Access to Critical Medicines: When are compulsory licenses effective in price negotiations? A Brazilian case study

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ABSTRACT

The availability of drugs for public health programs depends on the quantity of drugs that the State is able to buy given its health budget, which in turn will depend on the pricing and distribution strategies of pharmaceutical companies, both local and multinational. With respect to patent protected drugs supplied by Western pharmaceutical majors, governments of developing countries are particularly in a vulnerable position as the technology may not be licensed or independently developed by local firms. Therefore, when there is a major disease that calls for patented medicines, the sustainability of public health programs may be put at great risk. When faced with such a problem, one possible solution is to negotiate for a price-drop with the patent holder in lieu of issuing a compulsory license. The present paper develops a game theoretic model of such bargaining and identifies the conditions under which compulsory licenses can be issued.

Key-words: *intellectual property rights; compulsory license; access to medicines; technological capabilities; Latin America; Brazil*

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1   INTRODUCTION

The availability of drugs for public health programs depends on the quantity of drugs that the State is able to buy given its health budget, which in turn will depend on the pricing and distribution strategies of pharmaceutical companies, both local and multinational. With respect to patent protected drugs supplied by Western pharmaceutical majors, governments of developing countries are particularly in a vulnerable position as the technology may not be licensed or independently developed by local firms. Therefore, when there is a major disease that calls for patented medicines, the sustainability of public health programs may be put at great risk. When faced with such a problem, one possible solution is to negotiate for a price-drop with the patent holder in lieu of issuing a compulsory license (i.e. when a government allows someone else to produce the patented product or process without the consent of the patent owner). Under which conditions will such price negotiations be successful? Under which conditions would a compulsory license (CL) be issued? What are the mechanisms to improve access to critical medicines in today's world in developing countries? These are the questions that we examine in the present paper via a game theoretic model, which is then tested by interviews with experts in Brazil.

Medicines and health care services, including diagnostics, are essential goods, and their universal accessibility is an important aspect in promoting a more equitable society. Accessibility can be seen as a function of both medicines availability and affordability vis-à-vis a patient population. Availability refers to the extent to which certain medicine can be readily obtained by a patient population[i], while affordability refers to the extent to which medicines are is affordable, as measured by theirs cost relative to the amount that the purchaser - (patient and/or public health system) is able to pay.

The price of medicines is one of the factors that can impede access to treatment (WHO, 2008). This is especially true in the case of patented drugs. Since patents allow a monopoly right to the inventor, the price of patented products tends to be higher than in a competitive market. As result, the consumption of such essential goods will be lower than the social desirable level.

The role of patents for pharmaceutical companies has at least one important political implication: the enforcement of stronger intellectual property rights worldwide in order to protect the innovative effort carried out by these companies, usually in more developed countries. The *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS) came into effect on January 1st, 1995 and is the most comprehensive multilateral agreement on intellectual property. Besides the minimum standards of protection, it also established a set of provisions deals with domestic procedures and remedies for the enforcement of intellectual property rights.

Due its potential negative impact on access to medicines, TRIPS contains flexibilities that could facilitate increased access to pharmaceutical products by developing countries. These flexibilities are in the Article 30 and 31.

Article 30 regulates exceptions, such as experimental use (also known as *research exception*) and "Boar" provision (also known as *regulatory exception*). Experimental use allows researchers to use a patented invention for research, in order to understand the invention more fully, and, therefore, to advance science and technology. "Bolar" provision allows drug manufacturers to use the patented invention to obtain marketing approval for generic versions — for example from public health authorities — without the patent owner's permission and before the patent protection expires. Doing so, generic producers can market their versions as soon as the patent expires (WTO, 2006).

The Article 31 regulates other uses without authorization of the patent holder, including compulsory license. Article 31 also limits compulsory license by requiring a period of negotiation between the member state and the patent holder unless it is for "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or against anti-competitive practices (WTO, 2006).

Although it is consensual that TRIPS do not and should not prevent countries from taking measures to protect public health, still there are many controversies concerning this subject. This discussion resulted on the *Declaration on the TRIPS agreement and public health* (also known as Doha Declaration) adopted by the World Trade Organization (WTO) Ministerial Conference in Doha on November 14, 2001. The Doha Declaration legitimates the use of the Articles 30 and 31 of TRIPS, stating that "*each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licences are granted*".

