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EVALUATING THE USEFULNESS OF COMPULSORY LICENSING IN DEVELOPING COUNTRIES: A COMPARATIVE STUDY OF THAI AND BRAZILIAN EXPERIENCES REGARDING ACCESS TO AIDS TREATMENTS

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Keywords
Drug accessibility, public health, intellectual property rights, compulsory licensing, developing countries, HIV/AIDS

ABSTRACT
While compulsory licensing (CL) is described in the TRIPS agreement as flexibility to protect public health by improving access to medicines in developing countries, a recent literature contends adversely that CL may harm public health. Therefore, this article intends to evaluate the usefulness of CL in the South through the prism of obligations and goals entrusted to patent holders (the effective and non-abusive exploitation of patents in order to achieve industrial and health developments) and in light of experiences in Thailand and Brazil regarding access to antiretroviral drugs. In this way, it shows that the obligations assigned to patent holders were better served by the recipients of CL and brought significant health and industrial benefits in the two high middle-income countries. In particular, CL allowed the scaling-up of free and universal access to antiretroviral drugs by assuring the financial sustainability of these public health programs endangered by monopolistic practices from patent holders.

INTRODUCTION

Since the ratification of the TRIPS agreement in 1994, the effect of a significant strengthening of intellectual property rights (IPRs) in the Southern hemisphere has been constantly questioned. Researches have been made to determine whether the implementation of minimum global standards for the protection of IPRs could hinder the protection of public health in developing countries by limiting the access to medicines.[1]

But the discussion has recently moved to the examination of another legal device closely related to patent: compulsory licensing (CL). Provided by the TRIPS agreement, this device allows any country member of the World Trade Organization (WTO) to suspend for a time the exclusive rights attached to a patent and to authorize itself or a third party to produce the patented drug without the consent of the patentee. In other words, it suspends temporary the monopoly granted to an innovator and introduces

[1]Abbott FM, Reichman JH. The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended trips provisions. Journal of International Economic Law. 2007; 10(4): 921–987; Dutfield G. Delivering drugs to the poor: will the TRIPS amendment helps? American Journal of Law and Medicine. 2008; 24 (2): 107-124; 'Thoen E. The global politics of pharmaceutical monopoly power. Drug patents, access, innovation and the application of the WTO Doha declaration on TRIPS and public health. Dimen: AMB; 2009; Velasquez G, Correa C. L'accès aux médicaments. Entre le droit à la santé et les nouvelles règles de commerce international. Paris: L'Harmattan; 2009; Poggen T, Rimmer M, Rubenstein K. Incentives for global public health: patent law and access to essential medicines. Cambridge: Cambridge University Press; 2010; Shadlen K, Guennif S, Guzman A, Narayanan L. Intellectual property, pharmaceuticals and public health: access to drugs in developing countries. Cheltenham and Northampton: Edward Elgar Publishing; 2011; Aginam O, Harrington J, Yu PK. The Global governance of HIV/AIDS: intellectual property and access to essential medicines. Cheltenham and Northampton: Edward Elgar Publishing; 2013; Löfgren H, Williams OD. The new political economy of pharmaceuticals: production, innovation and TRIPS in the global South, London: The Palgrave Macmillan; 2013.

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competition in the market in order to drive the prices of medicines down. Thereby, it allows for the protection of public health by improving access to medicines.[2]

However, since the end of the 2000s a literature has grown and warns against inconsiderate use of this safeguard in the developing world. According to it, by preventing the exclusive enjoyment of IPRs by innovators, CL undermine drug accessibility and harm public health in developing countries[3] (15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27). Hence, CL should be used scarcely, with the utmost caution, if at all, not to damage public health in the Southern hemisphere.

This article intends to fill the gap in a recent literature dealing with the usefulness of CL in the South. Too often, this literature focuses on the exclusive rights of patent holders and considers CL as a threat to the full and effective enjoyment of a patent, thereby inhibiting real benefits expected from this institutional arrangement for society. Moreover, multiplying assertions about the harmful effects of CL on public health, this literature neglects to carry out accurate assessments of this mechanism in the South, in the few developing countries that have in practice used it to date.[4]

This article proposes to scrutinize the usefulness of CL in the Southern hemisphere through the prism of obligations and goals entrusted to patent holders and in light of practical experiences in developing countries. Methodologically, a conceptual framework is built on the basis of the obligations and goals entrusted to patent holders and data are collected to evaluate through it the efficacy of CL in two high middle-income countries: Brazil and Thailand. The objective is so to evaluate whether the obligations and goals entrusted to patent holders were better served by recipients of CL in the these countries. Therefore, in a first part, we set the obligations and goals assigned to patentees through an examination of international agreements governing the protection of IPRs as well as the patent law implemented in Brazil and Thailand afterwards. These obligations refer merely to an effective and non-abusive exploitation of an invention with the aim of fulfilling industrial and health objectives in a territory. Then, in a second part, we evaluate the usefulness of CL in regards of these obligations and goals entrusted in the first place to patentees, on the basis of comparative case studies of Thai and Brazilian episodes of CLs in 2006 and 2007. These cases studies establish to what extent the obligations and goals assigned to patentees were better served by the recipients of CL and brought significant health and industrial benefits in both Thailand and Brazil. In particular, in high middle-income countries heavily affected by HIV/AIDS and committed to provide free and universal access to antiretroviral drugs (ARVs), CL allowed the scaling-up of public health programs endangered by monopolistic practices from the patent holders.

