# Compulsory licence threats in a signaling game of drug procurement

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**Abstract**

Under the TRIPS Agreement, developing countries (DCs) can use compulsory licensing (CL) to promote access to medicines and authorise the local production or import of more affordable generic medicines on their territory. For this reason, a literature examines the impact of such licenses on access to medicines in developing countries, on theoretical and empirical grounds. The aim of this article is to contribute to this literature by proposing a game theory model that can explain under what circumstances developing countries resort to CL and that fits with the stylized facts.

Keywords: patent, compulsory license, threat strategy, health, drug procurement.

JEL classification: C7, D4, I18.

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# 1 Introduction

According to the Trade-Related Aspects of Intellectual Property Rights agreement (TRIPS) ratified by the country-members of the new World Trade Organization (WTO) in 1994, a compulsory license (CL) occurs when a government allows a third party to produce the patented invention without the consent of the patentee. This licence may be granted for instance in case of national emergencies, other circumstances of extreme urgency and anticompetitive practices threatening drug accessibility and public health; and without the requirement to make efforts to obtain a voluntary license (VL) from the patentee on reasonable conditions. So CL is a flexibility made to ensure the protection of public health, before those of IPRs, specifically in developing countries.

Actually, there has been a limited but growing resort to CL in the South since the turn of the century (Beall and al., 2015; Son and Lee, 2018). Thus, a literature has developed on the occurrence of such licences and their effects on drugs accessibility and public health protection in the Southern hemisphere. Especially, the grant in late 2006 and early 2007 of several CLs in Thailand and Brazil, two countries with strong similarities, explains the development of theoretical models aimed at understanding the decision-making process leading to the implementation of a CL[1]. In this literature, game theory is used for modelling the interaction between governments and pharmaceutical firms[2].

For instance, Stavropoulou and Valletti (2015) emphasis the role of the domestic production costs on the decision to exercise or not a CL. When unable to produce the drug at low price, a Southern country will be reluctant to exercise the license. Similarly, Bond and Saggi (2014) indicate that for a government, wishing to get the best medicine at the lowest price, there is a trade-off between price controls and access to high-quality medicines produced by multinational firms on one side, and the issue of a CL associated with a decrease in the quality of the generic drug produced by local manufacturers on the other side. They conclude that the CL option increases Southern welfare as it either reduces the fees paid to patent holders or encourages the firms to offer a good quality drug[3]. Lastly, Ramani and Urias (2015) consider the negotiation between a government and a foreigner firm in an imperfect information game where the latter ignores the costs for the former issuing a CL. Assuming high costs, they show that the firm may refuse important price reductions to a government with low costs which will finally find convenient to grant a CL.

[1] Precisely, both countries issued particular CL: "government use" or "public non-commercial use" of patent under which a government may use the patent without the patentee's consent for the purpose of supplying free medicines in hospitals.

[2] These models are part of a larger strand of research that uses game theory to scrutinize the decision-making of private and public actors to address health issues, i.e. the implementation of vaccination programs, the provision of health care in community-based approaches, or the commitment of health workers in limited-resources countries (cf. Malhotra, 2012; Westhoff et al., 2012).

[3] More recently, Bond and Samuelson (2019) study the dynamics of the bargaining process between a pharmaceutical firm and a government and show the influence of private information about the firm's payoffs on the timing of the negotiations.

One common aspect of these papers is to consider that the possibility of CL exerts an *implicit* threat on the pharmaceutical industry. However, the explicit use of the CL threat is not directly studied even if case studies exhibit a wide variety of examples where the public agency negotiating used the threat with various outcomes (see Beall and Kuhn, 2012; Cherian, 2016).

This paper contributes to the literature by considering the threat of CL as a tool explicitly used or voluntarily omitted by countries during their negotiations with the patent holders. These negotiations demonstrate the applicant's efforts to obtain price reductions from the patentee under reasonable terms and conditions.

Since the 2001 Doha declaration, several countries efficiently used CL threat during a bargaining process to gain access to drugs at more affordable prices. For instance, the Brazilian government extensively used the CL threat for HIV/AIDS medicines during the negotiations with multinational firms. This strategy was followed by some countries in Asia, Latin America and Africa where CL appeared not only as a flexibility to circumvent IPRs, but also as a convenient threat used during the negotiations to increase the bargaining power of governments (Shankar et al. 2013; Cherian 2016).

In this line, we propose a model exploring the interactions between a developing country and a pharmaceutical firm holding a patent over a medicine whose objectives are opposed. On one side, the government of the developing country tries to reduce the global cost of the drug provision and negotiates to gain either the lowest feasible price or a VL from the patentee. On the other side, the multinational firm from the North tries to maximize its profits. During the negotiations, the government explicitly considers the opportunity to use the CL threat to obtain lower prices and improve drug accessibility.

As suggested by Ramani and Urias (2015), the occurrence of a CL can only be understood in an incomplete information setting in which beliefs about the country's characteristics are key elements. While issuing a CL, public authorities are aware that they will have to bear implementation costs reflecting the burden supported by the economy. These costs include the industrial investment required by the local production of the drug, research and development (R&D) necessary for the manufacture of high-quality products, the costs of law adjustments (obligations and flexibilities covering the use of IPRs) and, above all, the value of the international sanctions in retaliation for the adoption of a CL (market withdrawal by producers, drop in FDI, formal or informal pressures from foreign trade ministry, or formal action before the WTO). They also reflect more imprecise political variables such as government policy orientations or domestic policy considerations (Benoliel and Salama, 2010; Ramani and Urias, 2015; Guennif, 2017). Overall, these costs may be difficult to assess for the firm which tries to evaluate the bargaining power of the public negotiator in an imperfect information setting.

In order to formalize this imperfect information, we assume that the patentee knows that it may be opposed to two types of governments: a Strong one or a Weak one. The difference between the two types of government is limited to the implementation costs: the costs borne by a Weak government in case of CL is higher than the one of the Strong government. As usual in this type of game, the government knows its characteristics but the information is unknown by the firm.

In these settings, we specifically focus on the signalling possibilities let to the government to reveal its type. We assume that the public negotiator, at the beginning of the game, may explicitly threaten the patentee to issue a CL. This threat is costly for the economy[4] and may so constitute an efficient signal of the government willingness to impose a CL in case of excessive drug pricing. Depending on whether or not the CL threat has been used, the firm updates its beliefs about the government's type and decides how to manage its patent. It may either issue a VL or post a monopoly price. When the firm chooses the monopoly option and posts a high drug price, the government may accept this price or issue a CL.

According to the implementation costs incurred by the government in the CL case and to the firm's beliefs of the government type, the model leads to three different market structures. In a nutshell, when the ex-ante probability of facing a Strong government (more likely to issue a CL) is high, the equilibrium strategy for the firm is to issue a VL and there is no need to use the CL threat. In the opposite case, when this probability is sufficiently low, the firm will post a price that maximizes its expected profit. While this price appears as affordable to the Weak type government, it allows a Strong type government to request a CL on the argument that drug prices are excessive. For intermediate values of the probability, the firm prefers to post a high price and the equilibrium is defined with random threat strategies for the government.

One important result of the model is that no separating equilibrium appears as a solution of the game. For a government, it is always useful to mislead the firm and to make it belief that the implementation costs are different from the actual ones. The basic argument is straightforward: if the firm considers the government as Weak, it will post a monopoly price and a Strong government will find sound arguments to grant a CL. On the other side, a firm which fears to be opposed to a Strong government will issue a VL and a Weak government would thus benefit from the drug at attractive conditions. In both cases misinterpretation by the firm of the government's type is beneficial for the government through the supply of more affordable drugs.

Our model sheds a new light on the variety of scenarii that followed the use of CL threat by government since the beginning of the century. These equilibria are consistent with stylized facts that occurred in various cases when governments used very opposite threat strategies in the negotiations. It also permits a reinterpretation of public policies that could influence the costs of setting up a CL and may indirectly affect the results of the price negotiation

[4]In the long run, this threat reveals that the government is reconsidering IPRs and may restrict technology transfers, inhibit FDI or limit R&D on local diseases. Bernd and Cockburn (2014) show, in India, that the implementation of what is considered abroad to be a weak IPR regime, induced a 5-year delay before the availability of innovative medicines. Earlier, Lee and Mansfield (1996) demonstrated that the perceived low level of IPR protection in middle-income countries substantially affects the volume and the composition of the US FDI.

between the Laboratory and the Government.

The rest of the article is organized as follows. Section 2 introduces the main assumptions. Section 3 presents the equilibria of the game and Section 4 presents the stylized facts about CL implementation. The last section concludes the paper.