This amendment goes further and emphasizes 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*". `

However, even after Doha Declaration, developing countries may face obstacles in the use of these flexibilities (WHO, 2008) due the political pressure from foreign governments and pharmaceutical industry lobby groups, especially against the use of compulsory licensing (Babovic & Wasan, 2011; Beall & Kuhn, 2012), and due flawed policies on several grounds (MSF, 2006; Chami & Wasswa-Kintu, 2011). Most developing countries' national legislation has provisions for use of compulsory licensing, but it does not mean they use it in practice though.

In practice, threats of compulsory licensing may be useful when negotiating with drug companies to lower medicine prices. Brazil is the most successful example of such strategy. Brazil has a universal access to antiretroviral (ARV) treatment programme since 1996, through the public health system. Nowadays, Brazil is presented worldwide as a model whose replication in developing countries, not only due the extension of the anti-AIDS program – which covers more than 217,000 in 2011 – but also due the capacity of the Brazilian government to reduce the price of treatments. This capacity results from bargaining disputes with patent holders, based on the threat of issuing compulsory license to local producers involved in the production of ARVs.

Currently 20 different ARVs are distributed through the Brazilian public health system, including second and third line drugs such as tipranavir, raltegravir, atazanavir, tenofovir and enfurvitide. Of these 20, nine are produced by local public laboratories, including Efavirenz, which Brazil issued a compulsory license in 2007 after Brazilian Government and Merck – the patent holder – failed to reach an agreement on price reduction.

Since the Brazilian first threat of compulsory license, in 2001, several other episodes could be pointed out, and Efavirenz was the very only compulsory license issued by Brazilian Government. Moreover, even when an agreement with the patent holder was reached, the final outcome was not always the best for the Brazilian Government. Why did it happen? In which circumstances a compulsory license will be issued? And which others the Government will be able to get a more affordable price?

In order to answer these questions we developed a conceptual framework based on a Game Theoretical Model with two players: (1) A **patent holder**, usually a large pharmaceutical company that sell its patented drug to developing countries' government; and (2) a **developing country** that buys this drug and try to negotiate prices with the patent holder using the compulsory license possibility as a threat. This model allows us to construct a general picture of the context, drivers and main obstacles to compulsory license of pharmaceutical products by developing countries.

Besides this Introduction, this paper is organised as follows. In the next section we present the Game Theoretical Model and the after that there is some discussion and preliminary conclusions.

2   A GAME THEORETIC MODEL OF DRUG PRICE NEGOTIATIONS

To understand the dynamics of drug price negotiation between a developing country and a foreign multinational, we develop two games in this section. The first considers the simple setting when there are no informational constraints for any player. The second considers the more realistic context, when the payoffs of the developing country are not completely known to the patent holder.

2.1   Game under complete information

Suppose that in a developing country, a multinational company, an original innovator holding a drug patent, is the sole supplier of a drug for a major health burden. Let public health agency of the developing country be given by *DC* and the foreign patent holder by *PH*.

The public health agency *DC* has a budget *B* to spend on drug provision. The patent holder *PH* has negotiated a price P_0 and is currently supplying $q_0 = \dfrac{B}{p_0}$. But the quantity, q_0, is not sufficient for the public health program to reach the poorer sections of society.

In this context, the developing country government, *DC* has the choice either accepting the status-quo or initiating the price negotiation. Under the latter case, the developing country *DC*, informs the patent holder *PH* that unless *PH* reduces the price of its branded drug to price $P_1 < P_0$, *DC* will issue a compulsory license and procure the technology to be manufactured by local firms or imported from the international market. The patent holder, *PH*, can respond

to this threat by accepting the large price drop to $P_1 < P_0$ or it can make a counter offer for a smaller price drop to P_2, where $P_1 < P_2 < P_0$. Then the developing country, *DC*, can either accept the counter offer or issue a compulsory license. In case it issues a compulsory license, *DC* has to ensure that the minimum target of the public health program is met through domestic production and imports as well as bear the costs of possible reprisal, *R*, from the government of the patent holder. Here the game ends.

What are the probable outcomes of this game? To identify these, we turn to a detailed examination of the payoffs and solve for the sub-game perfect Nash equilibrium of this sequential game, or the probable strategies that would be deployed by the two players *DC* and *PH*.

1.1.1 *The structure of payoffs.*

The objective of *DC* is to maximize the provision of the drug. Thus, its payoff at price p_i is given by $q_i = \dfrac{B}{p_i}$ where $q_i = q_i(p_i)$ is the quantity of the drug bought by *DC* at price p_i.