DESIGNING A FRAMEWORK FOR THE EVALUATION OF COMPULSORY LICENSING IN DEVELOPING COUNTRIES

From the Paris Convention to the Doha Declaration through the TRIPS agreement, CL is defined as a tool to fulfill specific obligations and achieve major goals entrusted in the first place to patentees, before ultimately the forfeiture of patents. While implementing their patent

[2] Correa C. Intellectual property rights and the use of compulsory licenses: options for developing countries. Geneva: South Centre; 1999; Scherer FM, Watal J. Post-TRIPS options for access to patented medicines in developing countries. Journal of International Economic Law. 2002; 5(4): 913-939; Musungu S, Oh C. The use of flexibilities in TRIPS by developing countries: can they promote access to medicines? Geneva: South Report/WHO; 2006; Durojaye E. Compulsory licensing and access to medicines in post-Doha era: what hope for Africa? Netherlands International Law Review. 2008; 55: 33-71; Reichman JH. Compulsory licensing of patented pharmaceutical inventions: evaluating the options. Journal of Law, Medicines & Ethics. 2009; 37: 247-264; Hilty RM, Liu KC. Compulsory licensing: practical experiences and way forward. Heidelberg: Springer; 2015.

[3] Rozek RP. The effects of compulsory licensing on innovation and access to health care. The Journal of World Intellectual Property. 2000; 3(6): 889-917; Skees S. Thai-ing up the TRIPS agreement: are compulsory licenses the answer to Thailand's AIDS epidemic? Pace International Law Review. 2007; 19(2): 232-285; Steinbrook R. Thailand and compulsory licensing of Efavirenz. New England Journal of Medicine. 2007; 356(6): 544-547; Stevens P. Will compulsory licenses improve treatment for patients? International Policy Network/Campaign for fighting diseases. Available from: www.Policynetwork.net. 2007. [Accessed 5 Sept 2016]; Norris J. The unraveling of compulsory licenses. Evidence from Thailand and India. London: International Policy Network/Campaign For Fighting Diseases; 2007; Outterson K. Should access to medicines and TRIPS flexibilities be limited to specific diseases? American Journal of Law and Medicine. 2008; 24(2): 279-301; Lybecker KM, Fowler E. Compulsory licensing in Canada and Thailand: comparing regimes to ensure legitimate used of the WTO rules. Journal of Law, Medicines & Ethics. 2009; 37: 222-240; Bird RC. Developing nations and the compulsory license: maximizing access to essential medicines while minimizing investment side effects. Journal of Law, Medicines & Ethics. 2009; 37: 209-222; Borowski SM. Saving tomorrow from today: preserving innovation in the face of compulsory licensing. Florida State University Law Review. 2009; 36(2): 275-317; Deroo P. Public non-commercial use compulsory licensing for pharmaceutical drugs in government health care programs. Michigan Journal of International Law. 2011; 32: 347-395; Abbas MZ. Pros and cons of compulsory licensing: an analysis of arguments. International Journal of Social Science and Humanity. 2013; 3(3): 254-259; Halajian D. Inadequacy of TRIPS and the compulsory license: why broad compulsory licensing is not a viable solution to the access to medicine problem. Brook. J. Int'L L. 2013; 38(3): 1191-1231; Stavropoulou C, Valletti T. Compulsory licensing and access to drugs. European Journal of Health Economics. 2014; 16(1): 83-94.

[4] Beall R, Kuhn R. Trends in compulsory licensing of pharmaceuticals since the Doha declaration: a database analysis. Plosmedicine. 2012; 9(1): 1001-1054; Beall R, Kuhn R, Attaran A. Compulsory licensing often did not produce lower prices for antiretrovirals compared to international procurement. Health Affairs. 2015; 34(3): 493-501.

law from the 90s, Brazil and Thailand tried to stick with the spirit of these statutory outlines. Describing this process enables the building of a framework to evaluate the usefulness of CL in developing countries.

Effective use of a patent for industrial benefits under the Paris convention

During the negotiations that preceded the ratification of the first international agreement on IPRs, the Paris Convention for the Protection of Industrial Property in 1883, conflicting positions were supported regarding CL. Especially, the United States of America were reluctant to introduce in the Paris Convention a mechanism commanding the working of an innovation as fair compensation for the grant of a patent and a temporary monopoly within a territory, as an intermediary step before the forfeiture of the patent. However, CL was introduced to foster industrial development.[5]

The article 5 of the convention specifies that "each country of the Union 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"[6] . Such a 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". But the CL "shall be refused if the patentee justifies his inaction by legitimate reasons".

This article establishes also that the patent can be revoked "where the grant of compulsory licenses would not have been sufficient to prevent the said abuses", the failure to work or insufficient working of an invention. But this revocation will intervene "two years from the grant of the first compulsory license". Finally, "importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent".

