CL earlier as well. In November 2002, after efforts to negotiate price reductions had failed, the MoH of Malaysia proposed the use of "government rights" to the Cabinet. In January 2003, upon receiving approval, the MoH applied to the Ministry of Domestic Trade and Consumer Affairs (custodian of the Patents Act) for an authorization to import generic versions of patented antiretrovirals (ARVs). In spite of Cabinet approval, the authorization was opposed by some other government agencies, citing concerns that it would deter foreign investors.

On 29 October 2003, however, the authorization for the exploitation of a patented invention on behalf of the government (government use authorization) was issued. It allowed a local company to import didanosine tablets, zidovudine tablets and a

These UHC technical briefs summarize current knowledge on strengthening health systems to achieve Universal Health Coverage. They outline key technical issues and international experience relevant to health policy and practice in low- and middle-income countries in the South-East Asia Region.

fixed-dose combination (FDC) of didanosine and zidovudine from a generic manufacturer in India.

The authorization was valid for two years. It required that the medicines be labelled with the words “Ministry of Health Malaysia” and imposed several other conditions, including a maximum price and a requirement that royalties be paid to the patent holder(s) within two months of importation of each successive batch. While the authorization did not specify the royalty rate, the MoH offered the patent holders 4% royalties. The patent holders, however, showed little interest in accepting or negotiating the proposed remuneration.

Following the government use authorization, the patent holders reportedly reduced their prices by 50–80%. However, treatment costs were lower than this with the use of generics, and the number of patients treated with (generic) ARVs in the public sector more than doubled.

In reaction to the government use authorization, one of the patent holders filed a lawsuit, which, however, was never activated, while complaints were received at some Malaysian embassies.

On 1 November 2005, the authorization expired. It was not renewed, as the price reductions offered by the patent holders were considered satisfactory.

## Zimbabwe

On 8 April 2003, Zimbabwe issued a CL for all HIV- and AIDS-related medicines. The licence was issued after a period of emergency on HIV/AIDS was declared. The declaration of emergency was issued in accordance with Zimbabwe’s own national law; it is not a TRIPS requirement (see Box 1). The CL allowed a local company, Varichem Pharmaceuticals Ltd, to produce ARVs or HIV/AIDS-related medicines during the emergency period. The licence required the company to supply three quarters of its production to State-owned health institutions and specified that the medicines produced under the licence would be subject to price controls.

Varichem reportedly launched its first ARV in Zimbabwe in October 2003, and has since launched several other ARVs. It supplies to both the government and private sector.

### Box 1. The “emergency” myth

There is a widespread misunderstanding that TRIPS allows for compulsory licensing only when there is an emergency. This is not correct; TRIPS leaves countries free to decide the grounds, or reasons, for issuing a CL.

TRIPS does, however, impose a number of conditions.

One of those conditions is that there should first be an effort to obtain a voluntary licence from the patent holder. This particular condition is waived in three cases: (i) when there is an emergency, or in case of “other circumstances of extreme urgency”; (ii) in case of public non-commercial use (or government use); or (iii) when the CL is granted to remedy anticompetitive behaviour.

## Brazil

Brazil, like Thailand, has a government-owned company that produces generic versions of certain ARVs, which are not under patent in Brazil. In addition, Brazil has used the fact that it is capable of producing generic versions of crucial HIV drugs, and that it would be willing to issue a CL, if necessary, to negotiate substantial price discounts for those drugs that are patented. For several years, this strategy was successful, and Brazil did not actually have to issue a CL.

However, on 24 April 2007, the Minister of Health passed Decree n<sup>o</sup> 866, declaring that efavirenz would be eligible for compulsory licensing for public non-commercial purposes. This was followed, on 4 May 2007, by the issuing of a CL for public non-commercial use of efavirenz. The CL was valid for a period of five years, and specified a royalty rate of 1.5%.