Now the goal of *PH* is to maximize its profit and its payoff is given by the profit associated with the sale of the quantity q_i at price p_i say $\pi_i = \pi(p_i, q_i(p_i))$.

At the start of the game, *PH* charges the negotiated price p_0 with corresponding payoffs $q_0 = \dfrac{B}{p_0}$ and $\pi_0 = \pi(p_0, q_0(p_0))$ to *DC* and *PH* respectively. However, the public agency is aware that there is a lower price, $p_1 < p_0$ for the corresponding drug in the world, either because it is the lowest price at which *PH* sells the branded drug or because there is a generic version at the lower price which can be imported.[1] Thus, the public agency proposes a large price drop p_1 to the patent holder. If *PH* accepts the price drop then the payoffs increase for the public agency because $q_1 > q_0$ since $p_1 < p_0$ and the budget *B* is fixed. On the other

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[1] Price discrimination across different countries is a widely practiced strategy in the pharmaceutical industry. Furthermore, it is possible indeed that a product is patented in a country while the same product is off patent in a different country due the period of adaptation provided by TRIPS Agreement. In order to make price information more widely available, several organizations, such as the World Health Organization and the *Medecins Sans Frontieres*, have compiled and published such information.

hand, for *PH*, $\pi_1 < \pi_0$ because any move from the profit maximizing price strategy lowers its profit.

Suppose, *PH* does not accept the strong price drop p_1, it proposes a lower price drop p_2. Since $p_1 \leq p_2 < p_0$ and the profit function is non-increasing for any $p < p_0$ we have:

$$q_1 \geq q_2 > q_0; \quad \pi_1 \leq \pi_2 < \pi_0 \tag{1}$$

The payoff structure gets more complex when the counter offer of the patent holder is refused and a compulsory license is issued.

First, the patent holder *PH* not only loses a contract but has to pay for fixed costs *F* and so:

$$-F = \pi_{cl} < \pi_1 \leq \pi_2 < \pi_0 \tag{2}$$

Second, turning to the developing country, if it issues a compulsory license, then the patent holder's country takes reprisal action which costs the *DC* a sum *R*. A reprisal cost *R* is included, because a counteroffer from a patent holder is likely to be accompanied with a counterthreat from pharmaceutical firms, such as not launching new drugs in the developing country anymore, and/or not including the country in clinical trials for drug development. In addition, patent holders can also create a strong lobby with their home country's government in order to put pressure on the developing country, especially in terms of trade retaliation.

Third, in addition to bearing possible reprisal costs, the *DC* must find another supplier when it issues a compulsory license, i.e. it must get the drug either from the local firms or import it from the international market, depending on who can offer the drug at a lower price. But if the two prices are equal, it will favour local firms. The prices offered in turn will depend on their manufacturing capacity. Let α_L and α_F be the indicators of manufacturing capacity of local and foreign generic producers respectively, where $\alpha_L = \{0 \; or \; \bar{\alpha}_L\}$ and $\alpha_F = \{0 \; or \; \bar{\alpha}_F\}$ where $0 < \bar{\alpha}_L \leq 1$ and $0 < \bar{\alpha}_F \leq 1$. Let the price offered by a local supplier (p_L) and the price offered by a foreign supplier (p_F) such that:

$$p_L = \frac{p_1}{\alpha_L}; \quad p_F = \frac{p_1}{\alpha_F}; \tag{3}$$

This means that if α_L or α_F is equal to 1, then they can offer the drug at the lowest possible price. However, if α_L and α_F are both equal to 0, there is no alternative source of drugs. Then the drug price under compulsory licensing is given by:

$$p_{cl} = Min(P_L, P_F) \qquad (4)$$

Manufacturing capacity, encompasses not only the production capacity physically installed (*i.e.* manufacturing facilities, equipment, labour skills, and so on) but also technological capabilities (*i.e.* skills, knowledge and experience, and institutional structures and linkages) needed to manufacture active pharmaceutical ingredients, to formulate and distribute them to the end user. In addition, α_F refers not only to the international manufacturing capacity but also to the availability of the drug for exports. The availability of the drug for exports is critical because several factors (e.g. patent status of the drug in the supplier's country, bilateral agreements, contracts between patent holder and generic suppliers, regulatory barriers, among other institutional arrangements) may prevent the foreign supplier to export the drug under a compulsory license. For these reasons, let us refer to α_L and α_F as determining the bargaining positions of DC.