So according to the Paris Convention, the grant of a patent may not guarantee the working or the sufficient working of an innovation by the patentee. So CL is designed to ensure such a working by a third party without the consent of the patentee in order to foster industrial development in a territory, before ultimately the forfeiture of the patent. But the hostility of some countries continued vis-à-vis CL and led a century later to the ratification of the TRIPS agreement. But, far from been diluted into the provisions of the most comprehensive agreement governing IPRs in the world, CL was reinforced as flexibility dedicated then to the protection of public health.

Non-abusive exploitation of a patent for both industrial and health benefits in the TRIPS agreement

Between 1979 and 1985, developed countries and the USA in the lead were pushing for a revision of the Paris Convention with the aim of limiting CL. They managed to introduce the IPRs issue into the agenda of the GATT and the Uruguay round with the intention of implementing a new international treaty voided of any reference to CL.[7] At the end of the Uruguay Round, the WTO was created and the TRIPS agreement was ratified in 1994 where the term CL is not mentioned but those of "patent without the consent of the patentee" are widely evoked[8] (34).

In Article 7, the objectives of the agreement are settled. Following the spirit of the Paris Convention, patent is a policy tool designed to foster industrial development by supporting innovation and technology transfer, and its protection must be accomplished in consideration of this goal. Furthermore, by establishing the principles of the agreement, Article 8 acknowledges the need for Members to "adopt measures necessary to protect public health and nutrition". In particular, appropriate measures should be taken to "prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology". Thus, since patents grant economic power to the right holders, countries may legislate to prevent any abuse of this power in order to promote industrial development without prejudice to public health.

Accordingly, flexibilities are provided in the TRIPS agreement. Principally, Article 31 sets the conditions under which CL may be used. The applicant has previously "made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time". However, this requirement may be waived in the case of "a national emergency or other

[5] Correa C. Intellectual property rights and the use of compulsory licenses: options for developing countries. Geneva: South Centre; 1999; Reichman JH, Hasenzahl C. Non-voluntary licensing of patented inventions. Historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA, Geneva: ICTSD/UNCTAD; 2003; Reichman JH. Compulsory licensing of patented pharmaceutical inventions: evaluating the options. Journal of Law, Medicines & Ethics. 2009; 37: 247-264; Gopalakrishnan NS, Annand M. Compulsory licence under Indian Patent Law. In: Hilty M, Liu KC. (eds.) Licensing: practical experiences and way forward. Heidelberg: Springer; 2015, p. 11-43.

[6] World Intellectual Property Organization. WIPO Lex, Geneva: WTO; 2016. Available from: http://www.wipo.int/wipolex/fr/. [Accessed 5 Sept 2016].

[7] Correa C. The use of compulsory licensing in Latin America. In: Hilty M, Liu KC. (eds.) Licensing: practical experiences and way forward. Heidelberg: Springer; 2015, p. 43-61.

[8] World Trade Organization. Agreement on Trade-Related Aspects of Intellectual Property Rights. Available from: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf. [Accessed 5 Sept 2016].

circumstances of extreme urgency or in cases of public non-commercial use". The patentee shall be notified "as soon as reasonably practicable" that a procedure for CL is launched (Article 31b). In any case, the rights holder will be entitled to "adequate remuneration, (...), taking into account the economic value of the authorization" (Article 31h). The CL shall be "non-exclusive" (Article 31d), "non-assignable" (Article 31e) and used "predominantly for the supply of the domestic market of the Member authorizing such use" (Article 31f). The CL is temporary and shall be "terminated if and when the circumstances which led to it cease to exist and are unlikely to recur" (Article 31g). Otherwise, this shall be renewable when the circumstances that led to its granting persist (Article 31g). At last, the agreement evokes the possibility to use CL to address emergency and extreme emergencies (Article 31b), to allow for public non-commercial use (article 31b), to remedy anti-competitive practices (Article 31k) and to ease the exploitation of a second patent (Article 31l). These situations do not constitute the exclusive grounds for CL: Members remains free to determine the grounds for granting such licenses as long as the conditions of use set out in the agreement are met.

Thus, CL has gained visibility in the TRIPS agreement in regards particularly to the protection of public health. Where a patentee may exploit his or her invention in an abusive manner, with detrimental effect to industrial development or public health, a CL may be granted to put an end to such a situation. Still, a significant challenge remains: how to use this provision in developing countries when manufacturing capabilities in pharmaceuticals are lacking?

Non abusive exploitation of a patent for sensible health benefits in the Doha Declaration

Before the WTO, the "African group" recalled the inability of most developing countries to actually use CL. Indeed, under Article 31f of the TRIPS agreement, using this device supposes, for a developing country, the existence of manufacturing capabilities in the pharmaceutical sector in its territory. But few countries hold such capabilities in the South.[9]

Given this impediment, the "Declaration on the TRIPS agreement and public health" adopted in November 2001 in Doha by the WTO ministerial conference recognizes first "the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" (paragraph 1).[10] In addition, the declaration confirms the principles and objectives of the TRIPS agreement and explicitly raises the issue of access to medicines: "We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all" (paragraph 4).

To that end, the declaration reaffirms so "the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provides flexibility for this purpose", that is the protection of public health and the access to medicines (paragraph 4). Specifically, the declaration recalls that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted" (paragraph 5b). Moreover, "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" (paragraph 5c). Thus, CL is considered essential to address public health problems related among others to epidemics such as HIV/AIDS, tuberculosis and malaria in developing countries. But, as mentioned previously, resorting to CL is not limited to these epidemics.