This action was taken after price negotiations with the patent owner, in 2006, failed. The time lag between the passing of Decree n<sup>o</sup> 866 and the issuing of the CL was intended to allow the patent owner to submit a better price offer. Reportedly, a 30% price reduction was proposed, which was considered insufficient, as the patent holder had offered a significantly lower price to Thailand.

Following the issuing of the CL, the first consignment of generic efavirenz was imported on 2 July 2007, at a price reduction of 65–70% (depending on dosage). Between 2007 and 2010,

Brazil imported generics of efavirenz from India. After this, the drug was locally produced and supplied to the government programme. By 2012, the savings to the Government of Brazil were estimated to be almost 58.47% as a result of the lower generic price.<sup>2</sup>

In May 2012, Brazil renewed the CL on efavirenz for an additional 5 years.

## Ecuador

In 2009, Presidential Decree 118 was issued “declaring of public interest access to medicines used in the treatment of diseases which affect the Ecuadorian population and which constitute a priority in terms of public health, and consequently authorizing the issuing of compulsory licences for patents for medicines for use on human beings which are necessary for their treatment”.<sup>3</sup> While the Ecuadorian Institute of Intellectual Property (IEPI) is identified as the competent authority to grant CLs and establish their scope, time period, etc. the Decree requires IEPI to grant CLs in coordination with the Ministry of Public Health. It further requires the drug regulator to register medicines produced or imported under a CL within 30 days. In 2010, the IEPI issued Resolution No. 10-04 P-IEPI with detailed provisions outlining the process for the application and grant of CLs in order to implement the Presidential Decree.<sup>4</sup> The resolution distinguishes the processes required for CL applications for commercial and public non-commercial use.

Based on these provisions, a CL for ritonavir was issued in 2010 by the IEPI and the National Directorate of Industrial Property (DNPI). In 2012, a CL for abacavir/lamivudine was also issued. The IEPI in a press release noted that the retail price of 30 pills of abacavir/lamivudine was \$753 per month; the cost of a year’s course was \$9036. After confirmation from the Ministry of Public Health that this was a priority medicine, the CL was granted to an Ecuadorean manufacturer with the aim of reducing the cost by 75%. Ecuador used the 2005 WHO/UNDP tiered royalty method (TRM) to set the royalty at 11.7 cents per capsule.<sup>5</sup> In 2014, CLs were also issued for medicines for cancer, arthritis and other diseases. Overall, since the CL decree was issued, there have been 32 CL applications, nine of which have been granted. Price reductions achieved from these CLs have resulted in 30% to 70% savings for the MoH.<sup>6</sup>

### Box 2. The “HIV, tuberculosis and malaria” myth

In 2001, the Doha Declaration specified that for the purposes of issuing CLs, “each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”

This provision clarified that “public health crises” can represent a national emergency or extreme urgency. The specific mention of “HIV/AIDS, tuberculosis, malaria and other epidemics” indicated that emergency or extreme urgency did not necessarily denote a short-term situation and could run over a long term as in the case of the diseases mentioned. The Declaration was thus adopted in response to concerns of developing countries about the obstacles they faced while seeking to implement measures to promote access to affordable medicines in the interest of public health in general, without being limited to certain diseases.

However, sometimes, there has been some misunderstanding about this list of diseases in the Doha Declaration. In fact, this was an inclusive, illustrative list and not meant to be a closed list of diseases. As noted above, TRIPS leaves countries free to decide the grounds, or reasons, for issuing a CL and this was confirmed in the Doha Declaration. As developing countries have demonstrated (see Summary table below), CLs, whether for national emergency or otherwise, can be issued in the case of any disease, including cancer, heart disease, arthritis, etc.

## Compulsory licensing in developed countries

CLs have also been used in developed countries. Some examples are listed below.

