Property rights, compulsory licensing and public health in developing countries: from an institutional controversy to another one.

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1. Introduction

When the TRIPS agreement was ratified in 1994, concerns were raised about the effect of a significant strengthening of intellectual property rights (IPRs) in the developing world. To date, this agreement is the most comprehensive multilateral agreement on IPRs. It institutes a harmonization of IPRs protection in the world by establishing minimum standards. In practice, this agreement commend the introduction of patent on medicines in developing countries, which explains apprehensions about the risk for monopolistic practices from patent holders and potential prejudice for drug accessibility in developing countries (CIPIH, 2006. Coriat, 2008; Dutfield, 2008; Thoen, 2009; Velasquez and Correa, 2009; Poggen et al., 2010; Shadlen et al., 2011; Aginam et al., 2013; Löfgren and Williams, 2013.

However, it was recalled that the agreement contains flexibilities provided specifically to developing countries to help them in their efforts to protect public health. In particular, compulsory licensing (CL) is one of these flexibilities by which any country member of the World trade Organization can suspend temporarily the exclusive rights attached to a patent and permits itself or a third party to produce the drug without the consent of the patent owner. In other words, the monopoly granted to an innovator may be suspended for a time and generic competition be introduced in the market in order to drive the prices of medicines down. In this way, any country member may work for drug accessibility and finally public health protection (Correa, 1999, Scherer and Watal, 2002, Gold and Lam, 2005, Musungu and Oh, 2006, Durojaye, 2008, Dutfield, 2008, Reichman, 2009).

But a literature has developed since mainly the end of the 2000s and the issuance of a series of CL in Thailand in November 2006 and March 2007. It warns against inconsiderate use of CL as this mechanism may severely damage global health and especially drug accessibility in developing countries. More precisely, CL limits the exclusive rights of patent holders and endangers patent as an essential incentive for innovation and source of progress and benefits for society. Accordingly, CL may compromise drug accessibility and public health in the South (Rozek, 2000; Skees, 2007; Steinbrook, 2007; Stevens, 2007; Norris, 2007; Zolataryova, 2008; Outterson, 2008; Feldman, 2009; Lybecker and Fowler, 2009; Bird, 2009; Borowski, 2009; Epstein and Kieff, 2010; DeRoo, 2011; Abbas, 2013; Halajian, 2013). Therefore, CL should be used scarcely, with the utmost caution, if at all, not to damage public health in the Southern hemisphere.

As a matter of fact, a shift has occurred from an institutional controversy surrounding patent since mostly the ratification of the TRIPS agreement to another one surrounding CL. From a lively debate about the effect of TRIPS on public health in the South, the discussion has moved today to an even more animated debate about the use of a mechanism defined as flexibility devoted to public health protection in the South. More importantly, this shift from one controversy to another one is indeed driven by an impressive proprietary logic defending the exclusive rights of patent holders as
essential for innovation and global health, and leads to a particular situation from a South point of view: a situation where developing countries are required at the same time to strengthen their IPRs regime to comply with the TRIPS agreement and to waive the flexibilities provided by this agreement to protect public health, with the promise that significant improvements in drug accessibility and public health will be achieved on their territory.

This paper aimed at questioning the impact of CL on public health in the South. Emphasizing the three dimensions of accessibility (availability, affordability and quality of drugs), it proceeds to a literature survey of pros and cons of CL. Therefore, theoretical arguments and stylized facts are confronted accurately to enlighten the presumed and confirmed impact of CL on drug accessibility and public health, in respect especially to access to antiretroviral drugs in developing countries. To do so, the influence of CL will successively be discussed in regards to the availability of essential drugs, the affordability of life-saving treatments or the supply of high-quality medicines in developing countries. At the end, specifically in the fight against HIV/AIDS, CL proves to be useful to protect public health by improving drug accessibility and supporting free and universal access to antiretroviral drugs in developing countries such as Brazil and Thailand.

1. Compulsory license: a threat for essential drug availability?

Patent is defined as an incentive to innovation, all the more important in the pharmaceutical industry where innovation costs are high and imitation costs are low (Cohen et al., 2000). As such, this legal device assures so the availability of medicines and contributes to the protection of public health (Grabowski, 2002, Lanjouw, 2002). From this point of view, CL may adversely affect the rationale of patent, inhibiting innovation and damaging drugs availability in developing countries.