In August 2003, the decision of the General council called "Implementation of paragraph 6 of the Doha declaration on the TRIPS agreement and public health" eventually introduced additional flexibility. Under CL and in respect of specific conditions, producers are authorized to manufacture and export generics of patented drugs to countries lacking industrial capabilities.[11] The countries will express their intention to issue a CL to import generics and demonstrate that they do not have the capabilities to manufacture the patented product under CL. They will further stipulate the quantities of drugs produced under CL in the exporting country to meet their needs. Besides, the exporting producer will distinguish its products by means of special packaging, color or form to prevent any confusion between the copy and the patented product.[12]

To sum up, from the Paris Convention to the Doha Declaration through the TRIPS agreement, CL has gained visibility. Hence, patentees must fulfill some obligations when exploiting an invention in a territory so to observe a fair balance of rights and duties. They must ensure the

[9] World Health Organization. The World Medicines Situation, Geneva: WHO; 2004.

[10] World Trade Organization. Declaration on The TRIPS Agreement and Public Health, Doha WTO Ministerial 2001. Available at: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. [Accessed 5 Sept 2016].

[11] World Trade Organization. Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Decision of the General Council of 30 August 2003. Available from: https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. [Accessed 5 Sept 2016].

[12] Abbott FM, Van Puymbroeck R. Compulsory licensing for public health, a guide and model documents for implementation of the Doha declaration paragraph 6 decision. Geneva: World Bank; 2005.

effective exploitation of their invention as well as the non-abusive exploitation of it within a territory in order to achieve industrial and health goals. Accordingly, CL may be granted when they do not fulfill these obligations and fail so to contribute to these targets. Subsequently, these obligations and goals constitute the first steps towards the definition of a framework dedicated to the evaluation of the usefulness of CL in developing countries. By examining the patent law in Thailand and Brazil, the outlines of this framework will be finalized.

The outlines of a framework dedicated to compulsory license use in developing countries

Thailand and Brazil suffered considerable international pressure to proceed to a reinforcement of their patent law. However, both countries incorporated legal provisions permitting the effective use of CL.

In 1989 and in the first edition of the "Special 301" report, the USA listed the countries whose patent system was considered inappropriate and detrimental to their economic interests. Thailand and Brazil were on the "Priority Watch List" alongside six other developing countries including China and India. Consequently, Thailand and Brazil were under threat of unilateral trade sanctions: their withdrawal from the "generalized system of preference" and so the removal of advantageous tariffs for exports to the US market. During the 90s, the two countries were systematically listed under "Special 301" and under constant threat of US trade sanctions.[13]

Thailand and Brazil adopted so a stricter patent regime. Thailand ran in 1992, two years before the ratification of the TRIPS agreement, and Brazil did the same in 1997, three years after this. In addition, they set up "TRIPS plus" provisions, going beyond their obligations under the WTO agreement. For instance, Brazil waived the transition period available to developing countries until 2005 to comply with the TRIPS agreement and implemented earlier a new and stronger patent regime where products were now patentable. Moreover, the two countries established a pipeline protection mechanism, which allowed multinational firms to get a monopoly, even a patent for molecules not patentable in both countries, especially for ARVs drugs in Brazil and Thailand.[14]

Nonetheless, Thailand and Brazil managed to establish a legal framework regulating the resort to CL.[15] First, in the spirit of the Paris Convention, each country provided for the use of CL to promote industrial development: such a license may be granted in case of non-working or insufficient working of a patented invention in a territory three years after the granting of a patent. The Thai Patent Act provides that any person may file an application for CL where "the patentee unjustifiably fails to exercise his legitimate rights" for the reason that "the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason" (section 46). Similarly, the Brazilian patent law states that CL may be issued in case of "non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted" (Section 68).