Thus, under compulsory licensing, the payoff of DC is:

$$q_{cl} = \frac{B-R}{p_{cl}} = \frac{B-R}{p_1} Max(\alpha_L, \alpha_F) \qquad (5)$$

This interaction is represented in figure 1 assuming that all parameters of the game are common knowledge to the two players.
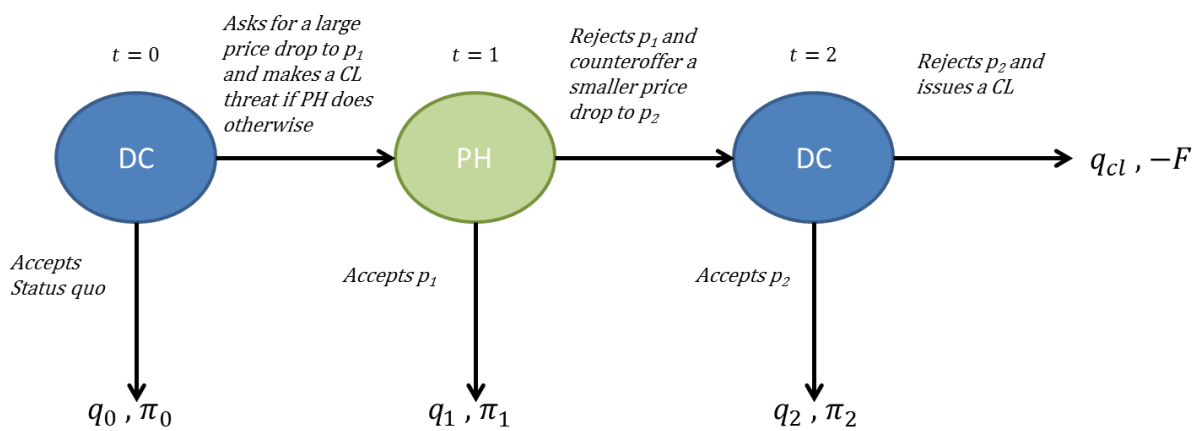
Patent Holder

	Accept p$_1$	Reject p$_1$
Accepts status quo	$q_0 = \dfrac{B}{p_0}, \pi_0$	$q_0 = \dfrac{B}{p_0}, \pi_0$
Threat + Accept p$_2$	$q_1 = \dfrac{B}{p_1}, \pi_1$	$q_2 = \dfrac{B}{p_2}, \pi_2$
Threat + CL	$q_1 = \dfrac{B}{p_1}, \pi_1$	$q_{cl} = \dfrac{\frac{B-R}{p_1}}{\max(\alpha_L, \alpha_F)}, -F$

Developing country (row label spanning the left side)

Now we can state the main propositions.

Proposition 1: When there are no informational constraints, a public agency:

- Cannot negotiate for any price drop if anticipated reprisals are very high (i.e. $R > \overline{R}$)

- Cannot negotiate for any price drop if DC has no bargaining strength and, therefore, the threat is not credible (i.e. the manufacturing capacity whether locally or abroad does not meet a threshold level $\underline{\alpha}$, such that. $\max(\alpha_L, \alpha_F) \leq \underline{\alpha}$ or it (i.e. $\alpha_L = 0$ and $\alpha_F = 0$).

- Can negotiate a price drop from p_0 to p_2 if reprisals are moderate (i.e. $R \leq \overline{R}$) and there is some bargaining strength (i.e. $\underline{\alpha} < \max(\alpha_L, \alpha_F) \leq 1$) In this case, the size of the price drop, in turn, will depend on both the size of the expected reprisal R and the actual level of manufacturing capacity $\max(\alpha_L, \alpha_F)$.

- Can negotiate a strong price drop from p_0 to p_1 only if there is no expected reprisal (i.e. $R = 0$) and the bargaining capacity is maximum (i.e. $\max(\alpha_L, \alpha_F) = 1$).