In practice, CL limits patents holders’ exclusive marketing rights, decreases their anticipated returns on R&D investments and prevents them from recovering their investments. As patentees will not totally enjoy a temporary monopoly, they are not eventually induced to develop new drugs or improve existing ones for the benefit of the society (Fisch, 1994, Rozek, 2000, Chien, 2003, Bird, 2009, Epstein and Kieff, 2010). In this way, CL may limit the availability of drugs.

Precisely, the CL creates two kinds of medicines depending on the political risk borne by firms (Stevens, 2007). On the one hand, some drugs present a low political risk: the risk is minor for the occurrence of a CL. In this case, firms are able to recover their investments in R&D during the marketing of these drugs under a temporary monopoly. On the other hand, some drugs involve a high political risk: the risk is great for the issuance of a CL. In that event, firms would not recover their expenditures on R&D.

Following this typology, firms are more likely to allocate resources to the development of drugs presenting a low political risk, those typically made for the treatment of widespread infections in developed countries. Sheltering producers and exporters of drugs, these countries are viewed as respectful of IPRs granted to firms and reluctant to utilize CL, not to hurt the innovative activity of their firms. On the contrary, firms are less willing to invest in the development of drugs incorporating a high political risk and disregard so R&D for prevalent infectious diseases in the South, i.e. for neglected tropical diseases. Importers of medicines, these countries are considered to have little heed for IPRs granted to innovators and are more incline to resort to CL.

At the end, new or improved drugs would lack for treating widespread infections in the South because of the risk CL imposes on firms. The risk would be too high of encountering developing countries using and abusing of CL, suspending temporary monopolies granted to innovators and ultimately harming the interests of those who have invested in long, uncertain and expensive R&D programs.
Finally, CL may be considered as a significant limitation to the full exploitation of patents granted in the Southern hemisphere and may divert firms from developing treatments for the benefit of people living in developing countries. And the amount of royalties set does not make a difference (Abbas, 2013). Thus, alike free market lacking IPRs, CL endangers innovation and hurts the availability of appropriate treatments for people in the South, and ultimately threatens future welfare (Borowski, 2009).

While the sceptics state that CL inhibits firms’ willingness to innovate, no empirical studies have to date established a negative effect of CL on innovation. On the contrary, studies show a positive effect of CL on innovation. For example, following Scherer (1977) and analyzing the patenting rate in the 80s and the 90s in the US in the pharmaceutical sector, Chien (2003) finds no inflection in innovation after six CL were issued in the sector during this period. More important, she states that “in all cases but one, activities of innovation continued at the same or even higher pace than before the advent of a license” (p. 892). Another example is provided by an analysis of long-run effects of CL on domestic innovation after World War I in the U.S., where Moser and Voena (2012) determine that “learning by doing” was the key mechanism by which CL increased local innovation by 20 percent. A last example is provided by Gorecki (1984) who recounted how Canada amended its patent law and provided large CL provisions in 1969. Between 1969 and 1982, 290 CL were then granted for 62 medicines to the local pharmaceutical industry. However, no decrease in R&D spending was recorded in the sector. So the massive use of CL had no detrimental impact on R&D investment in the pharmaceutical sector.

Anyway, how the existence of CL could explain a striking deficit in R&D, which has been prevailing for decades in the field of widespread infectious diseases from the South? As “90/10” syndrome indicates, 90% of global spending on R&D deal with diseases that affect 10% of the world population living in high-income countries (Global forum for health research, 2004). Furthermore, between 1975 and 2004, among the 1,556 new drugs marketed worldwide, only 21 were meant to treat neglected diseases, just over 1% (Chirac and Torreele, 2006).

As a matter of fact, firms are busy developing medicines for lucrative markets from rich countries and have no desire to allocate resources to the development of treatments for people living in poor countries (Ridley and al., 2006). If there is a political risk due to CL, this is unlikely to be the reason for the reluctance of firms to invest in the field of neglected tropical diseases. Particularly endemic in Africa, Asia and Latin America, these infections affect 1.4 billion people who are mostly living on less than a dollar a day. Therefore, the resort to CL and the risk of an excessive burden on firms’ exclusive marketing rights cannot explain or amplify their obvious and persistent disinterest for diseases heavily affecting poor countries.