# 2 The signaling game:

## 2.1 Main assumptions:

We consider a two-player signaling game involving a pharmaceutical firm (hereafter the Lab), patent holder of a drug essential to solve a local health problem, and a public body in charge of drug supply for the whole country (hereafter the Government). Both players are risk neutral. The Lab negotiates with the Government the procurement of a fixed quantity $Q$ of drug. In sake of simplicity, we normalize quantity and set $Q = 1$.[5]

In order to commercialize its drug, the Lab has two options. It may decide either to issue a Voluntary Licence (VL strategy) to the local industry or to produce the drug and to sell it as a monopoly.[6]

The Government wishes the population to benefit from the drug at the lowest possible cost. If the Lab refuses to grant a VL and decides to exploit the market as a monopoly, it may Accept this decision (A strategy) or react and impose a Compulsory Licence (CL strategy) allowing the local marketing of the generic equivalent of the drug.

In case of a VL or a CL, the prices of the drug are exogenously set as $P_{VL}$ and $P_{CL}$ according to international benchmarks (with $P_{VL} > P_{CL}$). When the Lab chooses to produce the drug, the monopoly price is endogenously set by the Lab in order to maximize its profit. Hereafter, we will denote by $P_M$ the price of the drug in the monopoly case.

According to the market regime, the Lab will reap a larger or a lesser share of the drug price. Its profit $\pi_L$ is thus:

$$\begin{cases} \pi_L(VL) = \alpha P_{VL} \\ \pi_L(CL) = \beta P_{CL} \\ \pi_L(P_M) = \delta P_M \end{cases} \text{With } \begin{cases} 0 < \alpha < 1 \\ 0 < \beta < 1 \end{cases}, \text{ and } \pi_L(VL) > \pi_L(CL) \tag{1}$$

In order to simplify notations, hereafter we adopt the normalization $\delta = 1$.

When a CL is granted, the government has to bear implementation costs. These costs reflect, among other, the industrial investment implied by the operation of the license, the costs of law adjustments, the value of the international sanctions in retaliation for the adoption of a CL. The model thus considers that there are two types of Government: the Strong and the Weak. In case of CL,

[5] In the case of an increase of $Q$, fixed costs per unit of medicine would decrease. We will come back on this point while considering the policy implications of the model.

[6] We assume here that the local industry exhibits sufficient capacities to be an efficient licensee.

the cost $C^S$ borne by a Strong Government is low as compared with the cost $C^W$ of a Weak Government ($C^W > C^S$). There is no other difference between Governments.

At the beginning of the game, Nature chooses the type of the Government involved in the negotiation. This one has then to decide if it wishes to make an explicit CL threat. If the Government decides to make this threat (hereafter strategy $s = T$), it will have to bear a threat cost $c$, i.e. a fraction of the implementation costs $C^\tau$ paid in advance as a consequence of the threat. For instance, in case of threat, foreign firms may worry about the respect of IPRs in the country and decide to postpone transfers of technology or to limit R&D on local diseases. For the government, these retaliatory measures induce sunk costs as the loss of confidence associated with the threat will persist even if the CL is not issued. If a CL is eventually granted, the implementation costs $C^\tau$ paid by the Government is reduced by the amount $c$ as the negative consequences of the threat have already been carried on (e.g. technology transfer have already been postponed). In this case, the implementation costs of the CL is reduced to $C^\tau - c$. Conversely, if at the outset of the game the Government does not use the threat (hereafter strategy s =N), it will bear no threat cost and will have to pay the complete implementation costs $C^\tau$ if a CL is finally issued.

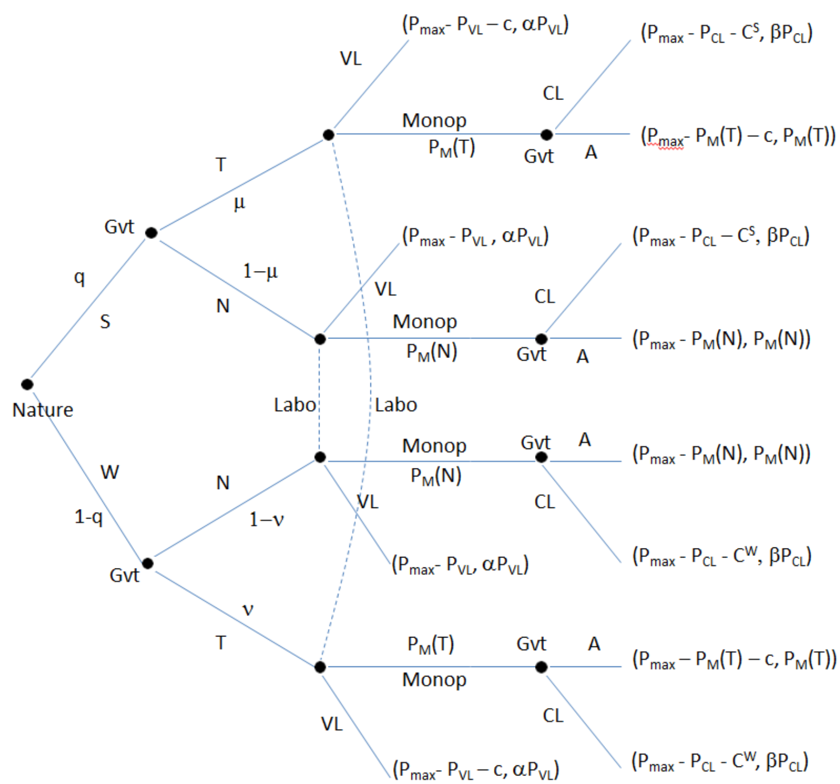
Ex ante, the Lab ignores the Government's type. It considers a priori a probability $q$ (resp. $1-q$) for the Government to be Strong (resp. Weak). Given the threat strategy played by the government, it updates its beliefs according to a Bayesian procedure and has to decide either to issue a VL or to sell the drug as a monopoly. In this last case, the price posted by the monopoly will vary according to the initial action of the Government. We thus denote by $P_M(s)$ with $s = T$ or $N$ the monopoly price set by the Lab given the Government threat strategy.

Let us denote by $1_{s=T}$ the indicator variable that takes the value 1 if the Government makes the threat and 0 otherwise. Define by $P_{\max}$ the highest price that the Government would accept to pay for the drug. The satisfaction $U_G^\tau(-|s)$ of a Government with type $\tau$ (with $\tau = S$ or $W$) playing strategy $s$ is measured by the following surpluses:

$$\begin{cases} U_G^\tau(VL|s) = P_{\max} - P_{VL} - 1_{s=T}c & \text{Voluntary license} \\ U_G^\tau(CL|s) = P_{\max} - 1_{s=T}c - P_{CL} - (C^\tau - 1_{s=T}c) & \text{Compulsory license} \\ \quad = P_{\max} - P_{CL} - C^\tau & \\ U_G^\tau(P_M(s)|s) = P_{\max} - P_M(s) - 1_{s=T}c & \text{Monopoly} \end{cases} \tag{2}$$

Figure 1 presents the decision tree of the game.

At the beginning of the game, Nature randomly chooses the Government's type. This one is Strong (S) with a probability $q$ or Weak (W) with a probability $1 - q$. The Government then decides if it uses the CL threat ($s = T$) or not ($s = N$). In answer, the Lab may either issue a VL or post a monopoly price ($P_M(s)$). In the latter case, the Government may accept the status quo (A) or refuse it and finally issue a CL. The rewards of the two players are given at the


(Pmax- PVL – c, αPVL)
VL
(Pmax - PCL - CS, βPCL)
CL
Monop
PM(T)
Gvt
A
(Pmax- PM(T) – c, PM(T))
T
μ
Gvt
(Pmax - PVL , αPVL)
(Pmax - PCL – CS, βPCL)
1–μ
VL
CL
q
S
N
Monop
PM(N)
Gvt
A
(Pmax - PM(N), PM(N))
Nature
Labo
Labo
Monop
Gvt
A
(Pmax - PM(N), PM(N))
W
N
PM(N)
VL
CL
1-q
1–ν
(Pmax - PCL - CW, βPCL)
Gvt
(Pmax- PVL, αPVL)
ν
T
PM(T)
Gvt
A
(Pmax – PM(T) – c, PM(T))
Monop
CL
VL
(Pmax - PCL - CW, βPCL)
(Pmax- PVL – c, αPVL)

end of each branch of the tree.

## 2.2 Monopoly pricing rule and Government answer

In order to solve the game, this section analyses first the pricing rule used by the Lab when the firm decides to rule the market as a monopoly.