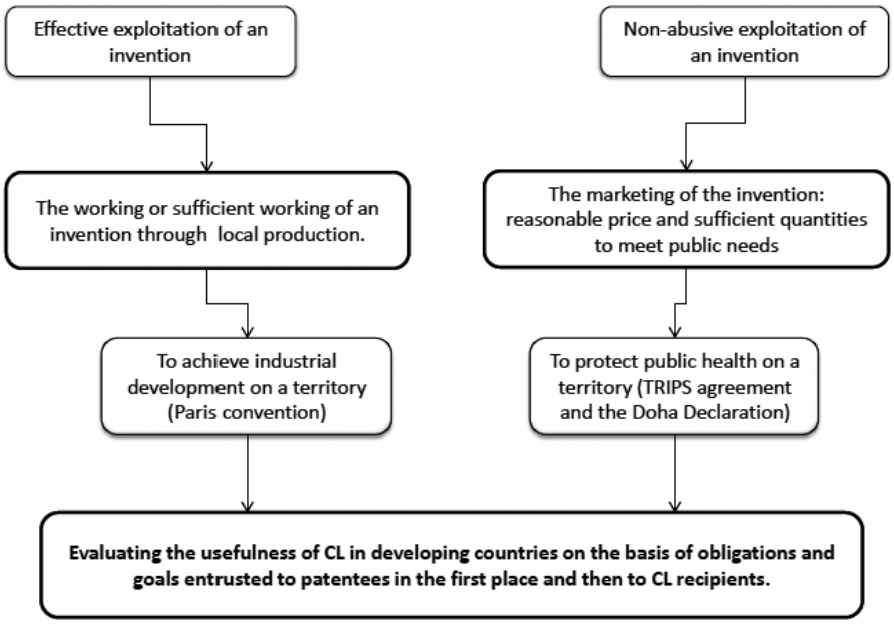
Second, in the spirit of the TRIPS agreement and the Doha Declaration, the Thai and Brazilian laws provide for the granting of CL to protect public health. First, such a license may be issued when the public needs are not met following the exploitation of the invention by the patentee during three years. The Thai law raises the possibility that "no product produced under the patent is sold in any domestic market, or that such a product is sold but (...) does not meet the public demand, without any legitimate reason" (section 46). Similarly, the Brazilian law evokes a "commercialization that does not satisfy the needs of the market" (section 68). In addition, both legislations provide for CL granting when the patented product is marketed at a prohibitive price three years after the granting and the exploitation of a patent. In Thailand, when "a product is sold but at unreasonably high prices", a CL may be issued (Section 46). In Brazil, a CL may be granted "on the grounds of abuse of economic power" by the patented (section 68), without giving further precisions or explicitly referring to situations where prices are considered prohibitive. But in both cases, the patentee may observe a monopolistic exploitation of his or her invention by marketing it in insufficient quantities or at prohibitive prices so that the needs of people are not satisfied.

To sum up, Thailand and Brazil have implemented a legal framework made of a stronger protection of IPRs but

[13] Office of United States trade Representatives. Special 301 report. Available at: https://ustr.gov/issue-areas/intellectual-property/Special-301. [Accessed 5 Sept 2016].

[14] Reis R, Foçaça Vieira M, Chaves G (2009), Access to medicines and intellectual property in Brazil: a civil society experience. In: ABIA (eds.) Intellectual property rights and access to ARV medicines: civil society resistance in the global South. Rio De Janeiro: Zit grafica. 2009, p. 12-55; Kuanpoth J. Give the poor patients a chance: enhancing access to essential medicines through compulsory licensing. Journal of Generic Medicines. 2008; 6(1): 15-28; Guennif S. Access to essential drugs in Thailand: intellectual property rights and other institutional matters affecting public health in a developing country." In: Shadlen K, Guennif S, Guzman A, Narayanan L. (eds.) Property, pharmaceuticals and public health: access to drugs in developing countries. Cheltenham and Northampton: Edward Elgar Publishing; 2011, p. 286-310; Rosenberg S. Assessing the primacy of health over patent rights: a comparative study of the process that led to the use of compulsory licensing in Thailand and Brazil. Developing World Bioethics. 2014; 14(2): 83-89.

[15] World Intellectual Property Organization. WIPO Lex, Geneva: WTO; 2016. Available at: http://www.wipo.int/wipolex/fr/. [Accessed 5 Sept 2016].



Graph 1. A framework for the evaluation of CL's usefulness in developing countries

patentees are required to fulfill some obligations when exploiting their protected invention in a territory, in respect of a proper balance of rights and duties. As sump-up in the following graph, in respect of the spirit of the Paris Convention as well as the one of the TRIPS agreement and the Doha declaration, CL should be evaluated in developing countries on the basis of obligations and goals entrusted to patentees: the effective and non-abusive exploitation of an invention with the purpose of achieving industrial and health goals within a territory. Subsequently, in-depth case studies of Thai and Brazilian CL experiences are conducted to establish whether significant industrial and health benefits were achieved in the two countries (Graph 1).

THE USEFULNESS OF COMPULSORY LICENSE: A COMPARATIVE STUDY OF THAI AND BRAZILIAN EXPERIENCES

A comparative analysis of Thai and Brazilian experiences emphasizes crucial points permitting to understand why these countries moved towards CLs in late 2000s and to what extend health and industrial benefits were achieved.

The first credible threat of compulsory licensing in Brazil

Brazil operated the same year the strengthening of its patent regime and the implementation of a free and universal access program to AIDS treatments, the first one in the developing world showing its high commitment to the struggle against HIV/AIDS epidemic. The country evoked then access to ARVs when the consensus at the World Bank focused exclusively on prevention in the fight against HIV/AIDS. Moreover, skepticism is high vis-à-vis public health programs providing treatments in countries where prevalence is high and resources are limited. Therefore, the World Bank took a dim view of the Brazilian initiative.[16]

However, driven by a more favorable national context (a return to democracy and the growing influence of a sanitarist movement), Brazil introduced the right to health in its constitution in 1988 and laid the foundations of a healthcare system based on decentralization and universalization.[17] This time, the Brazilian initiative went against IMF recommendations that required the drastic reduction of public expenditures in developing countries, including those allocated to health, as well as the privatization of healthcare systems in exchange for loans. Notwithstanding, Brazil implemented its free and universal access program to AIDS therapies.

[16] Araujo de Mattos R, Terto V, Parker R. World Bank strategies and the response to AIDS in Brazil. Divulgação em saúde para debate. Geneva: World Bank; 2003.

