

# ***South Views***

No. 60, 15 April 2013

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## **The Use of Compulsory Licenses in Latin America**

**By Carlos M. Correa**

**This article examines the situation in Latin American countries with respect to their laws and policies relating to compulsory licenses—and how Brazil and Ecuador have made use of such compulsory licenses for drugs.**

Compulsory licensing is one of the important 'flexibilities' recognized under article 31 of the Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement).

Since January 1995—the general date of entry into force of the TRIPS Agreement—at least 12 developing and Least Developed Countries (LDCs) have granted compulsory licenses (CLs) or decided the public non-commercial use (hereinafter 'government use') of patents. The great majority of CLs/ government use involved drugs for HIV/AIDS. Only a few related to drugs for other communicable or non-communicable diseases: cancer (Thailand and India) cardiovascular disorders (Thailand) and avian flu (Taiwan). In one case a CL was also granted for patents unrelated to the pharmaceutical field.

Latin American countries have used the policy space left by the TRIPS Agreement to design national legislation on intellectual property (IP) to a different extent. So far, only two countries (Brazil and Ecuador) have threatened or made effective use of CLs/government use provisions.

Complaints under the Dispute Settlement Understanding (DSU) of the WTO based on the alleged inconsistency of national provisions on CLs with the TRIPS Agreement, were submitted against two countries in the region (Argentina and Brazil), in both cases by the USA. These complaints, however, did not lead to changes in legislation.

This paper examines, first, the modalities for CLs/government use available in Latin American legislation, and addresses its relationship with the provisions relating to test data protection. Second, it describes cases in which the TRIPS-consistency of the provisions on CLs was questioned in the context of the WTO rules. Third, it considers cases in which the possibility of the grant of a CL led to price reductions of the concerned products; the case of an unsuccessful request for a CL is also mentioned. Fourth, the CLs/government use granted in the region are briefly reviewed. Fifth, the status of implementation of the WTO Decision of August 30, 2003 in the Latin American region is examined. Finally, some conclusions are drawn from the previous analysis.

### **Provisions on CLs and government use**

Patent legislation in Latin America provides for different grounds for the grant of compulsory license, as well as for the possibility of ordering the government use of any patent. An illustrative list of such grounds is provided in the Table below.

| <b>Grounds for issuing CLs</b>   | <b>Countries where these grounds are provided for</b>   |
|--|---|
| Failure to exploit a patent  | Andean Community, Argentina, Brazil, Dominican Republic, Honduras, Mexico, Chile, Uruguay, Costa Rica                         |
| Public interest  | Andean Community, Brazil, Dominican Republic, Honduras, Mexico, Chile, Uruguay, Guatemala, Costa Rica                         |
| National emergency and other circumstances of urgency                              | Andean Community, Argentina, Brazil, Dominican Republic, Honduras, Mexico, Chile, Uruguay, Guatemala, Costa Rica, El Salvador |
| Remedy for anticompetitive practices   | Andean Community, Argentina, Brazil, Dominican Republic, Chile, Uruguay, Guatemala, Costa Rica                                |
| Failure to obtain a license under reasonable terms                                 | Argentina, Dominican Republic, Honduras, Uruguay  |
| Dependent patents (when a patent cannot be exploited without using another patent) | Andean Community, Argentina, Brazil, Dominican Republic, Honduras, Chile, Uruguay, Costa Rica                                 |

### **Grounds for granting CLs and government use in Latin American legislation**

While a number of Latin American countries have signed free trade agreements (FTAs) with the USA and the European Union, such agreements have not introduced limitations on the possible grounds for CLs. This is possibly the result of the unambiguous confirmation by the Doha Declaration on the TRIPS Agreement and Public Health (hereinafter ‘the Doha Declaration’) of the WTO Members’ right to determine the grounds for CLs.

As a result of such FTAs, however, the execution of CLs may be impeded if test data are subject to exclusive rights. Although the TRIPS Agreement only requires, under article 39.3, to protect such data against unfair competition, the FTAs with the USA and the European Union impose the so-called ‘data exclusivity’ that, under certain conditions, prevents a generic company from using or relying on the data developed by another company to obtain marketing approval of a medicine containing the same chemical entity. In these situations, while a CL may allow the use of a patent, the compulsory licensee may not be able to obtain the required marketing approval for its own product.

Although in an imprecise manner, some FTAs have attempted to clarify the relationship between CLs and test data protection, through ‘side letters’ that state that the FTA would not prevent the Parties from taking measures to protect public health.