- Perfect Information

Let us first consider the simple case in which the Lab is able to identify the Government's type. In this case, the former may force the latter to accept the monopoly regime by posting a price $P_M(s)$ such as, given the Government's type $\tau$, the drug procurement would be less expensive than under a CL. Such a price would respect the following inequality:

$$U_G^{\tau}(P_M(s)) \geq U_G^{\tau}(CL), \text{with } s = T \text{ or } N, \text{ and } \tau = S \text{ or } W$$

When the Lab is matched with a Strong Government this inequality leads to the definition of a low price $P_M^L(s)$ such as:

$$\begin{aligned} U_G^S(P_M^L(s)) &\geq U_G^S(CL), && (3)\\ &\Leftrightarrow P_{\max} - P_M^L(s) - 1_{s=T}c \geq P_{\max} - P_{CL} - C^S && (4)\\ &\Leftrightarrow P_M^L(s) \leqslant P_{CL} + C^S - 1_{s=T}c. && (5) \end{aligned}$$

As the monopoly aims at maximizing its profit, it will choose the highest price consistent with this inequality:

$$P_M^L(s) = P_{CL} + C^S - 1_{s=T}c \quad (6)$$

When the Lab is matched with a Weak Government the optimal price is:

$$P_M^H(s) = P_{CL} + C^W - 1_{s=T}c \quad (7)$$

with $P_M^H(s) > P_M^L(s)$.

Under perfect information, the monopoly price is posted according to the Government's type and to its threat strategy. This price is satisfactory for the Government who gets the drug at the same cost than under a CL. It is optimal for the Lab as it precludes the possibility of a CL. Under perfect information, neither VLs nor CLs may be issued. The Lab always posts a price that may be accepted by the government.

- Imperfect information

Even when information is imperfect, a monopoly which posts the low price $P_M^L(s)$ knows that, whatever its type, the Government will accept this price. In this case, the Lab's profit, $\pi_L(P_M^L(s))$ is certain and equal to:

$$\pi_L(P_M^L(s)) = P_{CL} + C^S - 1_{s=T}c \quad (8)$$

If the Lab posts the high price, $P_M^H(s)$, a Weak Government will be indifferent between the monopoly price and the production under CL, $U_G^W(P_M^H(s)) = U_G^W(CL)$, therefore it may accept the monopoly price. On the opposite, as $U_G^S(P_M^H(s)) < U_G^S(CL)$, a Strong Government with low implementation costs will find optimal to grant a CL.

In order to focus only on the relevant equilibria, hereafter we will assume that, for the Lab, the profits obtained through the VL are higher than those arising from a low price $P_M^L(N)$ (i.e. the monopoly price in the no threat case) but are lower than those reached with the price $P_M^H(T)$ in the monopoly case with threat:

$$\begin{aligned} P_M^L(N) &< \alpha P_{VL} < P_{VL} < P_M^H(T) \\ &\Leftrightarrow P_{CL} + C^S < \alpha P_{VL} < P_{VL} < P_{CL} + C^W - c \end{aligned} \quad (9)$$

The first part of this inequality, $P_M^L(N) < \alpha P_{VL}$, states that the low monopoly price $P_M^L(N)$ leads to lower profits than the issue of a VL.[7] Posting a low price is therefore inefficient and these prices can be removed from the Lab's set of feasible strategies. According to the government's threat decision, the set of prices that a Lab may rationally post is restricted to the two high prices:

$$\begin{cases} P_M^H(T) = P_{CL} + C^W - c & \text{In case of threat} \\ P_M^H(N) = P_{CL} + C^W & \text{In the no threat case} \end{cases} . \quad (10)$$

Note that in answer to a CL threat the Lab always concedes a price reduction equal to the cost $c$.

According to the second part of inequality (9), $P_{VL} < P_M^H(T)$, the monopoly price is higher than the price posted in case of VL. This implies $\pi(VL) < \pi(P_M^H(-))$,ie. the issue of a VL is not a dominant strategy for the Lab. In the opposite case, the Lab would always issue a VL.

In the model, three market structures are therefore feasible. Given the threat strategy applied by the Government, the Lab has to choose between granting a VL in order to avoid the risk of a CL or trying to sell the drug at the high price $P_M^H(s)$. In the latter case, a Strong Government will grant a CL while a Weak one will accept the status quo.

# 3 Equilibria

In such a game, a strategy for the Government is defined as a function that associates to each Government's type a specific choice, i.e.: use the CL threat

[7] Under the alternative assumption, $P_M^L(N) > \alpha P_{VL}$, the Lab always prefers posting a low monopoly price to the issue of a Voluntary license. The model precludes the VL and allows instead studying high price reductions as a result of the negotiation. In this case, the model would present basically the same equilibria but with a Lab posting a low price $P_M^L(s)$ instead of issuing a voluntary license. See Infra the discussion of the Bezilian case.

(action $T$), don't use it (action $N$) or a random choice between the two actions $T$ or $N$. For the lab, a strategy is a function that associates an answer to each feasible action of the Government. When the Government decides to threaten the Lab (resp. if it doesn't threaten the Lab) the Lab may decide to issue a VL, to post the monopoly price $P_M^H(T)$ or to make a random choice between the two alternatives.

In this classical imperfect information game, we are looking for a Perfect Bayesian Equilibrium (PBE) such as the Government makes its decision in order to maximize its expected surplus given laboratory's beliefs and the laboratory, which maximizes its profit, updates its beliefs given the optimal behavior of the Government. Following backward induction, the resolution starts with the definition of the Lab's optimal behavior.

As usual in this kind of model, we consider the signaling opportunities in separating, pooling or hybrid equilibria.

## 3.1 Separating Equilibrium

Let us consider first the feasibility of a separating equilibrium in which a Strong Government always threatens to issue a CL while a Weak one never uses the threat. In such an equilibrium, a Lab which is threaten by the Government considers that it is matched with a Strong type Government. In the no threat case, the Lab assumes that the Government is Weak. Equilibrium beliefs must respect:

$$\begin{cases} P[\tau = S|s = T] = 1 \\ P[\tau = S|s = N] = 0 \end{cases} \tag{11}$$

Lab's optimal behavior : In this equilibrium, the government decision perfectly reveals its type. Hence, if the government uses the threat, the Lab which expects to be faced with a Strong Government will issue a VL and will get profit $\pi_L(VL) = \alpha P_{VL}$ (if the lab posts the monopoly price, it anticipates the issue of a CL and the laboratory's profit would be $\pi_L(CL) = \beta P_{CL}$ with $\pi_L(CL) < \pi_L(VL)$). In the other case, if the government doesn't threat the Lab it will be considered as Weak and the Lab will post the monopoly price $P_M^H(N)$ which leads to the higher profits $\pi_L(P_M^H(N)) > \pi_L(VL)$.

Government's strategy : If, according to the equilibrium strategy, the Strong Government uses the CL threat, the Lab will answer by the issue of a VL and the Strong Government's surplus will be $U_G^S(VL|T) = P_{\max} - P_{VL} - c$. If the Strong Government deviates and refuses to threaten the Lab, it will be considered as Weak and the Lab will post the monopoly price $P_M^H(N)$. In turn, the Strong Government will grant a CL and reach the surplus: $U_G^S(CL) = P_{\max} - P_{CL} - C^S$. This deviation is optimal for the Strong Government as, $P_{CL} + C^S < P_{VL} + c$ (Cf. Eq 9). The separating equilibrium is impossible.

Note that a deviation is also optimal for a Weak Government. If the Weak Government does not use the CL threat, the Lab will post the monopoly price $P_M^H(N)$ and the Weak Government's surplus will be therefore: $P_{\max} - P_M^H(N)$. If the Government decides to deviate and to threaten the Lab, it will be considered as Strong and the Lab will voluntarily issue a license, the government surplus will therefore be $U_G^W(VL|T) = P_{\max} - P_{VL} - c$. Deviation is optimal as $P_M^H(T) = P_M^H(N) + c > P_{VL}$ (Cf. Eq 9).

In our model, a separating equilibrium is impossible as both types of Government have strong incentives to manipulate the information sent to the pharmaceutical industry. The rejection of the CL threat allows a Strong Government to appear as Weak, it drives the Lab to post the high price and enables the Government to grant a CL. On the other hand, using the threat, a Weak Government induces the Lab to believe that it is Strong and, in answer, to issue a VL which is efficient for the Weak government. For both Governments, misinterpretation of their real goal by the Lab leads to a drop in the drug procurement cost.

## 3.2 Pooling equilibria

Let us consider now the possibility of pooling equilibria. We start with the equilibrium in which the governments, whatever their type, use the threat option.