Proof:

It is easy to note that there always a reprisal value, $\bar{R}$ where $\bar{R} = B - p_1 \cdot q_0$ such that we have:

$$\left. \begin{array}{l} q_0 > \dfrac{(B-R)}{p_1} \geq q_{cl} \ \text{for } R > \bar{R} \\[3mm] \dfrac{(B-R)}{p_1} \geq q_{cl} > q_0 \ \text{for } R < \bar{R} \end{array} \right\} \tag{6}$$

Therefore for any reprisal $R \geq \bar{R}$, the public agency will never initiate the game and status quo will prevail – even when the price under compulsory license can be the lowest price for the product (i.e. when $p_{CL} = p_1$.)

On the other hand, there is a threshold level of manufacturing capacity $\max(\alpha_L, \alpha_F) = \underline{\alpha}$, where $\underline{\alpha} = \frac{p_1}{p_0} \cdot \frac{B-R}{B}$ such that we have:

$$p_{CL} = \frac{p_1}{\bar{\alpha}} > p_0 \tag{7}$$

$$\Leftrightarrow q_0 > q_{CL} = \frac{B-R}{p_{CL}}$$

Therefore for any manufacturing capacity $\max(\alpha_L, \alpha_F) \leq \underline{\alpha}$, the public agency's threat will never be credible and status quo will prevail – even when there is no expected reprisal (i.e. when $R = 0$).

Now let us turn to the strategy of the patent holder, *PH* when $R < \bar{R}$ and the game is initiated with a request for a strong price drop. If it rejects p_1, it runs the risk of having a compulsory licensing being issued. Thus, its strategy will be to fix the maximum value for p_2 such that:

$$\begin{cases} q_2 > q_{CL} \\ \pi_2 > \pi_1 \end{cases} \Leftrightarrow \begin{cases} \frac{B}{p_2} > (B-R)/p_{cl} \\ p_2 > p_1 \end{cases} \tag{8}$$

Defining $p_2 = p_1 + \varepsilon$ ($\varepsilon > 0$), the condition for DC not issue a compulsory license (i.e. $q_2 > q_{CL}$) is given by:

$$\frac{B}{p_1 + \varepsilon} > \frac{B - R}{\dfrac{p_1}{\max(\alpha_L, \alpha_F)}} \tag{9}$$

Rearranging (9) we have

$$\varepsilon < p_1 \left(\frac{B}{B - R} \cdot \frac{1}{max(\alpha_L, \alpha_F)} - 1 \right) \tag{10}$$

Since all parameter in Equation 10 are known to PH, if we assume that he behaves rationally, then his optimal choice is to fix the maximum value of $\varepsilon = \bar{\varepsilon}$ that satisfies the restriction imposed by Equation 10. It means that, by doing this, PH will get an expected payoff of $\pi_2 > \pi_1$ and DC will get an expected payoff of $q_2 > q_{cl}$. Therefore, PH will be better off by rejecting the large price drop from p_0 to p_1, and counter-offering a smaller price drop from p_0 to $p_2 = p_1 + \bar{\varepsilon}$. Given that $q_2 > q_{cl}$, DC will accept price p_2 whatever is its type.

Note that the condition imposed by Equation 10 c only in one very particular case: when there is no expected reprisal (i.e. $R = 0$) and the bargaining capacity is maximum (i.e. $\max(\alpha_L, \alpha_F) = 1$). In addition, we can clearly see by Equation 10 that lower the expected reprisal and the higher the manufacturing capacity, the lower will be the margin ε that PH can fix above the minimum price p_1.

Given the above (equations (6) to (7)) and the payoff structure outlined in equations (1) to (5), by application of the principle of backward induction we can identify the rational play of the two players as presented in Table 1.

Table 1 –Nash- equilibrium strategies under complete information

Context		Equilibrium strategy of DC	Equilibrium strategy of PH	Price outcome
Reprisal	**Bargaining position**			
$R > \bar{R}$	$for\ all\ \alpha_L, \alpha_F$	Accepts status quo	N/A	p_0
$for\ all\ R$	$\max(\alpha_L, \alpha_F) \leq \underline{\alpha}$	Accepts status quo	N/A	p_0
$0 < R \leq \bar{R}$	$\underline{\alpha} < \max(\alpha_L, \alpha_F) \leq 1$	Proposes price drop p_1; Accepts p_2 if offered	Rejects p_1 and counter-offers p_2.	Price of drug drops from p_0 to p_2.

$R = 0$	$\underline{\alpha} < \max(\alpha_L, \alpha_F) < 1$	Proposes price drop p_1; Accepts p_2 if offered	Rejects p_1 and counter-offers p_2.	Price of drug drops from p_0 to p_2.
$R = 0$	$\max(\alpha_L, \alpha_F) = 1$	Proposes price drop p_1 and issues CL if is p_1 rejected	Accepts p_1	Price of drug drops from p_0 to p_1.