In the case of the FTA between the USA, the Central American countries and Dominican Republic (CAFTA-DR) an “Understanding Regarding Certain Public Health Measures” states that “[T]he implementation of provisions of Chapter 15 of the Agreement does not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all. This will concern, in particular,

cases such as HIV/AIDS, tuberculosis, malaria and other epidemics as well as circumstances of extreme urgency or national emergency.” This wording is clearly limitative as it refers to cases where a measure is ‘necessary’ (a concept generally interpreted narrowly under WTO law) and to particular diseases.

In order to overcome the ambiguities in the relationship between data exclusivity provisions and CLs, the Chilean regulation on test data has clarified that such protection ‘shall not apply, when: ... the pharmaceutical or agrochemical product is subject to a compulsory licence, as established in this Law’ (consolidated text, Industrial Property Law, No. 19.996, Article 91). This clause provides a good model for countries where a conflict between data exclusivity and CLs may arise.

## **Consistency of CLs provisions with the TRIPS Agreement**

### ***Lack or insufficient working of a patent***

The obligation to work a patent –understood as the local manufacturing of a patented product or the industrial use of a patented process – was provided for in a large number of national laws in the XIXth century. During the twentieth century, however, most industrialized countries relaxed or eliminated such an obligation in order to ensure patent holders the option of exploiting their patents merely through importation and thereby facilitate transborder activities in an increasingly globalized world market.

During the Uruguay Round negotiations there was an intense North-South debate on the admissibility of CLs for lack of or insufficient working of a patent. Developing countries wanted to secure that a future Agreement did not restrict the possibility of granting CLs on those grounds, as allowed by article 5A of the Paris Convention. The divergences on this issue remained unsettled until the very final stage of the negotiations in December 1991, when a compromise was reached on the basis of wording incorporated into article 27.1 of the Agreement:

‘...patent rights shall be enjoyable without discrimination...whether the products are imported or locally produced”.

Many commentators and policy makers have read this provision as the death sentence of working obligations for patent owners. In fact, although some national laws have maintained or specifically provided for the grant of CLs for lack of or insufficient working, after the adoption of the TRIPS Agreement such provisions are not so common as before. In some cases, ‘working’ is interpreted broadly so as to encompass the importation of the patented product or of the product manufactured with a patented process. This obviously dilutes the working obligation as a tool to promote local manufacturing.

A proper interpretation of article 27.1, in accordance with articles 31 and 32 of the Vienna Convention on the Law of Treaties, however, suggests that the grant of compulsory licenses due to the lack or insufficient work are TRIPS-consistent. In effect, Article 27.1 of the Agreement does not specify whether the products that are “imported or locally produced” are those of the patent owner or third parties’ infringing products. The “patent rights” referred to in Article 27.1 are defined in Article 28.1 of the Agreement, which only requires the granting of *negative* rights with regard to the exploitation of the invention, that is, the right to prevent third parties from using in various forms (without authorization) the patented invention. Hence, an interpretation of Article 27.1 read in conjunction with Article 28.1, suggests that the products mentioned in Article 27.1 are *infringing* products, not the products of the patent owner himself, since patents only confer exclusionary rights in relation to the former. In other words, Article 27.1 forbids discrimination between *infringing* imported and *infringing* locally made products, but it does not prevent the establishment of differential obligations with regard to products made or imported by the patent owner or with his/her consent.

Thus, the non-discrimination clause of Article 27.1 applies in cases where the rights enjoyed by patent owners are different (substantially or procedurally) depending on the foreign or domestic origin of the third parties’ products. For instance, Section 337 of the U.S. Tariff Act was found inconsistent with the GATT in *United States -- Section 337 of the Tariff Act of 1930*, since it accorded less favorable treatment to imported products challenged as infringing U.S. patents than the treatment accorded to similarly challenged products of United States origin.

It should also be noted that Article 5(A)(2) of the Paris Convention –incorporated into the TRIPS Agreement via its article 2 - provides that each party to the Convention “shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, “*failure to work*” (emphasis supplied). In accordance with international law principles, there is a presumption against treaty conflict; that is, the Paris Convention and the TRIPS Agreement need to be read in a manner that reconcile their respective

provisions. Notably, the latter does not explicitly ban or otherwise refer to CLs. In contrast, the TRIPS Agreement specifically excludes the provision on CLs (article 6.3) contained in the Washington Treaty in respect of Integrated Circuits.