### 3.2.1 Pooling equilibrium with generalized CL threat.

In this equilibrium, both type of Government find optimal to use the CL threat. Moreover, the Lab considers that a Government which refuses this invest can only be Weak.[8] Equilibrium beliefs must be:

$$\begin{cases} P[\tau = S|s = T] = q \\ P[\tau = S|s = N] = 0 \end{cases} \tag{12}$$

- Lab's optimal strategy

Consider first the case where the Government plays the equilibrium strategy and decides to threaten the Lab. In answer, as the Government may be Strong with a probability $q$, a Lab which decides to sell directly the drug and posts the monopoly price, $P_M^H(T)$, expects that the Government will accept the status quo with probability $(1-q)$ (if the Government is Weak) and will impose a CL with probability $q$ (if the Government is Strong). The expected profit of the Lab is:

$$E[\pi_L(P_M^H(T))|T] = q(\beta P_{CL}) + (1-q)P_M^H(T) \tag{13}$$

If the Lab decides to issue a VL, its profit will be $\pi_L(VL) = \alpha P_{VL}$. This last strategy is the optimal answer to the CL threat if $E[\pi_L(P_M^H(T))|T] < \pi_L(VL)$, i.e. if:

$$q > q_1 = \frac{P_M^H(T) - \alpha P_{VL}}{P_M^H(T) - \beta P_{CL}} \tag{14}$$

[8] Under the alternative out of equilibrium beliefs, $P[\tau = S|s = N] = 1$, the equilibrium doesn't exist. As a the use of the No Threat strategy would reveal a Strong government and would be followed by the issue of a VL, a Weak government would always prefer not to threaten the Lab.

with $0 < q_1 < 1$ as $\beta P_{CL} < \alpha P_{VL} < P_M^H(T)$ (Cf. Eq. 9 and 1).

The optimal answer of the Lab to the CL threat thus relies on the frequency of Strong and Weak Governments. When $q$ is high, the probability of being faced to a Strong Government leads the firm to issue a VL. If $q$ is low, the firm will try to impose a monopoly price.

When a Government deviates and does not use the threat, the Lab considers the Government as Weak and posts the monopoly price, $P_M^H(N)$.

- Government optimal strategy

We must now study the conditions under which the Government finds optimal to use the threat.

Case 1. $q > q_1$

In this first case, a Strong Government has no incentive to use the threat.

If the Government threaten the Lab, the issue of a VL is optimal for the pharmaceutical firm and the Government's surplus will be (whatever its type): $U_G^\tau(VL|T) = P_{\max} - P_{VL} - c$. If the Government decides not to use the threat, the Lab will post the monopoly price. In answer, a Strong Government will grant a CL and its surplus will be $U_G^S(CL|N) = P_{\max} - P_{CL} - C^S$. As $P_{CL} + C^S - c < P_{VL}$ (Cf. Eq : 9), a Strong Government strictly prefers not to use the threat. In Case 1, the equilibrium is impossible.

Case 2. $q < q_1$

In this second case, whatever the government threat policy, the Lab will post a monopoly price. It will post $P_M^H(T) = P_{CL} + C^W - c$ if the Government uses the CL threat and $P_M^H(N) = P_{CL} + C^W$ in the opposite case.

As a Weak Government may accept the monopoly price, its surplus is: $U_G^W(P_M^H(T)) = P_{\max} - P_M^H(T) - c$ in the threat case and $U_G^W(P_M^H(N)) = P_{\max} - P_M^H(N)$ in the other case. Given the definition of the two prices, we have $U_G^W(P_M^H(T)) = U_G^W(P_M^H(N))$, and whatever the threat strategy, the Weak government reaches the same surplus.

The Strong Government answers to the monopoly price by granting a CL. In this case, whatever its threat policy, its surplus will be $U_G^S(CL) = P_{\max} - P_{CL} - C^S$. For such a Government, the choice to use or not the threat doesn't matter.

A pooling equilibrium may thus appear under the necessary condition $q \leq q_1$. As the probability of being matched to a Strong Government is low, the pharmaceutical firm will post the monopoly price despite the risk of a CL. Whatever its threat strategy, the optimal answer of a Strong government (resp. a Weak governement) to the lab decision would lead to the same surplus. There is no incentive for a government to deviate and this pooling equilibrium exists under condition $q < q_1$.

#### 3.2.2 Pooling equilibrium without CL threat.

In this equilibrium, a Government never threatens the Lab with a CL issue. We further assume that from the Lab point of view, the threat may only be used by a strong Government. Equilibrium beliefs must be:[9]

$$\begin{cases} P[\tau = S|s = T] = 1 \\ P[\tau = S|s = N] = q \end{cases} \tag{15}$$

- Lab optimal strategy

We know that, in answer to the monopoly price, a Strong Government will impose a CL and a Weak one will accept the status quo. Given the equilibrium beliefs, the expected profit for a Lab which doesn't receive any threat and chooses to post the monopoly price is: $E[\pi_L(P_M^H(N))|N] = q(\beta P_{CL}) + (1-q)P_M^H(N)$. If the Lab grants a VL, it will get the certain profit $\pi_L(VL) = \alpha P_{VL}$. Posting a monopoly price is thus an optimal answer to the no threat strategy if:

$$\begin{aligned} E[\pi_L(P_M^H(N))|N] &> \pi_L(VL) & (16)\\ &\Leftrightarrow q(\beta P_{CL}) + (1-q)P_M^H(N) > \alpha P_{VL} & (17)\\ q &< q_2 = \frac{\left(P_M^H(N) - \alpha P_{VL}\right)}{\left(P_M^H(N) - \beta P_{CL}\right)} < 1, \text{ with } 0 < q_1 < q_2 & (18) \end{aligned}$$

If the Government decides to use the CL threat, the Lab will consider this threat as a signal of Strength and will issue a VL.

- Government optimal strategy

Let us check the conditions under which a Government prefers not to make the threat.

Case 1. $q < q_2$:

In this case, the equilibrium is impossible as a Weak government would strictly prefer to use the CL threat.

When $q$ is low and no threat occurred at the beginning of the game, the firm's optimal strategy is to post the monopoly price. The Weak Government which accepts the price get the surplus: $U_G^W(P_M^H(N)) = P_{\max} - P_{CL} - C^W$. If the Weak Government threatens the Lab, the firm will issue a VL and the Government's surplus will be $U_G^W(VL|T) = P_{\max} - P_{VL} - c$. As $P_{CL} + C^W - c > P_{VL}$ (Cf. Eq. 9), the Weak Government must deviate from the equilibrium strategy. The equilibrium is impossible.

Case 2. $q > q2$:

For high values of $q$, the Lab will issue a VL whatever the threat strategy of the Government. Whatever its type, the Government has no interest to make the threat as this would induce a retaliation cost $c$ and increase the procurement costs.

[9] With the alternative out of equilibrium beliefs, $P[\tau = S|s = T] = 0$, the equilibrium is impossible. If a Strong goverment uses the threat, the lab will answer by posting the monopoly price and the government will grant a CL. The CL threat thus appears as a dominant strategy.

Finally, the pooling equilibrium may occur under the necessary condition: $q > q2$. In this equilibrium, the pharmaceutical firm which fears to be faced with a Strong Government issues a VL. For the government, the threat has no impact on the firm's behavior and appears both costly and useless.

### 3.3 Hybrid equilibrium

In this section, we focus on the hybrid equilibrium defined for $q$ in the range $[q_1, q_2]$ (hybrid equilibrium 1). In this equilibrium, we assume that both players use mixed strategies whatever their type or the signal they observe. An Appendix at the end of this paper studies the feasibility of all other hybrid equilibria in our model.

In a general form the Government mixed strategy may be defined as:

$$\begin{cases} \text{for a Strong Government: } \begin{cases} CL \text{ Threat} & \text{with probability } \mu \\ \text{No Threat} & \text{with probability } (1-\mu) \end{cases} , \text{ with } \mu \in [0,1] \\ \text{for a Weak Government: } \begin{cases} CL \text{ Threat} & \text{with probability } \nu \\ \text{No Threat} & \text{with probability } (1-\nu) \end{cases} , \text{ with } \nu \in [0,1] \end{cases} \tag{19}$$

A Strong Government thus uses the threat with a probability $\mu$ and renounces to the threat opportunity with probability $(1-\mu)$. In the same way, a Weak Government will make the threat with a probability $\nu$ and won't use the threat with probability $(1-\nu)$.