Furthermore, as suggested by Chien (2003), a more relevant distinction needs to be done between “global drugs” and “developing-country specific drugs”. The former are made for markets from developed countries and useful as well for developing countries for diseases such as cancer or HIV/AIDS. The latter are dedicated for markets from poor countries to treat malaria or tuberculosis for instance. On this basis, if there is a risk for CL, it may for sure concern global drugs since big firms are involved almost exclusively in the development of such drugs. But this will marginally affect innovation for the reason that these firms will remain responsive to the incentives provided by wealthy markets and continue to develop global drugs with the residual risk of CL in marginal export markets from the South. And especially, the issuance of CL for AIDS treatments in developing countries will not deter firms to made R&D in this field. Finally, firms will remain deaf to the need

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1 Analyzing the trend in CL between 1995 and 2011 in the world, Beall and Kuhn (2012) found that 16 out of 24 CL episodes involved HIV/AIDS treatments and all occurred in a developing country. Nevertheless, multinationals are still making R&D in this field to develop new treatments or improve existing ones focusing on high profits expected in rich markets from the North.
of developing countries and this reality has nothing to do with a hypothetical risk for CL in the South.

Besides, the Drugs for Neglected Diseases initiative (DNDi) was created in 2003 on the premise that R&D for these infections remained insignificant and left millions of people without treatment in developing countries. This initiative calls for an alternative R&D model with the objective to reverse the trend and strongly foster the development of new medicines or new formulations for existing drugs for neglected diseases. This model is supported by the public sector and built on the coordination of R&D projects involving the international scientific community and the pharmaceutical industry for diseases such as leishmaniosis, human African trypanosomiasis, Chagas disease or malaria (Banerji and Pecoul, 2007). Most of all, this model aims at developing drugs as public goods when possible in order to come out of a proprietary logic. Within a decade, DNDi’s has spent 253 million dollars in R&D and established 130 partnerships worldwide with significant results: 6 new treatments and 12 new chemical entities in its R&D pipeline to treat the most neglected disease in the South (DNDi, 2014).

In summary, concerning the impact of CL on drugs availability in the South, theoretical arguments of the opponents to CL are strongly refuted by stylized facts. The existence or potential use of CL cannot explain the lack of R&D and the blatant unavailability of drugs to treat the more prevalent infections in the South on the ground that this legal device limits the exclusive rights of firms. By contrast, the strategy of firms more focused on lucrative markets can explain the lack of R&D devoted to the health needs of developing countries, of low-income populations. Thus, it is totally vain to conceal the market failure of the drug development paradigm based on patent in respect to infectious diseases in developing countries, on the ground furthermore of recent and episodic resort to CL in these countries².

2. Compulsory license: an obstacle to drugs affordability?

As regards to drugs affordability, theoretical arguments advanced by opponents to CL state that the convexity of the demand curves determines firms’ pricing strategy. Aimed at segmenting markets and differentiating prices, this strategy promotes affordability of medicines in a world with strong IPRs and without CL. But there is no getting away from the facts: the enjoyment of IPRs by innovators does not guarantee access to more affordable drugs in the South while CL helps.

Indeed, under patents and temporary monopolies, firms sell their products at different prices to different consumers for the reason that the elasticity of demand is low and the switch towards the closest substitute is limited. Consequently, firms have the opportunity to segment the market according to individual’s willingness to pay. Then they maximize both the number of people benefiting from the drug and their profits (Stevens, 2007, Flynn et al., 2009, Epstein and Kieff, 2010).

Following this logic, prices will be higher in developed countries where income per capita is larger and health insurances systems more extensive, compared to prices set in developing countries where per capita income is lower and health insurance systems limited. Subsequently, market segmentation and price differentiation adopted by firms will primarily benefit patients in poor countries where the lowest prices will be charged, close to the marginal costs of production.

Moreover, due to humanitarian concerns, and especially in the case of an epidemic such as HIV/AIDS, firms will even choose to sell medicines at prices lower than their marginal costs of production (Stevens, 2007). In doing so, the poorest countries with the highest prevalence rate of HIV/AIDS (mainly Sub-Saharan African countries) will get treatments at very low prices. The middle-

² For a discussion of push and pull incentive mechanism initiated to overcome this paradigm failure and promote R&D into neglected infectious diseases, see Muller-Langer (2013).
income countries with lower prevalence rates (such as Brazil and Thailand) will pay higher prices. At last, high-income countries will pay the highest price regardless of prevalence. Armed with this price differentiation strategy, firms will generally recover their R&D expenditures while supporting drugs affordability in the South.