Two inferences are most interesting. First, whether or not the patent holder accepts a small or large price drop does not depend at all upon its production capacity, but on the capacity of the local industry of the developing country and import possibilities as well as the power of reprisal of the patent holder's country. The existence of local manufacturing capacity and import possibilities, indeed have a critical role in defining the size of the price drop, even when the initial request is refused. Second, under complete information a compulsory license is never issued. Now, in reality there have been instances when compulsory licenses have been issued. To explain this phenomenon, we turn to a second version of the game introducing incomplete information.

2.2 Game under incomplete information

Let the developing country, DC, be one of two types: DC' that is subject to a reprisal $R = R'$, and DC'' that is subject to a reprisal $R = R''$, in way that $R'' > R'$. Thus, the DC's payoff associated to the issuance of the compulsory licence will vary according to its type, as follows

$$q'_{CL} = \frac{B - R'}{p_{cl}} \tag{11}$$

$$q''_{CL} = \frac{B - R''}{p_{cl}} \tag{12}$$

It is worth highlighting that the payoffs to issuing a compulsory license for both types still depends on the strength of local production capacity and possibilities for import the drug (i.e. $p_{CL} = \frac{p_1}{\max(\alpha_L, \alpha_F)}$).

Given that in this game there are two possible levels of reprisal (i.e. $R = (R', R'')$), thus, if PH refuses the large price drop p_1 there will be a price p_2' that will be optimal under $R = R'$ and a price p_2'' that will be optimal under $R = R''$, as we can see below.

Assuming that $R'' > R' > 0$, so:

$$\varepsilon' < \left[\left(\frac{B}{B - R'}\right) \cdot \frac{1}{\max(\alpha_L, \alpha_F)} - 1\right] p_1 \tag{13}$$

$$\varepsilon'' < \left[\left(\frac{B}{B - R''}\right) \cdot \frac{1}{\max(\alpha_L, \alpha_F)} - 1\right] p_1 \tag{14}$$

Applying the same reasoning as in the discussion related to Equation 10 in the previous section, we can say that the optimal price when the expected reprisal is $R = R'$ and $R = R''$ are given by Equation 15 and Equation 16, respectively.

$$p_2' = p_1 + \bar{\varepsilon}' \tag{15}$$

$$p_2'' = p_1 + \bar{\varepsilon}'' \tag{16}$$

$$p_2'' > p_2' \tag{17}$$

$$q_2' > q_{CL}' > q_2'' > q_{CL}'' \tag{18}$$

Now, we can present the game. The developing country, DC, knows its own type but this is not known to the patent holder, PH. The beliefs of PH are given by γ, where γ is the probability that DC is of type DC'. The belief γ and all other parameters of the game are common knowledge to all players.

This new game is represented in Figure 1. How will PH decide whether he counteroffers the price p_2' or p_2'' if he does not know what reprisal level R DC is subjected to? How will the equilibrium or probable outcomes change? We turn to this question now.

Figure 1: Game under incomplete information

PH

	Accept p_1	Reject p_1 + offer p_2'	Reject p_1 + offer p_2''
Accepts status quo	q_0 , $\pi_0(q_0,p_0)$	q_0 , $\pi_0(q_0,p_0)$	q_0 , $\pi_0(q_0,p_0)$
Threat + Accept p_2	q_1 , $\pi_1(q_1,p_1)$	q_2' , $\pi_2'(q_2',p_2')$	q_2'' , $\pi_2''(q_2'',p_2'')$
Threat + Issue CL	q_1 , $\pi_1(q_1,p_1)$	q_{CL}' , $-F$	q_{CL}' , $-F$

DC'

$h_1(DC)$

Nature

DC$_L$

DC$_H$

γ

$1-\gamma$

$h_2(DC)$

PH

	Accept p_1	Reject p_1 + offer p_2'	Reject p_1 + offer p_2''
Accepts status quo	q_0 , $\pi_0(q_0,p_0)$	q_0 , $\pi_0(q_0,p_0)$	q_0 , $\pi_0(q_0,p_0)$
Threat + Accept p_2	q_1 , $\pi_1(q_1,p_1)$	q_2' , $\pi_2'(q_2',p_2')$	q_2'' , $\pi_2''(q_2'',p_2'')$
Threat + Issue CL	q_1 , $\pi_1(q_1,p_1)$	q_{CL}'' , $-F$	q_{CL}'' , $-F$

DC''

$h_1(PH)$

- – PH's information set
- – DC's information sets

Under the given configuration of payoffs, the probable or equilibrium outcomes are summarized in proposition 2. In order to save space, we will focus only in the situations when the negotiation starts (i.e. $R < \overline{R}$ and $\underline{\alpha} < \max(\alpha_L, \alpha_F) \leq 1$).