In order to remain as general as possible, we consider that the Lab answers to a CL threat by the issue a VL with probability $\lambda$ and by posting the monopoly price with probability $(1-\lambda)$. If the Government doesn't use the threat opportunity, it will issue a VL with probability $l$ and will post the monopoly price with probability $(1-l)$. The Lab's mixed strategy is therefore:

$$\begin{cases} \text{In the threat case: } \begin{cases} \text{Voluntary license} & \text{with probability } \lambda \\ \text{Monopoly price} & \text{with probability } (1-\lambda) \end{cases} , \lambda \in [0,1]\} \\ \text{In the no threat case: } \begin{cases} \text{Voluntary license} & \text{with probability } l \\ \text{Monopoly price} & \text{with probability } (1-l) \end{cases} , l \in [0,1]\} \end{cases} \tag{20}$$

- The Lab indifference condition:

Given the equilibrium strategy of the Government, the Lab revises its beliefs according to a Bayesian procedure. Posterior beliefs are:

$$\begin{cases} P[\tau = W|T] = \frac{P[T|\tau=W]P[\tau=W]}{P[T|\tau=W]P[\tau=W]+P[T|\tau=S]P[\tau=S]} = \frac{\nu(1-q)}{\nu(1-q)+q\mu} \\ P[\tau = W|N] = \frac{P[N|\tau=W]P\tau=[W]}{P[N|\tau=W]P[\tau=W]+P[N|\tau=S]P[\tau=S]} = \frac{(1-\nu)(1-q)}{(1-\nu)(1-q)+q(1-\mu)} \end{cases} , \tag{21}$$

If the Lab decides to post a monopoly price, its expected profit is:

$$\begin{cases} E[\pi_L(P_M^H(T)|T] = \frac{\nu(1-q)}{\nu(1-q)+q\mu} P_M^H(T) + \frac{q\mu}{\nu(1-q)+q\mu} \beta P_{CL} & \text{In the Threat case} \\ E[\pi_L(P_M^H(N))|N] = \frac{(1-\nu)(1-q)}{(1-\nu)(1-q)+q(1-\mu)} P_M^H(N) + \frac{q(1-\mu)}{(1-\nu)(1-q)+q(1-\mu)} \beta P_{CL} & \text{In the no Threat case} \end{cases},$$

and the profit is $\pi_L(P_{LV}) = \alpha P_{LV}$ if it decides to issue a VL. If Eq. (20) properly describes the optimal strategy of the laboratory, this one must be indifferent between issuing a VL and posting the monopoly price, thus:

$$\begin{cases} E[\pi_L(P_M^H(T)|T] = \pi_L(P_{LV}) \\ E[\pi_L(P_M^H(N))|N] = \pi_L(P_{LV}) \end{cases}$$

After some calculations, these two equalities lead to:

$$\begin{cases} \nu = \frac{(1-q)P_M^H(N) + q\beta P_{CL} - \alpha P_{LV}}{(1-q)c} \\ \mu = \nu \frac{(1-q)}{q} \frac{\left[P_M^H(T) - \alpha P_{LV}\right]}{\left[\alpha P_{LV} - \beta P_{CL}\right]} \end{cases}, \tag{22}$$

with $\nu \in [0,1]$ and $\mu \in [0,1]$ if and only if $q \in [q_1, q_2]$.

- Government's indifference condition

Given the laboratory's strategy, the expected Government's surplus induced by its threat policy is (recall that a Strong Government will request a CL if the monopoly tries to post a monopoly price):

$$\begin{cases} E[U_G^S(T)] = \lambda (P_{\max} - P_{VL} - c) + (1-\lambda)\left(P_{\max} - P_{CL} - C^S\right) & \text{Threat case} \\ E[U_G^S(N)] = l\,(P_{\max} - P_{VL}) + (1-l)\left(P_{\max} - P_{CL} - C^S\right) & \text{Opposite case} \end{cases}, \tag{23}$$

for a Strong Government and:

$$\begin{cases} E[U_G^W(T)] = \lambda (P_{\max} - P_{VL} - c) + (1-\lambda)\left(P_{\max} - P_{CL} - C^W + c - c\right) & \text{Threat case} \\ E[U_G^W(N)] = l\,(P_{\max} - P_{VL}) + (1-l)\left(P_{\max} - P_{CL} - C^W\right) & \text{Opposite case} \end{cases}, \tag{24}$$

for a Weak one. If Eq. (19) properly describe the government's strategy, whatever its type the government must be indifferent between using or not the threat. We must have:

$$\begin{cases} E[U_G^S(T)] = E[U_G^S(N)] \\ E[U_G^W(T)] = E[U_G^W(N)] \end{cases} \tag{25}$$

which, after a few calculations, leads to $\lambda = l = 0$. In other words, whatever government threat policy, in equilibrium the Lab always posts the monopoly price.

As $\nu$ and $\mu$ defined by Eq. (22) are two decreasing functions of $q$ with $\nu = \mu = 1$ for $q = q_1$ and $\nu = \mu = 0$ for $q = q_2$, the hybrid equilibrium therefore exists for $q \in [q_1, q_2]$ and the two pooling equilibria appear as the limiting cases of the hybrid equilibrium. Note that $\mu < \nu$ when $q > q_1$, in equilibrium, the Weak Government uses more frequently the threat than the Strong one.

0 Low probability of Strong Gvt q1 q2 High probability of Strong Gvt 1

<table>
<tr><td>Pooling 1: Generalized Threat</td><td>Hybrid 1</td><td>Pooling 2: No Threat</td></tr>
<tr><td>1. Strong and Weak Governments use the CL Threat<br>2. The Lab posts $P_M^H(T)$<br>3. The Strong government grants a CL<br>The Weak government accepts $P_M^H(T)$</td><td>1. Governments Randomize between the two threat options $s \in \{T, N\}$<br>2. The Lab posts $P_M^H(s)$<br>3. The Strong government grants a CL<br>The Weak government accepts $P_M^H(s)$</td><td>1. Strong and Weak Governments don't Threat the Lab<br>2. The Lab issues a voluntary licence</td></tr>
<tr><td colspan="2">Hybrid 4 (Cf. Appendix 1)</td><td></td></tr>
<tr><td colspan="2">1. Strong Governments don't use the CL Threat s=N<br>2. Weak Governments Randomize between the two threat options $s \in \{T, N\}$<br>3. The Lab posts $P_M^H(s)$<br>4. The Strong government grants a CL<br>The Weak government accepts $P_M^H(s)$</td><td></td></tr>
</table>

Figure 1: Fig. 2 The equilibria

Appendix 1 shows that an alternative hybrid equilibria may occur if Strong governments never use the threat while Weak ones choose randomly between the two threat options (strategy $s_4$ in the appendix). This equilibrium is only feasible in the case $q < q_2$.

Finally, Fig. 2 presents the feasible equilibria for each values of $q$.

When the lab considers that it has a high probability of negotiating with a Strong government ($q > q_2$), its optimal strategy is to issue a VL to avoid the risk of CL. In this case, there is no need for the government, whatever its type, to use the CL threat. In the opposite case, $0 < q < q_2$, multiple equilibria may occur. In this case, according to the lab's beliefs, the government will optimally decide or not to use the threat. Beliefs are self-fullfilling.

## 4 Stylized facts

Even if our theoretical approach may hardly pretend to capture all dimensions of a complex multidimensional problem, it encompasses and contributes to explain the occurrence of a large variety of situations in which CL threats are used with various outcomes. Negotiations under the threat of CL are often kept secret. It is therefore difficult to find evidences that stylized facts perfectly fit with the model. However, case studies allow recognizing some patterns identified by the model.

## 4.1 High q, no CL threat and the issue of a VL: The South-African case (2001-2003)

At the end of the last century, in South-Africa, more than 4.5 million people were infected by HIV/AIDS and a large proportion needed ARV. But the drugs were patented and their prices were between three and ten times higher than the generic ones available on the global market.

Consequently, in 1997, the South-African parliament adopted a new legal provision (Section 15C) allowing "parallel imports" of patented drugs from countries where they were marketed at cheaper prices. Fearing a domino effect, over forty of the World's most important pharmaceutical firms initiated an action before the South-African High Court, arguing that the new provision was depriving them of their IPRs and was inconsistent with the TRIPS agreement. Besides, South-Africa was placed on "Special 301 watch list" by the US government and was at one step before the triggering of trade sanctions from the USA.

However, these pressures attracted international public awareness on the antagonism between the interests of the pharmaceutical industry and those of developing countries. The US government was urged to change its policy toward South-Africa and foreigner firms withdrew their complaint against the South-African government due to huge international pressure. More important, this dispute introduced the CL issue in the public debate (Fisher and Rigamonti, 2005). In January 1998, the Executive Board of the World Health Assembly adopted a resolution urging the country members "to review their options under the Agreement on Trade Related Aspects of Intellectual Property Rights to safeguard access to essential drugs". A series of discussions followed where CL was considered as an efficient option for increasing access to essential drugs. In 2001, the Doha declaration reaffirmed thus that each member has the right to grant CL and the freedom to determine the grounds upon which such licenses can be granted (WTO, 2001). Seriously fearing the resort to CL in South-Africa, patent holders granted eventually a number of VL that paved the way for local production of cheaper generic ARV.

In the line of our model, the South-African Government may be considered as a Strong one. Little retaliations could be expected in case of CL as pharmaceutical industry already withdrawn its lawsuit and USA publicly recognized the right for poor countries to access essential medicines[10]. Struck by the epidemic, South-Africa benefited furthermore from an efficient local generic industry. For that reason, the implementation of a CL would not have generated an important burden. Although the CL threat was never explicitly used, the implicit pressure induced by a new legal provision enforced by social pressure was sufficient to induce the firms to issue VL (Cf. pooling equilibrium 2).