[17] Flynn M. Public production of anti-retroviral medicines in Brazil, 1990–2007, Development and Change. 2008; 39(4): 513-536; Nunn A. The politics and history of AIDS treatment in Brazil, New-York: Springer; 2009; Rosenberg S. Assessing the primacy of health over patent rights: a comparative study of the process that led to the use of compulsory licensing in Thailand and Brazil. Developing World Bioethics. 2014; 14(2): 83-89; Guennif S. La licence obligatoire: outil emblématique de la protection de la santé publique au Sud. Revue De La Régulation. 2015; 1st Semestre. Available at: http://regulation.revues.org/11248. [Accessed 5 Sept 2015].

From this date, the stakes were major for Brazil: controlling its drug budget to ensure free and universal access to AIDS treatments to an increasing number of patients. Consequently, the country used repetitively the threat of CL to negotiate lower prices with multinational firms.[18] Between 1999 and 2001, negotiations were intense since many patients underwent changes in their therapeutic regime, from off-patent drugs, locally produced and supply at low prices, to more effective drugs, patented and imported at higher prices by multinational firms. In particular, the provision of two drugs (Efavirenz and Nelfinavir) was absorbing 22% of the Brazilian drug budget and could quickly pass near the half of it. Accordingly, under intense negotiations and threatened with CL, Merck and Roche conceded price reductions: respectively of 59% for Efavirenz and 40% for Nelfinavir. Brazil did not issue a CL and saved tens of millions of US dollars.

Between 2001 and 2007, Brazil constantly used the threat of CL and negotiated lower prices with firms to ensure the sustainability of its AIDS program.[19] Especially, in 2005, after tough negotiations with Abbott and Gilead, the country obtained substantial price reductions using the threat of CL: 46% discount price for the cocktail Kaletra and 51% for Tenofovir. Once more, Brazil accepted these price reductions and waives CL.

Besides, Thailand mentioned for the first time CL in 1998.[20] At that time, the country was facing a major health crisis: one million adults and children were infected with HIV/AIDS and thousands of patients needed treatment and care. Due to the high price of AIDS drugs, less than 5% of patients had access to them. Consequently, the country was considering CL for ddI, a drug marketed by BMS. But due to international pressure, the country quickly renounced to issue a CL. Yet, in a surprise move, in 2006, Thailand was the first to issue a CL. This paved the way a few months later to a CL in Brazil.

But an effective use of compulsory license first in Thailand

Following the issuance of a CL in November 2006, Thailand was the subject of sharp attacks by the US trade representatives. They argued that the country was violating its international commitments and expropriating a patent holder without even initiated prior negotiations with it, the US multinational firm Merck for its Efavirenz drug. Still, in January 2007, Thailand announced a new CL for another AIDS treatment and another US multinational firm: Abbott for its Kaletra.[21]

In February 2007, the Thai Ministry of Health and the National Health Security Office[22] published a document in which they recalled first the legitimate right of Thailand to use the flexibilities provided by the TRIPS agreement, then supported by the WHO and UNAIDS among others. Additionally, they mentioned the efforts made to negotiate with the patent holder, to obtain lower prices for essential medicines and to address a major health crisis. But the granting of CL in case of health emergency or public non-commercial use does not require the country to begin prior negotiations with patent holders. The latter must be informed promptly about it and receive an adequate compensation following the conditions of use stipulated in the TRIPS agreement.

Furthermore, Thailand noted that in recent years substantial resources were allocated to improve access to healthcare. In 2001, the country implemented the "30 Baht Scheme", the universal health coverage. In 2003, free and

[18] Flynn M. Public production of anti-retroviral medicines in Brazil, 1990–2007, Development and Change. 2008; 39(4): 513-536; Possas de Albuquerque C. Compulsory licensing in the real world: the case of ARV drugs in Brazil. In: Coriat B. (eds.) The political economy of HIV/AIDS in developing countries: TRIPS, public health systems and free access. Cheltenham and Northampton: Edward Elgar Publishing. 2008, p. 150-169; Ramani S, Urias E. Access to critical medicines: when are compulsory licenses effective in price negotiations? Social science and medicines. 2015; 135:75-83.

[19] Flynn M. Public production of anti-retroviral medicines in Brazil, 1990–2007, Development and Change. 2008; 39(4): 513-536; Nunn A. The politics and history of AIDS treatment in Brazil, New-York: Springer; 2009; Ramani S, Urias E. Access to critical medicines: when are compulsory licenses effective in price negotiations? Social science and medicines. 2015; 135:75-83.

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universal access to AIDS treatments was established. It covered 80,000 patients and the budget increased from USD10 to 100 million between 2001 and 2007. The budget was expected to increase due to shifts in therapeutic regime for a growing number of patients developing resistance to initial treatments. But the high price of Efavirenz and Kaletra compromised the care of these patients.[23] Thus, the Thai government tried for two years to negotiate with Merck and Abbott to get lower prices. These negotiations failed, so in November 2006, symbolically few days before the World AIDS Day, Thailand announced the granting of a CL for Efavirenz to a public laboratory for five years.