However, this pricing strategy benefiting developing countries is underpinned by the existence of patents and temporary monopolies. As soon as those are weakened, firms lose control over their pricing strategy and unwillingly cease to work for public health in the South by supporting drugs affordability (Stavropoulou and Valletti, 2014). For instance, as soon as a middle-income country issues a CL and obtains substantial price reduction for a drug, the innovator will have to compensate his losses and ensure somehow the recovering of its expenditure on R&D by setting higher prices in other countries, including low incomes countries. Therefore, under CL, an income transfer may take place from low-income countries to middle-income countries.

In the end, CL may limit the ability of firms to exploit, to the full, their innovation with the possibility then to segment markets and differentiate prices in order to supply drugs at lower prices in the poorest countries. CL may not be a convincing cost-controlling means by adversely affecting essential drugs affordability in most needed countries.

Though, within the theoretical framework developed by opponents to CL, firms’ pricing strategy may be refined and negative effects on drugs affordability in developing countries may be revealed. It is enough to assume here that this strategy is turned toward the maximization of profits and depends on the income distribution within a country.

Indeed, enjoying patent and temporary monopoly in developing countries, a firm may be induced to differentiate prices, to ration the market and set high prices, close or similar to those existing in developed countries. In this way, instead of supplying a large share of the market and offering relatively low prices in developing countries, a firm may rationally choose to supply a lower share of the market and charge higher prices.

The strategy is all the more sustainable that the income distribution is uneven in a country and individuals display propensity to pay high prices. In this case, a large share of the population with low income will face high prices and unaffordable drugs. In comparison, in a country where income distribution is more equal, alike most developed countries, firms may produce more, charge lower prices, and supply a larger share of the market in order to maximize their profits. Finally, the more uneven the income distribution will be in a country, the more prices will be high and the less affordable drugs will be.

Unsurprisingly, pushing through this assumption, the same prices may be observed in rich countries and poor countries due to a global pricing strategy followed by firms. Worse, higher prices may be observed in middle-income countries with major uneven distribution of income compared to high-income countries with less uneven distribution of income (Flynn et al., 2009).

As a matter of fact, firms do not always differentiate prices for the benefit of developing countries, nor even to assist them in their efforts to deal with health crises. In this case, CL proves to be an efficient means to activate competition and lower prices.

In the 90s, public health programs were initiated in developing countries in order to struggle against HIV/AIDS with the support of international agencies (including WHO, UNAIDS and the World Bank). Soon, these programs aspired to put patients under treatment and ran into a major obstacle: the price of antiretroviral drugs. These were often marketed in developing countries with the same prices than those charged in developed countries (UNICEF, UNAIDS, WHO and MSF, 2004). For instance, in the 90s, when Uganda launched a national program to fight HIV/AIDS and progressively

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3 In fact, the announcement of a CL may lead to price negotiation for a patented drug and brings about price reduction without even a CL is issued.
started to treat people, it had to spend per year and per patient 12,000 dollars for a therapy, the price charged by patent holders in developed countries (WHO/UNAIDS, 2002). As a consequence, supplying antiretroviral drugs was not considered by international agencies (first among them the World Bank) as a cost-effective measure. At that time, the prevailing consensus within international agencies was that developing countries should allocate their limited resources to the prevention in order to stop the spread of the epidemic among the general population.

In 2000, the Accelerating Access Initiative (AAI) was launched because of the prohibitive prices charged by firms for antiretroviral drugs. This initiative brought together several international agencies (UNAIDS, WHO, UNICEF, the World Bank and United Nations Population Fund) and multinationals producing antiretroviral drugs (Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck and Hoffman-La Roche joined two years later by Abbott and Gilead). The objective was to improve drugs affordability so to increase the number of patients treated. As part of this initiative, the firms conceded “preferential prices” to developing countries, prices below those charged in developed countries (WHO/UNAIDS, 2002).

Precisely, through the establishment of the AAI, firms agreed to practice differential pricing in accordance with HIV/AIDS prevalence and per capita income observed in the developing countries needing treatment. This initiative helped to lower antiretroviral drugs prices and to increase the number of patients treated: they were less than 50,000 in 2000 and nearly 828,000 in 2006 (UNAIDS/WHO, 2006). Still, the price cuts offered by firms, variable from one country to another, were considered opaque and insufficient compared to prices proposed by generic manufacturers.