[10] See President Clinton's speech at the 1999 WTO Ministerial Conference in Seattle and the confirmation by administration Bush that the USA would not react if WTO members use the flexibilities provided by the TRIPS in case of major health crises; moreover, after the US threat Bayer to resort to CL for Anthrax in 2001.

## 4.2 Low q, no CL threat and CL issue: the Thailand case (2006)

Situations in which a CL is issued without prior threat often arise in case of public health emergencies. In such a case, there is no prior negotiation required and no public occasion for a government to play the Threat Strategy (see for example the cases of Zimbabwe in 2002, Mozambique and Zambia in 2004 which issued CLs for a number of ARVs). However, to stay closer to our model assumptions, we focus on the specific example of Thailand which issued in November 2006 a CL for Merck's ARV (Efavirenz). At that time, the firm considered the country as Weak.

Early 21st century, the needs of people living with HIV/AIDS were critical in Thailand and the price of medicines jeopardized the sustainability of its Universal Access to Antiretroviral Treatment Programme implemented in 2003. Besides, CL was not considered as an efficient solution by the government. Indeed, in 1999, a first application for a CL for an ARV was quickly rejected due to immediate and strong US pressure as well as the lack of governmental support. Moreover, in the mid-2000s, negotiations with patentees to obtain lower prices for ARVs were timid and vain. Timid since the threat of CL was hardly mentioned during negotiations. Vain as they lasted several years, from 2004 to 2006, and gave no result (MOPH/NHSO; 2007; Steinbrook, 2007). Subsequently, Thailand seemed unlikely to use a CL from the point of view of patentees.

Likewise, other reasons contributed to support the idea of an apparent weak government. First, Thailand was stuck in a rather unfavourable institutional environment. Threatened with "Special 301" and withdrawal from "Generalized System of Preferences", in 1992 and two years before the ratification of the TRIPS agreement, patent on medicine was introduced in the country. The safeguard provisions allowing so far parallel imports and CL were limited or repealed under the new Thai Patent Act. And the price control mechanism implemented for patented medicines was quickly dismantled. Under international pressure, Thailand made thus many concessions in the fields of IPRs and public health protection. Second, the country had a weak industrial base. A few local firms, dependent on imports of raw materials, were operating in a drug market dominated by foreign exporting multinationals. For ARVs, where the issue of patents was lively, the Government Pharmaceutical Organization (GPO) was the only (public) lab to locally formulate some drugs. But their quality was questioned after GPO failed to obtain WHO prequalification, a guarantee of quality. Multinationals were then convinced that the Thai government would not take the risk of entrusting the production of ARVs to GPO under CL and lose the support of international funders[11].

For all these reasons, during negotiations with multinationals, Thailand was unable to gain substantial price reduction for ARVs. From an international point of view, the country was not perceived as a major risk. In 2006, the country

[11] International donors, such as the World Bank, agree to fund the supply of ARVs prequalified by the WHO, considered to be safe, effective and of high quality.

was no longer on the US Special 301 "Priority Watch List". The probability of a CL was clearly underestimated by multinationals considering that it would induce an adjustment cost unaffordable for the Thai government.

Nevertheless, the universal access program was a growing financial burden for Thailand, with the increasing number of patients covered and the use of patented drugs, more effective and more expensive for those developing resistant to unpatented and less expensive first-line treatments. From 2001 to 2006, the ARV budget increased from 10 to 100 million dollars. Compared to the several costs induced by the issue of a CL, this increasing financial burden was a major determinant of the governmental final decision ; in addition to the growing pressure from civil society (Rosenberg, 2014, Guennif, 2017). In the line of our model, the cost of a CL issue was low for the Thai government and the multinationals under-estimated the CL risk. The issue of a CL without any preliminary warning is consistent with the strong governement's behavior described in Hybrid equilibrium 4.

## 4.3 Medium q, CL threat and price reductions: the Taiwan case (2005)

In 2005, in the midst of the threat of an influenza pandemic in South-East Asia, Taiwan ordered 2.3 million treatments of Tamiflu, the antiviral patented and marketed by Roche, to be delivered by the middle of the year; with the goal of covering 10% of the population according to WHO guidelines (WHO, 2005).

Since Roche was unable to meet the order in due time, the Taiwanese government tried to negotiate a VL to produce the antiviral locally. The multinational refused, offering instead alternative ways to guarantee the availability of stocks. In response, the Ministry of health (MOH) applied in October 2005 for a CL and the credibility of this threat was demonstrated by the local manufacturing of kilogrammes of the raw material. To defend also the country's reputation for protecting IPRs, the Taiwanese Intellectual Property Office announced that, in the event of a national emergency, it would exhaust the stockpiles of Tamiflu before resorting to generic drugs. The office specified additionnally that the CL was subject to revocation if Roche met its supply commitments within schedule. The license was therefore clearly a threat to encourage Roch to increase its production capacity.

Roche was finally able to deliver the 2.3 million doses of Tamiflu by 2007 and the license was not used. Moreover, the threat led the multinational to enter into VLs with China, South-Africa and India to supply neighbouring countries and build up local stockpiles. The Lab also increased significantly the production of Tamiflu in its own facilities, initiated a Tamiflu Reserves Program, offered an important price discount of 70% on the drug to developing countries, and donated millions of doses to the WHO for distribution in poor countries unable to afford it (Cherian, 2016). Over the months, Roche tried hard so to maintain its control over the supply of Tamiflu around the world (Baker, 2005).

In the Taiwanese case, the risk of an influenza pandemic created a health emergency with a high probability of CL as Roche was not able to guarantee the availability of Tamiflu. This induced a cooperative behaviour from the Lab. Unwilling to issue a VL in Taiwan and to maintain control over the drug supply, Roche reacted both by an increase of quantity and by price reductions in Taiwan. Price reductions as an answer to a CL threat are another possible output of Hybrid equilibria 1 or 4 .

## 4.4 Low or medium q, CL threat and CL implementation: the Malaysian case (2003)

In November 2003, after the failure of negotiations initiated in 2001 with the patentee to gain substantial price reductions on various ARVs, Malaysia issued the first CL after the 2001 Doha Declaration (Ling, 2006).

At that time, nearly 75,000 people were living with HIV/AIDS and, given the high prices of ARVs, the country could not afford the implementation of a universal access programme. Late 2002, the country set up a policy of almost free access to treatment (MOH Malaysia, 2019). More precisely, monotherapies were supplied for free to all patients in public hospitals while triple therapies were free only for infected mothers after delivery, infected children, health professionals infected at work and people infected through contaminated products and blood transfusions. Otherwise, only one in three drugs was provided free of charge to the remaining patients (Ling, 2006).

However, encouraged by the Doha declaration, the MOH issued a note in November 2002 advising the importation of generic ARVs. This was soon followed by the issue of a CL, allowing so the importation of generic ARVs and their supply in hospitals and clinics. In January 2003, the MOH began price negotiations with an Indian company, Cipla, and applied for CLs from the Ministry of Domestic Trade and Consumer Affairs.

Under the threat of a CL, a new round of price negotiations began with the patentees of critical ARVs. In February, GSK offered to drop the price of Combivir by 57% and two months later conceded important price reductions on three ARVs. Still, international pressure was great on the Malaysian government and some public agencies feared the potential consequences of the CL on FDI. As a final point, the government decision was reaffirmed and authorized for two years and from 1 November 2003 the import under CL of several ARVs and their supply in public hospitals and clinics.

Malaysia provides the example of a situation where a multinational underestimated the CL risk. Early negotiations were unfruitful and only after the CL threat was raised, the firm started considering the possibility of such a risk. Even after the threat, the CL authorization was matter of question as the decision involved three successive governments and the advice of multiple public agencies. While the threat was not fully credible, the price reductions offered by GSK was insufficient to deter the government's decision. The CL was issued by a Strong government determined to use the flexibility but whose Strength was underestimated by the firm. This case is consistent with the Pooling 1 equilibrium (and to a lesser extend with one of the two Hybrid equilibria).

If the previous cases seem to match with the theoretical model, others apparently do not. For instance, the "Brazilian Model" illustrates the possibility for a government to use the CL threat in order to get significant discounts from firms. From 2001 to 2007, the Brazilian government used seven times the CL threat with, as a reward, price reductions that could exceed 70% of the initial price. At this time, Brazil had built a generic industry able to produce generic ARVs. Retaliation threats from the laboratories or foreign governments were ineffective as Brazil could answer with other retaliatory measures such as rises in tariffs (Bird and Cahoy, 2008).