### Canada

Before it acceded to the North-American Free Trade Agreement (NAFTA) in 1992,<sup>b</sup> Canada made extensive use of compulsory licensing to promote the public interest; thus, between 1969

<sup>b</sup> NAFTA is a pre-TRIPS trade agreement, but contains provisions on intellectual property rights that are very similar to those in TRIPS.

and 1992, there were 1030 applications to import or manufacture medicines under such licences, of which 613 were granted.<sup>7</sup> From 1970 to 1978, 142 CLs were issued on 47 prescription drugs. Prices of generic versions were 20–60% below the original price, depending on the number of competitors.<sup>8</sup>

## United States of America

Unlike most other countries, the United States of America has never enacted a law that generally authorizes compulsory licensing of patents in the public interest. However, “the United States Government has broad powers to seize and use any invention protected by privately owned patents, subject to the payment of reasonable and entire compensation, and it makes extensive use of this power”.<sup>8</sup> CLs are also granted in cases of antitrust violations. In the United States, any department of the Federal Government can use or authorize “government use” of a patent. The United States Government does not have to negotiate first, and neither the government nor its contractors can be sued for infringement; the patent holder’s only remedy is to seek compensation.

While the majority of CLs in the United States are not for pharmaceuticals, the possibility of using this mechanism was contemplated seriously for ciprofloxacin, in the wake of the 2001 anthrax scare. US Federal Courts have effectively issued CLs in some patent infringement cases by rejecting requests for permanent injunctions. Examples in this regard relate primarily to medical devices, including the intellectual property related to drug-eluting stents with a rapid exchange delivery system (2005), to guiding catheters for performing angioplasty (2006) and on patents related to contact lenses (2010).

## Germany

In 2016, the Federal Patent Court of Germany issued a CL under Section 24 of the Patent Act, allowing Merck (US) to continue to market the HIV drug raltegravir. The decision arose from proceedings between Merck and the Japanese company Shionogi, which had requested a preliminary injunction against Merck in 2015 for use of its patent. After Shionogi rejected Merck’s offer for a voluntary worldwide licence on the patent, Merck requested a CL. Based on expert opinion, the Court came to the conclusion “that the drug is needed by certain groups of HIV-infected and/

or AIDS-affected patients for medical reasons and cannot avoid these without considerable health risks on other preparations. This applies in particular to pregnant women, infants and children, as well as patients treated for HIV for many years. In doing so, the Senate has also taken into account that an effective risk of contagion for third parties is reduced by an effective reduction in viral load. This is a public interest in granting a forced licence.”<sup>9</sup>

## Compulsory licensing for export (under Article 31bis of the TRIPS Amendment)

The WTO’s decision of 30 August 2003<sup>10</sup> set up a system that allows production of a pharmaceutical product under a CL predominantly or exclusively for export to a country that lacks domestic manufacturing capacity, provided certain procedures are followed.<sup>c</sup> This mechanism waived the requirement in the TRIPS Agreement that any CL be predominantly for the domestic market. In 2005, the 30 August Decision was also reflected in a protocol for the first-ever amendment to the TRIPS Agreement in the form of Article 31*bis*. As of January 2017, this amendment to the TRIPS Agreement is now in effect after being accepted by two thirds of WTO Members. This amendment applies to those WTO Members who have accepted it so far and those who have not, have till 31 December 2017 to agree to it.<sup>11</sup> Before it became a permanent part of the TRIPS Agreement, this system was used by Canada and Rwanda.

## Canada and Rwanda

In July 2007, Rwanda notified the WTO Secretariat of its intention to import 260 000 packs of an FDC of zidovudine+ lamivudine + nevirapine from Apotex, a generic manufacturer in Canada. This was the first attempt to make use of this system. The notification stated that Rwanda reserved the right to modify the quantity as necessary. It furthermore stated that Rwanda would make use of its right, as an LDC, to not enforce any patent rights that may have been granted with regard to this product.

Following this request, the Canadian Commissioner of Patents granted, in September 2007, a CL to Apotex, allowing Apotex to

<sup>c</sup> For more information, see document 2 in the Bibliography section (at the end of this briefing note).

manufacture the concerned product exclusively for export to Rwanda. This CL was valid for a period of two years.