From the 2000s, the Indian firm Cipla made a noteworthy entrance on the market by offering a generic antiretroviral therapy below 300 dollars per year and per patient (against more than 10,000 dollars under original drugs as noted above) (MSF, 2014). This competition forced multinationals to cut prices. Following the entry of several Indian generic producers and a strong competition in the market, the therapy is today available at 70 dollars per year and per patient. Unsurprisingly, these results are consistent with those stated from the 90s by a series of studies made in developed countries concerned then about health expenditure control: the more generic competition is fierce in a market and the more drugs prices tend to drop significantly (see for instance Caves et al., 1991).

In other words, face with multinationals’ strategies selling antiretroviral drugs at high prices in the South, close to those charged in high income countries, competition has been an efficient means to break these strategies and make treatments more affordable. It appears then that the CL could be a valuable tool to boost generic competition and significantly improve the affordability of life saving drugs as suggests the Brazilian program in the fight against HIV/AIDS.

In 1997, Brazil was the first country in the South to provide free and universal access to AIDS treatment. Between 1997 and 2011, this program increased the number of patients treated from 36,000 to 215,000 while the budget grew from 224 to 427 million dollars. Per capita expenditure decreased from 6,222 to 3,714 dollars over the period notably through Brazil's ability to negotiate with multinationals using the threat of CL for patented antiretroviral drugs (Possas de Albuquerque, 2008, Nunn, 2009, Guennif, 2012, Flynn, 2013). From 2001, on several occasions, Brazil threat to resort to CL and negotiated lower prices in order to ensure the sustainability of its AIDS program. But, in 2007, it actually issued a CL after vain negotiations with a multinational for further reduction in the price of its antiretroviral drug. Hence, Brazil imported the drug from India with a price reduction of 70 percent compared to branded drugs.

To date, the last episode of CL in the Southern hemisphere occurred in 2012. For the first time, India issued a CL to improve the affordability of a drug for chronic disease widespread among the population (Chopra and Muthapa, 2012, Jain and Darrow, 2013, Abbas and Riaz, 2014). The Indian firm Natco got a CL on the ground that the patent holder Bayer abused its monopoly position and the invention was not worked locally: the imported treatment was marketed at a prohibitive price
so that less than 2% of patients could afford it. Against the payment of royalties to Bayer, Natco was allowed to produce a copy of the patented drug marketed at 3% of the price charged by Bayer for a monthly treatment. Few months later, another Indian firm, Cipla, announced the marketing of the drug at 2.5% of the price proposed by Bayer and 60% of the one offered by Natco.

Thus, once more the arguments developed by opponents to CL are denied by stylized facts. In practice, patent may undermine drug affordability whereas CL may help to prevent or remedy to such a risk. This legal device enables developing countries to suspend temporary monopoly associated with patent, to introduce competition in the market and to drive prices down for the benefit of patients and most of all for the sustainability of public health programs implemented in the South.

3. Compulsory license: a barrier to the supply of high quality drugs?

According to opponents to CL, developing countries are not armed in regards of technical and regulatory requirements to produce high quality medicines. Accordingly, it is inefficient and undesirable to limit the exclusive marketing rights of firms to allow the local production of medicines under CL in countries at the risk of providing low quality drugs and severely damaging public health.

Undeniably, a small number of multinationals dominate the production of drugs in the world, from the manufacturing of raw materials to the formulation of finished products (WHO, 2004). Geographically, the production of drugs is concentrated to over 90% in some high-income countries. Major multinationals located in the US, Japan, Germany, France and the UK supply two thirds of the world production. In comparison, in developing countries, the production is low and concentrated in the final stages of manufacturing, i.e. the formulation and the packaging of medicines.

Moreover, the drugs produced in the South are copies of those patented and marketed in developed countries. First, these are not necessarily generics, since mostly bioequivalence studies are not always required by a local drug agency before their marketing. These studies establish that the drug candidate is strictly equivalent to the original one already marketed. Secondly, and upstream, a “drug master file” is not always required before the marketing of a product or according to lower standards than those observed in developed countries. The submission of this file sets up the traceability of an active substance incorporated into the manufacturing of a drug and ensures by this means its high quality. At the end, in the absence of such file and studies, doubts are raised about the quality of the active ingredients selected, the manufacturing processes used and the finished products marketed. Eventually, the relevance of issuing a CL to be consistent in supplying high quality medicines and promoting public health in developing countries is questioned.