Finally, article 7 of the TRIPS Agreement makes it clear that one of the objectives of the Agreement is to promote technology transfer, which may be ensured, in some circumstances, by means of compulsory licenses for non-working.

In January 2001, the US brought a complaint against Brazil arguing that the Brazilian law's authorization to grant compulsory licenses when patents were not worked was TRIPS-inconsistent. In accordance with article 68 of the Brazilian law:

(1) The following may also be grounds for compulsory licensing:

I - failure to exploit the object of the patent within the Brazilian territory for failure to manufacture the product or failure to fully use a patented process, except in case of economic unfeasibility, in which case importing shall be admitted; or

II - marketing that does not satisfy the needs of the market.

While Brazil and the USA failed to clarify the issue at the consultation stage of the WTO dispute settlement procedures and the USA was, hence, entitled to request the establishment of a panel, the USA withdrew the complaint, on the basis of an agreement reached with the Brazilian government. In accordance with this agreement, without prejudice to their respective positions, the United States and Brazil agreed to enter into bilateral discussions before Brazil makes use of Article 68 against a U.S. patent holder. This agreement does not prevent Brazil from granting a CL based on article 68, but only requires it to enter into bilateral discussions; Brazil may subsequently decide to grant a CL. It may be speculated that the USA withdrew the complaint against Brazil because of fears that an adverse ruling in WTO could set a negative precedent—from the US perspective - on the interpretation of articles 27.1 and 31 of the TRIPS Agreement. The fact is that the TRIPS-compatibility of CLs provisions for non-working has never been raised again under the DSU, despite the fact that several national laws contain provisions allowing for compulsory licenses in such cases.

### ***CLs as a remedy to anti-competitive practices***

The US questioned, in 2000, the consistency with article 31(k) of the TRIPS Agreement, of the provisions of the Argentine patent law No. 24.481, regarding the availability and grant of compulsory licenses to remedy anti-competitive practices. The US objection concerned the process for the grant of such licenses, as it wanted to make it clear that a prior determination of the existence of anti-competitive practices by the competition authority was required. US and Argentina reached an agreement on the matter, on the basis of the joint reading of the law and its implementing regulation (Decree 260/96). The agreement confirmed that 'in order to justify the granting of a compulsory license... a prior decision must have been handed down by the National Commission on the Defense of Competition (or the body that might substitute it in the future) analyzing the practice in question based on Law No. 25.156 (Law of Defense of Competition). According to this law, the existence of an abuse of a dominant position in the market must be established in order for a practice to be considered "anti-competitive".

### **CLs as a tool for price reduction**

The number of CLs/government use granted worldwide has been low. This does not mean, however, that the provision of CL in national laws may not contribute to mitigate the effects of the exclusive rights granted to title-holders. A credible threat of a CL can discipline title-holders, particularly in respect of prices charged for protected products.

A good example of this situation is provided by the price reductions for two anti-retrovirals that the Brazilian government could secure after indicating that CLs could otherwise be granted. The Ministry of Health made HIV/AIDS medicines available free of charge to all citizens under the National STD/AIDS Programme. In 2001 the Ministry was able to obtain price reductions of 40 to 70% for Nelfinavir and Efavirenz on which Roche and Merck, respectively, held patents. The bargaining position of the Ministry was strengthened by the fact that Brazil already had manufacturing capacity in pharmaceuticals. Farmanguinhos, the main government drug producer, was able to produce several anti-retrovirals at low cost, as well as to reverse engineer and realistically estimate production costs for the drugs of interest to the Ministry of Health. This capacity was probably key in conveying Roche and Merck the message that the threat of CLs was real.

Another case that led to a reduction of the price of a combination of anti-retrovirals, but in this case, without issuing a CL, was triggered in Colombia by a request by non-governmental organizations in 2008 for the grant of a CL on Abbott's patented combination of lopinavir and ritonavir (Kaletra). This product was sold by Abbott at several thousands of dollars per person per year. However, the Ministry of Social Protection declined to issue a declaration of public interest and a CL. An "Acción Popular" (a type of class action lawsuit that can be filed when collective fundamental rights are violated or limited) was filed before the competent court. The court held that Abbott had violated a 2009 government pricing order and directed the Ministry to initiate procedures for the application of sanctions against it. On appeal, the Administrative Tribunal of Cundinamarca upheld in part the lower court's decision in September 2012. While it also declined to grant a compulsory license, it found that the Ministry of Social Protection had violated the collective right to health by not enforcing price regulations on Kaletra.