## Other TRIPS flexibilities

Compulsory licensing and other safeguards such as parallel importation are important mechanisms that allow governments to protect the public health interest after a patent has been granted (i.e. these are “post-grant” safeguards). Some countries also focus on using “pre-grant” flexibilities. Pre-grant flexibilities seek to ensure that patents are not granted unnecessarily; for instance, when a country has no obligation to grant patents as in the case of least-developed countries (see Country experiences in using TRIPS safeguards: Part II), or when an invention does not deserve a patent. Examples of pre-grant flexibilities include pre-grant opposition and the right to define the standards for patentability (see example of India below).

### India

In 2005, India was the first country to incorporate a provision in its law that specifically aimed at preventing the grant of “evergreening” patents (see Box 3). This provision, or a simplified equivalent, can be used to prevent the issuing of unnecessary or frivolous “evergreening” patents. The Indian law also allows for pre- and post-grant patent oppositions. Public interest groups in India have successfully used these provisions to oppose patent applications on several medicines of public health importance, including the following ARVs: nevirapine hemihydrate, tenofovir, abacavir, ritonavir, and the combination of lopinavir and ritonavir, among others.

For instance, in March 2006, a coalition of public interest groups filed an opposition against GlaxoSmithKline (GSK)’s application for a patent on Combivir (an FDC of zidovudine + lamivudine). Referring to section 3(d) of India’s Patents Act (see Box 3), they argued that “a combination of two drugs in one pill is not considered an invention under Indian patent law”;<sup>12</sup> therefore, no patent should be granted. Following the filing of the pre-grant opposition and public protests, in June 2006, GSK announced the withdrawal of pending patent applications for an FDC of zidovudine + lamivudine in India (as well as Thailand).

In 1998, Novartis filed a patent application for the beta crystalline form of imatinib mesylate (Gleevec), an anti-cancer drug. Imatinib was originally patented in 1993. The application was opposed by several Indian generic manufacturers as well as a cancer patients’ group, who alleged, among others things, that the claimed invention was not patentable under section 3(d) of the Patent (Amendment) Act, 2005. According to the opponents, Gleevec is a polymorph form of imatinib mesylate; section 3(d) considers polymorphs to be the same substance unless they differ significantly in properties with regard to efficacy – which they argued was not the case. The patent office rejected the application, and the patent was not granted in India.

Novartis challenged the decision to reject the patent application as well as the relevant section (section 3(d)) of the Patents Act under both the Indian Constitution and the TRIPS Agreement. After the Chennai High Court found that the concerned section did not run counter to the Indian Constitution, and dismissed the second challenge, on the ground that it has no jurisdiction to decide compliance with TRIPS, Novartis appealed the interpretation of the provision, in particular, that of the word “efficacy” in the Supreme Court of India. On 1 April 2013, the Indian Supreme Court<sup>13</sup> dismissed Novartis’ appeal, upholding the strict application of section 3(d) and finding that the new form of imatinib did not meet the requirement of the Indian law, i.e. of significantly enhancing the therapeutic efficacy of the drug.

## Initiatives of Other Countries

Several developing countries are now using similar TRIPS flexibilities. In April 2008, the **Philippines** amended its Intellectual Property Code and introduced a similar “anti-evergreening” clause.<sup>d</sup> In 2016, **Indonesia** amended its patent law to also include restrictions on evergreening.<sup>14</sup> An alternative approach would be to incorporate an “anti-evergreening” provision in the section of the law that deals with patentability criteria, notably inventiveness. In 2012, **Argentina** issued regulations for the examination of pharmaceutical patent applications that detail how new forms of existing medicines may not meet the patentability criteria.<sup>15</sup> Successful patent oppositions by public

<sup>d</sup> In fact, it introduced it twice; once under “non-patentable inventions” and once under “inventive step”. See Section 5, Universally Accessible Cheaper and Quality Medicines Act of 2008 (Republic Act No. 9502), Philippines.