When regulatory procedures do not require drug master files and bioequivalence studies, resorting to CL and enabling the local production of medicines in the South may draw on the market poor quality drugs (Rozek, 2000). These may seriously damage public health and public spending in resource-limited countries. In fact, beyond the immediate benefits gained from the provision of more affordable drugs under CL, less immediate and more substantial costs may appear with the production and supply of drugs of doubtful quality. In the case of HIV/AIDS, the use of low-quality drugs in a public health program may generate severe side-effects and resistance among patients, and the need to switch to other treatments. Patients will have to take less toxic, more effective and eventually more expensive therapies, increasing finally public spending. In comparison, the supply

4 In the absence of such studies, the drug is not a generic but a similar.
of patented and more expensive quality drugs would have benefitted patients and public spending by avoiding severe side-effects, resistance and large additional costs.

When reading these formal arguments, one could easily conclude that firms holding patents are the only ones able to provide high quality medicines in the whole world. In reality, evidences suggest that developing countries are not sentenced to produce and supply generics of dubious quality under CL.


First, it was pointed out that the private monopoly of the firm holding the patent was replaced by a public monopoly. Furthermore, it was recalled that the Government Pharmaceutical Organization (GPO), the only recipient of the CL, was unable to meet its commitments vis-à-vis the Global Fund: it could not ensure the compliance of its manufacturing units with international standards (Skees, 2007). Consequently, the public lab never obtained the prequalification of its products by the WHO and drugs produced were quickly labeled experimental copies (Norris, 2007).

Actually, since 2003, GPO was provided an unpatented therapy to thousands of patients. Few years later, high level of resistance to treatment was observed among patients (Sukasem et al., 2007). These resistances induced a premature switch to other treatments for many patients, more effective and more expensive. In light of these facts, the use of CL was predicted to be inevitably detrimental to public health and seriously burdening for public spending in Thailand, and more widely in limited-resources countries (Skees, 2007, Lybecker and Fowler, 2009). Implicitly, the argument was that the use of CL, by limiting the full enjoyment of IPRs granted by firms, could only lead to the production and supplying of poor quality drugs in the South.

It is worth mentioning that the authors of another clinical study about the use of a first-line treatment produced by GPO confirmed high level of resistance among patients. But they called for the strengthening of the health care structures, improvements in treatment compliance and progresses in the continuous provision of antiretroviral drugs. All of which might explain for them, other than the quality of the drugs dispensed, the resistance level observed among patients (Sungkanuparph et al., 2012).

Besides, the recipient of the CLs, GPO, was not able to produce locally the antiretroviral drugs during several years for technological and industrial reasons. Instead, Indian firms prequalified by WHO were very supportive as providers of affordable quality drugs to Thailand. The country was able so to ensure the sustainability of its AIDS program: price reduction of more than 70% for

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5 For HIV/AIDS, the WHO publishes periodically a list of prequalified medicines: the organization certifies the high quality of these drugs through audits made in the manufacturing units of candidate firms. These prequalified drugs can then be supplied in AIDS programs implemented in developing countries with the support of international donors: the World Bank, the Global fund to fight against HIV/AIDS, tuberculosis and malaria, The US President’s Emergency Plan for AIDS relief, the Clinton Foundation, UNITAID, ...

6 An AIDS cocktail therapy is composed of several antiretroviral drugs produced in the form of one tablet taken several times a day. This presentation reduces the number of drugs taken daily, increases patient compliance and reduces the risk of resistance. The cocktail produced by GPO, the GPO-VIR, consisting of three antiretroviral drugs, comes in the form of a tablet taken twice daily. It was celebrated in 2002 as the cheapest triple therapy in the world. This tablet cost 1.1 dollar per day against 6.9 dollars a day for the version marketed by multinationals.
antiretroviral drugs provided by Indian firms compared to branded drugs permitted to increase substantially the number of patients under treatment (Krikorian, 2009, Kuanpotth, 2010, GPO, 2015). In other words, Indian firms have become key partners for public health stakeholders in the South and, under CL, Thailand and other developing countries are not condemned to providing affordable medicines of poor quality.

In the end, while the CL is for sure a limit to the exclusive rights of firms, one should not associate the use of this legal device with the production and the provision of cheaper low-quality medicines in the South. This risk may not be the result of the supposed weakness of the IPRs regime in a country, but mostly the consequence of a lack in regulatory procedures governing the marketing of drugs as mentioned above.