Proposition 2.1 For all beliefs γ and for all reprisal $R > 0$, PH will refuse the large price drop from p_0 to p_1.

Proposition 2.2: There exists a $\overline{\gamma}$ such that for all $\gamma < \overline{\gamma}$, *PH* will refuse the request for a large price drop and instead will counteroffer smaller price drop from p_0 to p_2'', and for all $\gamma > \overline{\gamma}$, will refuse the request for a large price drop and instead will counteroffer smaller price drop from p_0 to p_2', with $p_2' < p_2''$.

Proposition 2.3: DC will issue a compulsory license only when PH holds a wrong belief concerning DC's types and when there are enough manufacturing capacity and/or import possibilities such that $\max(\alpha_L, \alpha_F) = \overline{\alpha} \geq \frac{p_1}{p_1 + \overline{\varepsilon}''} \cdot \frac{B}{B - R'}$

The proof can be understood as follows. Again we solve the game by the principle of backward induction, starting from the bottom of the tree (or right hand end) and working upwards to the origin to the tree (left hand end).

When $R > 0$, for PH the strategy of accepting p_1 is strictly dominated by the strategy of rejecting p_1 and counter-offering $p_2' = p_1 + \bar{\varepsilon}'$, regardless DC's type, as long as $\bar{\varepsilon}'$ satisfies Equation 15. It means that DC will never issue a compulsory license when the price p_1 is rejected and the price $p_2' = p_1 + \bar{\varepsilon}'$. Therefore, we can say that the <u>PH's expected payoff associated to the strategy reject p_1 and counter-offer p_2'</u> will be π_2 for all DC's types.

On the other hand, the <u>PH's expected payoff associated to the strategy reject p_1 and counter-offer $p_2'' = p_1 + \bar{\varepsilon}''$</u> indeed depends on the DC's type. If DC is of type DC'', then DC will be better off by accepting the price drop from p_0 to p_2'' than by issuing a compulsory license (see Equation 18 above). However, if DC is of type DC', then DC will be better off by issuing a compulsory license than by accepting the price drop from p_0 to p_2''. To find the expected payoff associated to this strategy we just have to multiply the expected payoff concerning each DC's type by the respective PH's belief, as follows:

$$\gamma \cdot (-F) + (1 - \gamma) \cdot \pi_2'' \qquad (19)$$

So, we can say that will reject p_1 and counteroffer $p_2'' = p_1 + \bar{\varepsilon}''$ if the expected payoff associated to this strategy is greater than the payoff associated to the strategy of rejecting p_1 and counter-offering $p_2' = p_1 + \bar{\varepsilon}'$, as in Equation 20

$$\gamma \cdot (-F) + (1 - \gamma) \cdot \pi_2'' > \pi_2' \qquad (20)$$

$$\gamma < \frac{(\pi_2'' - \pi_2')}{(\pi_2'' + F)} = \bar{\gamma} \qquad (21)$$

Through Equation 21 we can conclude that:

- If the patent holder strongly believes that the developing country is a weak reprisal target, i.e. o $\gamma \leq \bar{\gamma}$, then it will accept the request for a large price drop.

- If the patent holder strongly believes that the developing country is a strong reprisal target, i.e. when $\gamma > \bar{\gamma}$, then it will oppose the request of DC for a large price drop and instead make a counter-offer of a small price drop. If the developing country is of type DC'', then it will accept the counter-offer of PH for a small price drop – if this is made. If the developing country is of type DC', then it will refuse the counter-offer of PH for a small price drop and instead issue a compulsory license if:

$$q'_{CL} > q''_2 \tag{22}$$

$$\frac{B - R'}{\frac{p_1}{\max(\alpha_L, \alpha_F)}} > \frac{B}{p_1 + \bar{\varepsilon}''} \tag{23}$$

Rearranging (23) we get:

$$\max(\alpha_L, \alpha_F) = \bar{\alpha} > \frac{p_1}{p_1 + \bar{\varepsilon}''} \cdot \frac{B}{B - R'} \tag{24}$$

Given the above discussion by application of the principle of backward induction we can identify the rational play of the two players as presented in Table 2.