Initially, the announcement of a CL provoked heated reactions from the multinational firms and the USA.[24] For instance, Abbott threatened Thailand not to market some drugs, including a formulation of Kaletra more convenient for hot countries. Instead, few months later, the firm announced a price reduction of more than 50% of its cocktail in Thailand and forty lower middle income countries that waive CL. The cocktail was offered at USD1000 per year and per patient against USD2200 previously. Likewise, Merck announced a price reduction of 14.5% for Efavirenz in least developed countries and middle-income countries heavily affected by HIV/AIDS including Thailand. The price decreased from USD0.76 to 0.65 per tablet per day or USD237 per patient per year. Thai authorities tried then to obtain larger price cuts and stated that Kaletra was sold by Merck at USD500 per year per patient in the poorest countries and Indian generic producers were proposing Efavirenz at USD0.6 the tablet. Finally, the CL was maintained with the objective of lowering the prices of treatments, covering a larger number of patients and achieving significant savings over five years.

The granting of CL to the Government Pharmaceutical Organization (GPO), a public lab raised many critics.[25] The private monopoly hold by the patent holder was replaced by a public monopoly. At that time, the GPO was still unable to put its production units in compliance with international standards and its drugs were never prequalified by the WHO. As a result, they were referred to as experimental copies of doubtful quality. Thus, this CL was predicted to be detrimental to public health and burdensome for public spending in Thailand, and more largely in any developing country.

Besides, for lack of substantial drop in the price of Efavirenz, Brazil issued its first CL in May 2007, several months after those granted by Thailand. Afterwards, the country continued however to negotiate price reductions with multinational firms and especially discussed for voluntary licenses. The goal was to sustain the development of technological and industrial capacities in the pharmaceutical sector, to increase the local production of essential medicines at more affordable prices and improve self-sufficiency of the country. Finally, this unique CL was granted for five years to local public and private labs.

With sizeable health and industrial benefits in Thailand and Brazil

In Thailand and Brazil, the granting of CLs generated substantial health benefits but more modest industrial ones. Regarding health benefits, the issuance of CLs brought about substantial price drops in the two countries. The price of Efavirenz (600mg) decreased from USD1.39 to USD0.29, i.e. a price reduction of 80%. Likewise, under the highest dosage available, the price of Kaletra (200mg/50mg) diminished from USD1.51 to USD0,46, generating a price reduction of 71% after a CL was granting and generic drugs made available.[26] In Brazil, the price of Efavirenz dropped from USD 1.56 to 0.45, a price reduction of over 70%.[27] So the resort to CL in the two countries meant the suspension of patent holders' monopolies and the introduction of competition on the market, which permitted access to more affordable AIDS drugs.

Moreover, these price reductions enabled the scaling-up of AIDS programs. In Thailand, the number of patients

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treated with Efavirenz increased from 4500 in 2006, few months before the issuance of a CL, to 13,600 in 2007 (few months after it). According to the latest data available, nearly 100,000 patients currently benefit from the treatment today. For Kaletra, there were 150 patients treated in 2006, before CL was granted, against 2,200 in 2007 and 30,000 patients today. In short, the coverage of patients was multiplied by 22 for Efavirenz and 13 for Kaletra. In Brazil, they were about 60,000 patients treated with Efavirenz in 2006, 80,000 in 2008 and around 100,000 in 2011; an increase of 66% in the number of patients treated. At the end, the total savings made were of about USD400 million between 2006 and 2015 in Thailand and USD102 million over the period 2007-2011 in Brazil thanks to CL and fierce generic competition introduced on the market.

In comparison, the industrial benefits were modest in Thailand and Brazil for lack of large technological and industrial capabilities in the pharmaceutical sector. On one side, the GPO began lately the production of ARVs. For Efavirenz, the public lab started the production in 2014 when it was expected in 2011. For Kaletra, the local production started in 2011, four years after the issuance of the CL. Thereafter, the GPO developed in few years the technological capabilities needed for the local production of Efavirenz and Kaletra in several formulations and dosages to cover as wide as possible the needs of patients. The GPO offered Efavirenz in all dosages available in tablet while it had yet to develop some formulations for Kaletra. But the industrial capabilities of the public lab were deemed insufficient: for each formulation, the quantity of drugs supplied was supplemented by importations of Indian generic drugs produced Aurobindo, Emcure or Mylan. For Efavirenz, five Indian generic producers supplied Thailand along with the public firm. For Kaletra, two Indian generic manufacturers exported to the country. So the GPO did not succeed to fully supply the AIDS program for lack of large technological and industrial capabilities.

On the other side, in Brazil, between the CL issuance and the occurrence of a domestic production of Efavirenz, three years passed. In 2007, the AIDS program was supplied by Indian firms at USD 0.45 the tablet since the national public and private labs were unable to develop the technological and industrial capabilities to market a generic drug. When they were finally ready to produce and supply the treatment to the AIDS program in 2010, the price of the tablet increased to USD0.75, of over 66% compared to the Indian generic drug. The price remained less than half the price charged by Merck before CL. So the price of the treatment per year and per patient increased from of USD159 under Indian generic drug to nearly USD300 under Brazilian generic drug.