5. Discussion

CL is not bad for public health in developing countries. Stressing on the three dimensions of drug accessibility (availability, affordability and quality), the arguments of opponents to CL have been confronted to stylized facts drawn from the experiences of developing countries to protect public health by means of improving drug accessibility. In this way, we successively points out that CL does not inhibit the availability of essential drugs, the affordability of life-saving treatments or the supply of high-quality drugs in the Southern hemisphere.

Indeed, following the arguments advanced by the sceptics, CL constitutes a substantial limit to the full enjoyment of property rights by innovators. As such, it undermines the rationale for patent and damages public health, including in the developing world. This device inhibits innovation and hurts drug availability especially for neglected diseases. It prevents also price differentiation and hinders drug affordability. At last, it delays the supply of high-quality drugs and draws on the market drugs of dubious quality.

However, evidences related to the measures taking by developing countries to protect public health and chiefly to sustain free and universal access to antiretroviral drugs has shown that, instead of CL, patent can impede drug accessibility. It can hurt drug availability in developing countries by driving R&D efforts of firms towards lucrative markets from the North. It can damage drug affordability due to monopoly practices observed by patentees. Finally, it can hamper the provision of affordable high-quality drugs because of exclusive marketing rights granted to patentees. Therefore, patent can be a serious threat for public health and CL an efficient tool to create competition on the market and reduce the price of medicines to ensure the large provision of affordable high-quality drugs to population in developing countries.

Accordingly, whether developing countries should be committed to an unprecedented reinforcement of their patent law in compliance with the TRIPS agreement but left with the practical incapability to resort to flexibilities provided by this agreement, a double burden may be put on them with harmful effects on public health. Definitely, an inconsiderate strengthening of IPRs in developing countries made of “TRIPS plus” provisions restricting the resort to CL may have deleterious effects on drug accessibility. Developing countries may be unable to resort to CL to prevent these effects by suspending temporary monopolies, introducing competition in the market and driving drug prices down.

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7 In 2001, WHO launched its prequalification program with the aim of assessing the quality, safety and efficacy of medicines, especially antiretroviral drugs to support developing countries’ efforts in ensuring access to treatment. Today, numerous Indian producers of antiretroviral drugs are prequalified by the WHO, providing 246 treatments, about 69% of all prequalified products (WHO, 2014). As a result, reputed as producers of affordable high quality antiretroviral drugs, Indian firms accounted for over 80% of the drugs purchases funded by international doners in developing countries between 2005 and 2010 (Waning et al., 2010).
For sure, CL cannot be considered in the long run as a means to expand drug accessibility in the developing world. As defined in the TRIPS agreement and the Doha Declaration, this is essentially a temporary solution, especially in case of health crisis, and nothing more. Nevertheless, to support a proper use of CL and ensure the most positive impact on public health in countries, which pay a heavy toll to global burden disease, some cautions should be taken. First, developing countries need to amend their patent law with the utmost attention to take full advantage of CL provided by the TRIPS agreement and to dispose of a legal tool to achieve public health goals, far from the risk of adopting “TRIPS plus” provisions under international pressure.

Second, there is no less crucial need for developing countries to implement stronger procedures to regulate the marketing of drugs to guaranty their quality, safety and efficacy. Besides, developing countries should pay attention to the implementation of proceedings to procure medicines from abroad; from global pooled procurement mechanism (initiated by the Global Fund, UNICEF, the WHO, or UNITAID to mention a few of them) or directly from generic drug producers from the South.

Third, all these measures should not prevent developing countries to initiative in the first place price control mechanism for essential, patented or generics medicines to improve affordability in countries where health insurance systems are limited and out-of-pocket health expenditures are so important (as largely do developed countries concerned with health spending control).

Last but not least, far from short-term and uncertain philanthropic actions aimed chiefly at providing drugs for free, developing countries should be further supported by international agencies capable of institutional innovations to improve drug accessibility. As aforementioned, DNDi, AAI or the WHO prequalification program have been crucial initiatives in improving drug accessibility in the South. In order to reduce more the gap between developed and developing countries concerning access to health care, such efforts should be developed further, particularly with more resources devoted to support developing countries in their effort to fight epidemics such as tuberculosis, malaria or HIV/AIDS.

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