Context of the game			Equilibrium strategy of DC	Equilibrium strategy of PH	Price outcome
Nature's choice	PH's beliefs	Bargaining position			
$for\ all\ DC's$ $types$	For all γ	$\max(\alpha_L, \alpha_F) \leq \underline{\alpha}$	Accepts status quo	N/A	p_0
DC=DC''	$\gamma < \gamma^*$	$\underline{\alpha} < \max(\alpha_L, \alpha_F) \leq 1$	Proposes price drop p_1; Accepts p_2''	Rejects p_1 and counter-offers p_2''.	Price of drug drops from p_0 to p_2''.
DC = DC'	$\gamma < \gamma^*$	$\underline{\alpha} < \max(\alpha_L, \alpha_F) < \bar{\alpha}$	Proposes price drop p_1; Accepts p_2''	Rejects p_1 and counter-offers p_2''.	Price of drug drops from p_0 to p_2''
		$\underline{\alpha} < \bar{\alpha} < \max(\alpha_L, \alpha_F) \leq 1$	Proposes price drop p_1; Rejects p_2'' and issues a CL	Rejects p_1 and counter-offers p_2''.	Price of drug drops from p_0 to p_{CL}.
$for\ all\ DC's$ $types$	$\gamma \geq \gamma^*$	$\underline{\alpha} < \max(\alpha_L, \alpha_F) \leq 1$	Proposes price drop p_1; Accepts p_2'	Rejects p_1 and counter-offers p_2'.	Price of drug drops from p_0 to p_2'.
$for\ all\ DC's$ $types,$ $R' = 0$)	$\gamma \geq \gamma^*$	$\underline{\alpha} < \max(\alpha_L, \alpha_F) \leq 1$	Proposes price drop p_1	Accepts p_1	Price of drug drops from p_0 to p_1.

3   Conclusions

The model developed in this paper sheds light on the complexity involved to the issuance of a compulsory license by developing countries. Although compulsory license can be an effective tool for lowering drug prices, there are other important variables that must be taken into account in order to evaluate in which extent it can be employed.

First, the reprisal that developing countries may be subject to in case of compulsory license issuance can be a detrimental factor. Nonetheless compulsory license is a legitimate tool and has been employed extensively by more developed countries such as United States and Canada, there is always a cost of issuing a compulsory license for developing countries, especially in terms of political and economic retaliation by developed countries and the pharmaceutical industry (e.g. trade retaliations, loss of foreign direct investment, reduction of incentives to invest in innovation, among others). So whenever is possible, the developing country will prefer a strong price drop to issuing a compulsory license , and depending on its bargaining position and/or how the developing country outweigh the risks, costs and benefits of issuing a compulsory license, it may prefer even a weak price drop to issuing a compulsory license.

Secondly, the existence of manufacturing capacity seems to be one of the most important components of developing countries' bargaining position when negotiating prices with innovative pharmaceutical companies. When there is no local capacity, the developing country can import a generic version – if there is any available in the international market. For drugs patented in India before 2005 – when India changed its intellectual property rights in order to be aligned to the requirements of the Trips Agreement – it is much more likely that such a generic version will be readily available for imports. However, if this is not the case, according to the Doha provision, developing country may rely on back-to-back compulsory license (i.e. an exporter country issues a compulsory license specifically designed to supply to the country with insufficient manufacturing capacities). But the very unique experience of practical use of this provision (by Ruanda, importing from Canada) raises several doubts on its practical value in fact.

This discussion is an example that intellectual property rights are only the tip of the iceberg. Even in the absence of intellectual property rights there is no guarantee that the needs of the poorest will be fulfilled. However, this doesn't mean that intellectual property rights do not have any negative impact on access of life saving drugs or that there is no room for institutional change on the international agreements that regulate this subject. Any step facilitating the export to countries with insufficient manufacturing capacity and / or protecting developing countries from reprisals related to compulsory license issuance seems to be important to build a framework more suitable to access to life saving drugs.

[ii] Patient population includes all people affect by certain disease and may be segmented according to demographics and other characteristics of a population being serviced, such as ethnicity, and socioeconomic status.