In the line of our model, the reputation of the Brazilian government must have led to a high value of q and the equilibrium, in the case $q > q_2$, would imply the issue of VL without the need of the CL threat. A prediction which does not fit with stylized facts. However, note that with a high value of $P_M^H(N)$ the threshold value $q_2$ may be close to 1 and the case $q < q_2$ is feasible. Moreover, if we assume $P_M^L(N) > \alpha P_{VL}$ (by opposition with Eq. 9) when the government has to choose between the low monopoly price and the issue of a VL, it prefers the former solution. Equilibrium in this case would therefore fit with one of the two hybrid equilibria with a CL threat, high price reduction offered by the firm and the issue or not of a CL, an equilibrium that matches with facts.

## 5 Conclusion

This paper studies the threat of a CL used during price negotiations between a pharmaceutical firm offering a life-saving drug and a public agency in charge of providing drugs. The latter may be mandated by a Strong or a Weak government which, in case of a CL issuance, may have to bear low or high retaliation costs from the patentee and/or from its home country. The nature of the government is unknown to the pharmaceutical firm which only uses a probability of the government's type. During negotiations, the public body may threaten the firm with a possible issue of a CL, a costly signal that may convey information on the type of government with which the firm is negotiating. Given the information conveyed by the signal, the firm determines its optimal pricing strategy.

In this imperfect information game, no separating equilibrium may occur. For a government, it is always optimal to fool the firm about its type. This would allow a Strong type government to issue a CL if the patentee considers the government as Weak (and accordingly posts a monopoly price). On the other side, if a Weak government can persuade the firm that it is Strong, the risk of CL would lead the firm to offer a low price and the Weak government would thus benefit from the drug at attractive conditions. In both cases, firms' errors in the assessment of the government's type is beneficial for the latter.

The equilibria of the game allow for three types of market structure. When the probability of a Strong government is high, the laboratory finds optimal to issue a VL and the threat is useless for the government. For intermediate or low probability, the pharmaceutical firm will post a monopoly price, a price that a Weak government may accept, but that will be refused by a Strong one which will issue a CL. In these cases, governments may always threaten the firm or randomize between the use or not of the threat.

Such a model is an oversimplified representation of the real game played by firms and governments. Among others, one limiting aspect of the paper is the mono-periodic dimension of the game. A more realistic approach should take into account the possibility of successive or multiples negotiations. For instance, in our model, a government which decides to issue a CL reveals that it is Strong. In a dynamic perspective, granting a CL may therefore be used by a Weak government in order to reinforce its bargaining power in future negotiations with pharmaceutical firms. The example provided by the Brazilian government which used the CL threat at many time before the effective issue of a CL cannot be properly considered under our assumptions. A same argument may be used for India and Thailand which issued CL in the past and are generally considered as potential future issuers.

The model also ignores the multiple political objectives that may enter into the decision process leading to the issuance of a CL. Noteworthy point, CL has mostly been invoked in upper-middle income countries holding technological and industrial capabilities in pharmaceuticals. These countries resorted offensively to CL with a first health objective, however, waving CL the countries also tried to gain VL for the benefit of national public and private laboratories. This strategy was also driven by the aim of supporting the development of technological and industrial capabilities in a sector marked by a strong dependence vis-à-vis foreigner firms (for imports of both active principle ingredients and medicines) and a huge trade deficit. This was the case for Malaysia, Taiwan, Thailand or Brazil.

Despite these limitations, this paper allows interesting conclusions in a political economy perspective. First, note that it is difficult for a government to signal its type through a basic signal such as a CL threat. In the Hybrid 1 equilibria, a Strong government may refuse to use the threat and conversely, except in the pooling 2, Weak governments may use the threat to manipulate firms' expectations and increase their bargaining power during negotiations.

One important parameter of the model is the value of the implementation costs $C$ paid by a Strong government which decides to grant a CL. For a given gap between the monopoly price and the price set in the case of a CL, this implementation costs will determine public policy by defining the less-expensive mode of supply. Any policy reducing these implementation costs thus increases the feasibility of a CL issue. For instance, a CL is more likely in countries where a developed pharmaceutical industry allows considering the production of generic drugs at low costs. India, Brazil and South-Africa are the best examples of countries where the implementation costs are lower (and pressures for CL by the industry on the Government are higher; see Shankar et al. 2013). In the same vein, a CL is more likely in countries where public health programs are implemented (Son and Lee, 2018). Particularly, HIV/AIDS health programs place additional burdens on health system and create a need to cut costs. As the implementation costs induced by a CL are fixed, an increase in the size of the public health program reduces the cost $C$ paid for each person included in the program. It therefore increases the strength of the government and raises the risk for firms to see this government issuing a CL. However, if such policies affect the costs of a CL and the propensity for a given government to grant CLs, from the firm's point of view, it may barely affect the subjective probability of the type of government. As signalling is impossible in this kind of negotiation, any political decision which could reveal a government's type may be used as a manipulation tool in order to mislead the Laboratories. It will therefore have the same effect as CL threat on the Laboratories expectations.

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# 7 Appendix: Hybrid equilibria (not to be published)

This appendix gives a formal proof of the existence of only one alternative hybrid equilibriun in this model.

In a general form, we will denote by $s(\tau) = \{\alpha T + (1-\alpha)N | \alpha \in [0,1]\}$ a mixed strategy of a $\tau-$type government where the threat (Action $T$) is played with probability $\alpha$ and is not played (Action $N$) with probability $(1-\alpha)$. If we exclude the pure strategies and the generalized mix strategies considered in section 3.3, the government may use one of the four following strategies:

$$s_1(\tau) = \begin{cases} s(S) = \{\mu T + (1-\mu)N | \mu \in [0,1]\} \\ s(W) = T \end{cases} \quad s_2(\tau) = \begin{cases} s(S) = \{\mu T + (1-\mu)N | \mu \in [0,1]\} \\ s(W) = N \end{cases}$$
$$s_3(\tau) = \begin{cases} s(S) = T \\ s(W) = \{\nu T + (1-\nu)N | \nu \in [0,1]\} \end{cases} \quad s_4(\tau) = \begin{cases} s(S) = N \\ s(W) = \{\nu T + (1-\nu)N | \nu \in [0,1]\} \end{cases} \tag{26}$$

In answer, the lab may choose one of the four following strategies $L(s)$ as a reaction to threat decision $s$ of the government (notation rules remaining the same):

$$L_1(s) = \begin{cases} L(T) = \{\lambda VL + (1-\lambda)P_M^H(T) | \lambda \in [0,1]\} \\ L(N) = VL \end{cases} \quad L_2(s) = \begin{cases} L(T) = \{\lambda VL + (1-\lambda)P_M^H(T) | \lambda \in [0,1]\} \\ L(N) = P_M^H(N) \end{cases}$$
$$L_3(s) = \begin{cases} L(T) = P_M^H(T) \\ L(N) = \{lVL + (1-l)P_M^H(N) | l \in [0,1]\} \end{cases} \quad L_4(s) = \begin{cases} L(T) = VL \\ L(N) = \{lVL + (1-l)P_M^H(N) | l \in [0,1]\} \end{cases} \tag{27}$$

## 7.1 Hybrid 1bis. Government plays strategy $s_1$

In this equilibrium, Strong governments are indifferent between the two threat possibilities while Weak always threaten the Lab. We have:

$$s_1(\tau) = \begin{cases} s(S) = \{\mu T + (1-\mu)N | \mu \in [0,1]\} \\ s(W) = T \end{cases} \tag{28}$$

With strategy $s_1(\tau)$, the N-strategy may only be played by Strong governments, the optimal Lab's answer in the no threat case is thus to grant a VL. This excludes strategies $L_2, L_3$ and $L_4$ and leaves only strategy $L_1$ in the set of the Lab's feasible strategies.

$$L_1 = \begin{cases} L(T) = \{\lambda VL + (1-\lambda)P_M^H(T) | \lambda \in [0,1]\} \\ L(N) = VL \end{cases} \tag{29}$$

According to strategy $L_1$, if, according to the equilibrium strategy, the Weak government uses the CL threat, the Lab will answer by choosing randomly between its two options and the government expected utility is:

$$U_G^W(T) = P_{int} - \lambda(P_{VL} + c) - (1-\lambda)(P_M^H(T) + c) \tag{30}$$

If the government doesn't threaten the Lab, the firm identifies the government as Strong and issues a VL. The government surplus will be: $U_G^W(N) = P_{int} - P_{VL}$. For a Weak government the threat is optimal if:

$$\begin{aligned} U_G^W(T) &\geq U_G^W(N) && (31)\\ &\Leftrightarrow P_{int} - \lambda(P_{VL} + c) - (1-\lambda)(P_M^H(T) + c) \geq P_{int} - P_{VL} && (32)\\ &\Leftrightarrow (1-\lambda)\left(P_M^H(T) - P_{VL}\right) \leq -c && (33) \end{aligned}$$

which is impossible as $P_M^H(T) > P_{VL}$.