In response to the lawsuit, the government ordered reductions initially of around 54-68% of the price. The price control measures generated savings in 2009-2012 of about 100,000 million Colombian pesos. It has been argued, however, that taking the price of generic alternatives into account, savings could have been 100% higher if a CL would have been granted.

In another case, a request for a CL submitted to the competent authority in the Dominican Republic has reportedly been dismissed. It referred to the drug clopidogrel ('Plavix') marketed by Bristol Myers Squibb and Sanofi Aventis, a French company. The French embassy was reported to have written to the Secretary of State of the Dominican Republic to voice opposition to the compulsory license request.

## **CLs granted in the region**

As noted, two Latin American countries, Brazil and Ecuador, have granted so far CLs, which are analyzed below.

### ***Brazil***

Brazil granted, in May 2007, a compulsory license regarding Efavirenz, an anti-retroviral patented by Merck Sharp & Dohme ('Merck') under the so-called *pipeline* mechanism (which allowed to retroactively obtain protection for products that would have otherwise been in the public domain in Brazil). 77,000 patients, equivalent to 42% of the total number of patients under the HIV/SIDA governmental programme, were treated with efavirenz.

Prior to the grant, the Brazilian government entertained negotiations with the patent-holder for a price reduction. The government noted that:

- a) Merck Sharp & Dohme was selling Efavirenz at cheaper prices in countries at the same development level but with fewer people in need of treatment than Brazil;
- b) Indian generic versions (supplied by Cipla, Ranbaxy and Aurobindo) were much cheaper than Merck's product, as cheap as US\$ 0.45/pill or an annual cost of US\$ 164.25/patient.

In negotiations prior to the CL, Merck offered a price reduction from US\$ 1.59 to US\$ 1.10 per dose, which was deemed unsatisfactory by the Brazilian government. Presidential Decree No. 6.108 (4 May 2007) decided the "compulsory license, on the ground of public interest, of Efavirenz's patents, for public non-commercial use", for a period of 5 years (renewable for an equal period), and a royalty fee for the patent owner of 1.5% of the finished product.

Initially, the CL covered the importation of generic versions from India at a third of the price offered by Merck. Farmanguinhos, the official pharmaceutical laboratory of the Oswaldo Cruz Foundation produced the first batch of Efavirenz in January 2009 at 45% of the price set by Merck before the CL. Due to the lack of sufficient technical information in the patent specifications, Farmanguinhos had to perform its own research activities in order to reverse engineer the product and to import small quantities of efavirenz from India; a preliminary injunction filed by Merck to stop the importation was rejected by the Brazilian courts.

The CL allowed the Ministry of Health to save around 58% (US\$ 103.5 million) of the resources otherwise needed for the period 2007-2012.

The pharmaceutical company reacted negatively against the granted CL. The president of Merck's Latin American division, was reported to state that "the perception of Brazil will not be the same" and that the company was reviewing its investment plan in the country. A Merck

spokesperson said that “[T]his expropriation of intellectual property sends a chilling signal to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world, potentially hurting patients who may require new and innovative life-saving therapies.” In a statement of 4 May 2007, the US Chamber of Commerce said that the ‘...[Brazilian] government has made a major step backward. Breaking off discussions with Merck and seizing its intellectual property sends a dangerous signal to the investment community. Merck researchers invested hundreds of millions of dollars to develop this ground-breaking medicine. Clearly, there was room to negotiate a solution acceptable to both parties...’.

Although the United States Trade Representative (USTR) had expressed concerns in the 2007 Special 301 Trade Report (drafted before Brazil issued its compulsory license) because Brazil had indicated consideration of the use of CLs on patented pharmaceutical products, no trade sanctions were pursued against Brazil after the grant of the efavirenz CL, nor an out-of cycle review of Brazil’s IP regime was carried out.

### ***Ecuador***

Article 363 (7) of the Constitution of Ecuador provides that, for the attainment of the good living regime (“el regimen de buen vivir”), it is an obligation of the State, to “guarantee availability and access to medicines of quality that are safe and efficacious, to regulate their commercialization, and to promote the national production and the use of generic medicines that correspond to the epidemiological needs of the population.

The grant of CLs in Ecuador has been based on Article 2 of the Presidential Decree 116 of November 16, 2009, issued in accordance with Article 61 of Decision 486 of the Commission of the Andean Community and Article 154 of the Law of Intellectual Property which, taken together, establish that a compulsory license can be granted at any time for reasons of public interest, emergency, or national security.