Hence, in Thailand and Brazil, the domestic pharmaceutical industry suffered from a lack of competitiveness compared to the Indian industry. This cuts the savings to be made by the countries. Nevertheless, CL allowed the scaling-up of the AIDS program in Thailand and Brazil. This was the result of substantial price cuts for drugs and larger supply of patients through the local production and the importation of ARVs. Thus, where patent holders failed to fulfill their obligations and contribute to health and industrial objectives (preferring to import and market drugs at prohibitive prices in the two countries), the issuance of CLs brought real health and industrial benefits in these countries.

As summarized in Table 1 below, CL was valuable in the two countries heavily affected by the HIV/AIDS epidemic and strongly committed to the fight against it by means of free and universal access to treatments. In regards to the industrial benefits, while patent holders failed to assure the working of their inventions in Thailand and Brazil, national labs achieved such a working, producing ARVs locally to some extent. Concerning health benefits, when patent holders were marketing ARVs at prohibitive prices and limited quantities, local producers and international generic producers ensured the competitive exploitation of protected inventions, marketing generics at more affordable prices and larger quantities. These industrial and health benefits were considerable in respect to the needs of people in these developing countries.

Table 1. The comparative usefulness of compulsory licensing in Thailand and Brazil

	Thailand	*Brazil*
Industrial benefits through effective exploitation of inventions	Setting-up of local production. Limited local technological and industrial capabilities supplemented by imports and international capabilities (Indian ones).	Setting-up of local production. Limited local technological and industrial capabilities supplemented by imports and international capabilities (Indian ones).
Health benefits through competitive exploitation of inventions	Decreasing in drug prices: 85% for Efavirenz and 71% for Kaletra. Scaling-up of the free and universal access program to AIDS treatments: increase in the number of patients under Efavirenz by 2000% and under Kaletra by pour 20 000%. Total savings for the AIDS program: USD400 million between 2006 and 2015.	Decreasing in the price of Efavirenz: 70% price reduction under Indian generic drugs, 52% price reduction under Brazilian generic drugs. Scaling-up of the free and universal access program to AIDS treatments: increase in the number of patients covered by 66%. Total savings for the AIDS program: USD102 million between 2007 and 2011.

Source: from GPO, 2015; Viegas Neves Da Silva et al., 2012.

CONCLUSION

Going beyond analysis focusing exclusively on the rights of patent holders and challenging thereby the usefulness of CL in the South, the efficacy of this mechanism in the South has been evaluated here. Specifically, a method of evaluation based on the obligations ad goals entrusted to patentees has been used. Then, this method has been applied to the emblematic CL episodes that occurred successively and within few months in Thailand and Brazil. Far from being a fortuitous coincidence, these episodes reveal salient common features between Thailand and Brazil: high middle-income countries, strongly committed to the fight against HIV/AIDS with a significant inflection of the epidemic as a result. Moreover, these countries tackled the sensitive issue of access to medicines with once again a tangible outcome, i.e. the introduction of free and universal access programs to ARVs for large populations infected; programs whose sustainability was continuously questioned.

A patent holder has rights but has also obligations when holding a patent and a temporary monopoly within a territory. Therefore, assessing the usefulness of CL in the South should be appreciated in respect to these obligations explicitly laid down in international arrangements governing the protection of IPRs (the Paris Convention, the TRIPS agreement and the Doha declaration). The obligations of a patentee refer to the effective and non-abusive exploitation of an invention in a territory to contribute to specific goals, i.e. health and industrial development. Accordingly, where a patent holder fails to meet one of these obligations and serve one of these objectives, a country may legitimately suspend the patent and issue a CL to ensure the fulfillment of these obligations and objectives by a third party.

Examining precisely CL episodes in Thailand and Brazil revealed health and industrial benefits. In both countries, granting CL to public and private labs helped to substantially reduce the price of AIDS medicines, to significantly increase the number of patients treated and to save public spending with the access to more affordable generic drugs compared to patented ones, imported and marketed at higher prices by multinationals. Overall, using CL allowed in both countries the rise of free and universal access programs to ARVs, providing a conclusive answer to a major challenge: the financial sustainability of public health programs covering large populations. Besides, the industrial benefits were real but modest. Lacking broad technological and industrial capabilities, Thailand and Brazil struggled to set up local production. When this was done with great delay, they were not always capable of completely satisfying the needs of people. However, in the two countries, technological and industrial capabilities enabled under CL to provide more affordable generic drugs from local or Indian producers, then covering health needs. In summary, the obligations and objectives attached to the exploitation of patents had been better met by recipients of CL, local producers orforeign generic producers, than patent holders.

So what to say to skeptics or opponents to CL? Mostly, far from damaging public health in the South as detractors predicted, CL was useful as evidenced by the Thai and Brazilian experiences. Hence a double burden should not be imposed on developing countries. They cannot be commended at the same time to strengthen their IPRs regime to comply with their obligations under the TRIPS agreement and to waive the flexibilities provided for by this agreement and the Doha Declaration to protect public health. Adopting such an approach would rightly lead to undermine public health in these countries where health issues are major in consideration of the worrying spread of multiple epidemics. Instead, it is worth helping them to implement policy tools for the provision of safe, effective and quality drugs, to design a comprehensive regulatory framework supporting the production and marketing of drugs in respect of industrial and health goals, including under the event of a CL.

Biography

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