**Summary table:** Examples of compulsory licences by/for developing countries<sup>a</sup>

Date	Country	Type	Product	Duration	Royalties
April 2003	Zimbabwe	CL	All HIV/AIDS-related medicines	Not indicated	Not indicated
October 2003	Malaysia	GU	Didanosine Zidovudine FDC didanosine+zidovudine	2 years	Not indicated
Sept. 2004	Zambia	CL	FDC of lamivudine+stavudine+nevirapine	until notification of expiry of the compulsory licence	2.5%
October 2004	Indonesia	GU	Lamivudine Nevirapine	7–8 years (remaining patent term)	0.5%
November 2006	Thailand	GU	Efavirenz	Until 31 December 2011	0.5%
January 2007	Thailand	GU	Lopinavir/ritonavir	Until 31 January 2012	0.5%
January 2007	Thailand	GU	Clopidogrel	Patent expiry or no longer needed	0.5%
March 2007	Indonesia	GU	Efavirenz	Until 7 August 2013	0.5%
May 2007	Brazil	GU	Efavirenz	5 years	1.5%
September 2007	Canada for export to Rwanda	CL	FDC of lamivudine+zidovudine+nevirapine	2 years	2%
January 2008	Thailand	GU	Letrozole Docetaxel Erlotinib Imatinib ( <i>GU implementation suspended due to free drug donation</i> )	Patent expiry or no longer needed	3–5%
April 2010	Ecuador	GU	Ritonavir	Patent expiry	\$0.041 per 100 mg ritonavir capsule \$0.02 per lopinavir 200 mg + ritonavir 50 mg capsule
March 2012	India	CL	Sorefanib tosylate	Patent expiry	7%
May 2012	Brazil	GU renewal	Efavirenz	5 years	1.5%
September 2012	Indonesia	GU	Efavirenz Abacavir Didanosine Lopinavir+ritonavir Tenofovir Tenofovir+emtricitabine Tenofovir+emtricitabine+efavirenz	Patent expiry	0.5%

Date	Country	Type	Product	Duration	Royalties
November 2012	Ecuador	GU	Abacavir+lamivudine	Patent expiry	\$0.117 cents per capsule
April–July 2014	Ecuador	CL	Etoricoxib Mycophenolate sodium Sunitinib Certolizumab	Not available	Not available

CL: compulsory licence; GU: government use (CL for public non-commercial use)

interest groups on key medicines for HIV, hepatitis C and other diseases have also taken place in Argentina, Brazil, China, Thailand, Ukraine and Viet Nam.

safeguards, in national laws. Yet even though compulsory licensing is allowed under TRIPS, some developing countries have experienced criticism and/or pressure when using this safeguard mechanism;<sup>e</sup> thus, there appears to be a need to safeguard the safeguards.

## Learning from the CL experiences of countries

Some preliminary conclusions and lessons can be drawn from these experiences. These include the following:

- ◉ Compulsory licensing can and has been used to protect public health in developed and developing countries.
- ◉ While the number of instances of compulsory licensing by developing countries is relatively limited, those experiences show that compulsory licensing/government use can be an effective mechanism.
- ◉ A CL, or a “credible threat” to issue one, can be instrumental in obtaining price reductions from the patent holder.
- ◉ Various “pre-grant” flexibilities can play a complementary role in safeguarding access to medicines.

This underscores the need for incorporating workable provisions for compulsory licensing and government use, as well as other (pre-grant)

### Box 3. Section 3(d) of India’s Patents Act (2005)

The following are not inventions within the meaning of this Act, - [...]

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation – for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

<sup>e</sup> However, no country has had its decision to issue a compulsory licence challenged at the WTO Dispute Settlement Body, which would be the appropriate forum for dealing with actions that contravene the TRIPS Agreement.

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