Presidential Decree No. 118 of November 16, 2009 declared “of public interest, access to medicines used for the treatment of diseases that affect the population of Ecuador and that are priorities for public health.” It specified that compulsory licenses could be issued for patents protecting medicines for human use that are necessary for the treatment of such diseases. This Decree opened the way for the grant of CLs on any patent relating to medicines considered to be a priority from a public health perspective.

In addition, Article 8 of Resolution No. 10-04 P-IEPI of January 15, 2010, provided guidelines for issuing compulsory licenses on pharmaceutical patents. It provided that “[O]nce the documentation is examined and the patent holder is notified, IEPI, through the National Office of Intellectual Property (Dirección Nacional de Propiedad Industrial, DNPI), will request the Ministry of Public Health to indicate whether the object of the request is a medicine that is used for humans for the treatment of diseases that affect the Ecuadorean population and are a priority for public health.”

On April 14, 2010 the government of Ecuador granted a CL for ritonavir, an antiretroviral drug, to Eskegroup SA, the local distributor of CIPLA, a generic company from India. The royalty (4%) was determined on the basis of the WHO/UNDP recommended ‘Tiered Royalty Method (TRM)’. Eskegroup was obligated to pay \$ 0.041 in royalties to Abbott for every 100 mg ritonavir capsule and \$ 0.02 per lopinavir (combination of ritonavir and lopinavir). The CL led to a reduction of the prices charged by Abbott, and to the importation of generic products, with savings in the order of 30% of the original price.

The US Emergency Committee for American Trade (a business coalition) criticized the grant of the CL arguing that Ecuador’s decision appeared to be ‘contrary’ to the TRIPS Agreement and qualified it as an effort “to nullify the protection of intellectual property”. However, the reaction of the pharmaceutical companies directly affected by the measure was quite moderate. Although they emphasized the ‘exceptional’ nature that, in their view, CLs should have, they did not question the government’s decision: ‘We realize that the interests of public health are not subordinated to rights of any kind, especially in circumstances of particular gravity. And, consistent with our principle of compliance with and enforcement of laws, democratically accept the decision of the President to make legal use of this exceptional mechanism...’.

A second CL was requested to the government of Ecuador, on June 15, 2012, by Acromax Laboratorio Quimico Farmaceutico S.A., regarding the combination of the anti-retrovirals lamivudine+abacavir, protected by patent PI-08-1913 held by the Glaxo Group Ltd. The patent application, filed on May 14, 1998, had been issued on January 5, 2007 (Patent No.: PI-08-1913, “Una Nueva Sal”). The CL was granted by IEPI, after confirmation by the Ministry of Public Health that abacavir+lamivudine was a priority medicine, on November 12, 2012. The CL is non-exclusive, for non-commercial public use. It can be executed through

importation or local production until the expiry of the patent, on May 14, 2018. In determining the royalty rate Ecuador also used the TRM. It was set as 11.7 cents per capsule. The government's aim is to reduce the cost of the medicine by 75%.

### **Implementation of the Decision of August 30, 2003**

The Decision of August 30, 2003 established a mechanism, based on the waiver of paragraphs (f) and (h) of article 31 of the TRIPS Agreement, to allow the export of patented pharmaceutical products under a compulsory license to countries without manufacturing capacity in pharmaceuticals. WTO members decided to transpose this Decision into an amendment to the Agreement, through the incorporation of a new article, 31bis. Approval by the WTO members of this amendment is still pending, after six years from the General Council's adoption.

No Latin American country has notified the Council for TRIPS of its interest in using the mechanism established by the Decision as an eligible importing country. No Latin American country has amended its legislation either to specifically change provisions that exclude (in line with article 31(f) of the TRIPS Agreement) the possibility of granting a CL for exports only. The WTO Decision mechanism has never been used in the region.

Nine Latin American countries have approved the amendment to the TRIPS Agreement so far:

El Salvador (19 September 2006)

Mexico (23 May 2008)

Brazil (13 November 2008)

Colombia (7 August 2009)

Nicaragua (25 January 2010)

Argentina (20 October 2011)

Panama (24 November 2011)

Costa Rica (8 December 2011)

Honduras (16 December 2011)

The reasons explaining the low interest shown in the region regarding the use of the WTO decision need to be further explored. A possible explanation is the perception that the system created by the Decision is cumbersome and does not generate sufficient incentives for potential suppliers of low cost pharmaceutical products.

### **Conclusions**

As examined above, the threat of CLs/government use has been effective in leading to price reductions for pharmaceuticals in some Latin American countries, while such licenses have only been granted in three cases, all of them relating to anti-retroviral drugs.

In comparison with other regions, Latin America has made a limited use so far of CL/government use provisions. This is despite the fact that national laws provide for different modalities of CLs, in line with article 31 of the TRIPS Agreement, and that domestic pharmaceutical companies control a significant segment (around 42% in value) of the regional market. The reasons for this limited use need to be further researched. They may relate to the fact that many drugs under patent in developed countries did not receive protection in Latin America in the pre-TRIPS era and, hence, the need for CLs/government use may have not been so pressing. Another reason may be the lack of expertise of health authorities in IP matters and on the ways to implement CLs/government use to address public health needs, and the limited weight of such authorities in decisions that may affect the country's relations with major trade partners. The fact that some patent offices have started to apply more rigorously the patentability standards may have also helped to avoid the need for CLs/ government use.

Importantly, CLs may be granted to address any public interest. For instance, a CL grounded on the lack or

insufficient exploitation of a patent may be conferred to allow a for-profit activity in the country of grant, in order to foster local manufacturing, incorporate technologies and create jobs. It is often wrongly assumed that CLs can only be used in cases of emergencies or public health crises, or that their use should be exceptional and always for non-profit. Nevertheless, CLs are an integral part of the patent system and they can be implemented where the generation of alternative supplies is necessary or convenient for national interests, including of an economic nature. In fact, the TRIPS Agreement leaves ample room to determine the grounds of CLs/government use; it only provides in article 31 for a number of *conditions* that need to be met.

Similarly, it is sometimes believed that the government use cannot involve the participation of private entities. However, the TRIPS Agreement clearly allows the intervention of contractors, without distinction of whether private or public. The experience of the USA shows that private companies have been normally involved in and benefit from the execution of such use.

In some cases, the information provided in the patent specifications is not sufficient to implement the protected invention, and complementary know-how is necessary. CLs/government use may include, where needed, an obligation to transfer such know-how, to enable the effective use of the patent. Precedents of this kind can be found in US decisions. There are no limitations under the Latin American legislation to impose this kind of requirement, which is not banned by the TRIPS Agreement.

The national laws of several Latin American countries should be amended in order to allow for a broader application of CL/government use, including in some cases an expansion of the grounds that can be invoked, a stricter definition of working requirements, and a simplification of procedures.

Concerns about possible negative reactions from developed countries' governments and their implications for trade or political relations, may also be a factor explaining the relatively low number of CLs/government use of patents in Latin America. Such concerns may, however, be exaggerated, as shown by the case of Ecuador and –outside the region - Indonesia, which has recently granted seven CLs without any known negative repercussions. Importantly, no complaint has been submitted against countries that granted CLs/government use under the WTO dispute settlement rules. This is a strong indicator that the legitimacy of the CLs and government use under the TRIPS Agreement are out of discussion, particularly after the clear confirmation by the Doha Declaration in this regard. This should provide sufficient comfort to governments facing situations of high pricing or lack of access to certain technologies or products, and should encourage them to consider CLs/government use as an ordinary measure they can adopt. CLs/government use should not be viewed as 'exceptional' mechanisms, but as one of the instruments, inherent to the IP system, that governments can normally implement to address national needs and attain their objectives in areas such as industrialization, agricultural development, environmental protection, education and public health.

Although CLs/government use can be applied in relation to patents in any field of technology, public health concerns are likely to continue to be the leading cause for their grant, particularly to the extent that governments elaborate IP strategies that fully integrate IP measures into their national policies on public health, and that it is feared that high prices of patented medicines, particularly, anti-retrovirals, may have 'devastating' effects in the region.

Importantly, notwithstanding the efforts that the US government made during the negotiation of the WTO Decision of August 30, 2003 to limit the use of CLs to certain infectious diseases, CLs/government use can be applied to *any* medicine. Moreover, as illustrated by the case of Taiwan – and indeed of the USA - CLs/government use can be implemented to ensure access to other technologies outside the pharmaceutical field, for instance, technologies necessary to address climate change adaptation or mitigation.

Finally, it will be important for competition authorities in the region to better understand the relationship between IP and competition law, and to use CLs as a remedy in cases of anti-competitive practices, including refusal to grant a voluntary license on reasonable commercial terms when access to an essential patented technology is precluded. The CL issued by the Italian competition authority with regard to a pharmaceutical product provides a telling example of the space available in this regard. Competition authorities may also consider to develop specific guidelines to address such relationship.

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