## 7.2 Hybrid 2: Government plays strategy $s_2$

$$s_2(\tau) = \begin{cases} s(S) = \{\mu T + (1-\mu)N | \mu \in [0,1]\} \\ s(W) = N \end{cases} \tag{34}$$

In this equilibrium, Strong governments are indifferent between the two threat options while Weak ignore the threat possibility. In this equilibrium, the T-strategy may only be played by Strong governments, the optimal lab's answer in the threat case is thus to issue a VL. The set of the lab's strategies restricts to $L_4$.

$$L_4() = \begin{cases} L(T) = VL \\ L(N) = \{lVL + (1-l)P_M^H(N) | l \in [0,1]\} \end{cases} \tag{35}$$

In this equilibrium, a Strong government which threatens the Lab signals its type and forces the firm to issue a VL. Its utility is $U_G^S(T) = P_{int} - P_{VL} - c$. If doesn't use the Threat, the lab will issue a VL with probability $l$ and will post the high price with probability $(1-l)$. In the latter case, the Strong government will grant a CL. Its expected utility is thus:

$$U_G^S(N) = l(P_{int} - P_{VL}) + (1-l)(P_{int} - P_{CL} - C^S) \tag{36}$$

In equilibrium, the Strong government must be indifferent between the two threat policies, this give the equilibrium value of the probability $l$:

$$\begin{aligned} U_G^S(N) &= U_G^S(T) && (37)\\ &\Leftrightarrow l(P_{int} - P_{VL}) + (1-l)(P_{int} - P_{CL} - C^S) = P_{int} - P_{VL} - c && (38)\\ &\Leftrightarrow lP_{VL} + (1-l)(P_{CL} + C^S) = P_{VL} + c && (39)\\ &\Leftrightarrow -(1-l)(P_{VL} - \left(P_{CL} + C^S\right)) = c && (40) \end{aligned}$$

As $P_{VL} > (P_{CL} + C^S)$, the last equation implies $l > 1$ which precludes the equilibrium.

### 7.3 Hybrid 3: Government plays strategy $s_3$

$$s_3(\tau) = \begin{cases} s(S) = T \\ s(W) = \{\nu T + (1-\nu)N | \nu \in [0,1]\} \end{cases} \tag{41}$$

In this equilibrium, Strong governments always use the CL threat, Weak governments are indifferent between the two threat options. As Weak governments only may refuse to threaten the Lab, the optimal lab's answer in the no threat case is thus to post the monopoly price $P_M^H(N)$. Therefore, the laboratory's set of feasible strategies is restricted to $L_2()$.

$$L_2() = \begin{cases} L(T) = \{\lambda VL + (1-\lambda)P_M^H(T) | \lambda \in [0,1]\} \\ L(N) = P_M^H(N) \end{cases} \tag{42}$$

In equilibrium, strategy $s_3$ describes a Strong government which systematically threatens the Lab with a CL issue. In answer, according to strategy $L_2()$ the lab grants a VL with probability $\lambda$ and posts the price $P_M^H(T)$ with probability $(1-\lambda)$. In the last case, the government will grant a Compulsory license and its expected utility is:

$$U_G^S(T) = \lambda\left(P_{int} - P_{VL}\right) + (1-\lambda)\left[P_{int} - (P_{CL} + C^S)\right] - c \tag{43}$$

If the government decided not to use the Threat, it would be considered as Weak and the lab would post the high monopoly price. As the Strong government would thus issue a Compulsory license, its surplus would therefore be: $U_G^S(N) = P_{int} - (P_{CL} + C^S)$.

A Strong government find optimal to Threaten the Lab if:

$$\begin{aligned} U_G^S(T) &\geq U_G^S(N) && (44) \\ &\Leftrightarrow \lambda\left(P_{int} - P_{VL}\right) + (1-\lambda)\left[P_{int} - (P_{CL} + C^S)\right] - c \geq P_{int} - (P_{CL} + C^S) && (45) \\ &\Leftrightarrow \lambda P_{VL} + (1-\lambda)(P_{CL} + C^S) + c \leq (P_{CL} + C^S) && (46) \\ &\Leftrightarrow \lambda(P_{VL} - \left(P_{CL} + C^S\right)) \leq -c && (47) \end{aligned}$$

Which is impossible as $P_{VL} > (P_{CL} + C^S)$.

### 7.4 Hybrid 4: Government plays strategy $s_4$

$$s_4(\tau) = \begin{cases} s(S) = N \\ s(W) = \{\nu T + (1-\nu)N | \nu \in [0,1]\} \end{cases} \tag{48}$$

According to this strategy, only Weak governments use the CL Threat. In case of Threat, the optimal Lab policy is thus to post the monopoly price. The lab strategy is therefore given by strategy $L_3$:

$$L_3() = \begin{cases} L(T) = P_M^H(T) \\ L(N) = \{lVL + (1-l)P_M^H(N) | l \in [0,1]\} \end{cases} \tag{49}$$

- Lab strategy:

Given the threat policy played by the government, the Lab updates its beliefs according to a Bayesian procédure:

$$\begin{cases} P[\tau = W|T] = 1 \\ P[\tau = W|N] = \frac{P[N|\tau=W]P[\tau=W]}{P[N|\tau=W]P[\tau=W]+P[N|\tau=S]P[\tau=S]} = \frac{(1-\nu)(1-q)}{(1-\nu)(1-q)+q} \end{cases} \quad (50)$$

If the government uses the threat, the lab considers that it is weak and posts the monopoly price which leads to a higher profit than the issue of a VL.

In the no Threat case, the Lab must be indifferent between the issuance of a VL and the post of a monopoly price. In the first case, its profit will be $\pi_L(VL) = \alpha P_{VL}$. In the second case, its profit relies on the actual type of the government. If the governement is Weak, the labs profit will be $\pi_L(P_M^H(N)) = P_M^H(N)$; if it is Strong the Government will issue a CL and the lab's profit will be : $\pi_L(P_{CL}) = \beta P_{CL}$.The expected profit of the lab which posts a monopoly price in the no threat case is:

$$E[\pi_L(P_M^H(N))|N] = \frac{(1-\nu)(1-q)}{(1-\nu)(1-q)+q} P_M^H(N) + \frac{q}{(1-\nu)\nu(1-q)+q} \beta P_{CL} \quad (51)$$

This leads to the indifference condition:

$$E[\pi_L(P_M^H(N))|N] = \pi_L(VL) \quad (52)$$

$$\Leftrightarrow \frac{(1-\nu)(1-q)}{(1-\nu)(1-q)+q} P_M^H(N) + \frac{q}{(1-\nu)(1-q)+q} \beta P_{CL} = \alpha P_{VL} \quad (53)$$

$$\Leftrightarrow (1-\nu) = \frac{q\left[\alpha P_{VL} - \beta P_{CL}\right]}{(1-q)\left(P_M^H(N) - \alpha P_{VL}\right)} > 0 \quad (54)$$

It is easy to check that $\nu \in [0,1]$ under the necessary condition:

$$q < q_2 = \frac{P_M^H(N) - \alpha P_{VL}}{P_M^H(N) - \beta P_{CL}}$$

- Government strategy:

Consider first a Strong government. If following the equilibrium strategy this government does not threaten the Lab, the firm will answer by issuing the VL with probability $l$ and by posting the monopoly price with probability $(1-l)$. In the later case, the government will grant a CL. The Strong government expected utility is: $U_G^S(N) = l\left(P_{int} - P_{VL}\right) + (1-l)\left[P_{int} - (P_{CL} + C^S)\right]$

On the contrary, if the government threatens the firm, the lab will consider that it is Weak and will post the monopoly price. Thus the Stong government will have the opportunity to grant a Compulsory license and will reach the surplus: $U_G^S(T) = P_{int} - (P_{CL} + C^S)$. Strategy $s_4$ may be optimal if $U_G^S(N) \geq U_G^S(T)$, i.e. if:

$$
\begin{aligned}
U_G^S(N) &\geq U_G^S(T) && (55)\\
\Leftrightarrow & \quad l\left(P_{int}-P_{VL}\right)+(1-l)\left[P_{int}-\left(P_{CL}+C^S\right)\right] \geq P_{int}-\left(P_{CL}+C^S\right) && (56)\\
\Leftrightarrow & \quad l\left[P_{VL}-\left(P_{CL}+C^S\right)\right] \leq 0 && (57)
\end{aligned}
$$

This equation implies $l = 0$ and in equilibrium the Lab must play the degenerated Lab strategy:

$$
L_3'() = \begin{cases} L(T) = P_M^H(T) \\ L(N) = P_M^H(N) \end{cases} \tag{58}
$$

Consider now the Weak government, if this government does not threaten the Lab, the firm will answer by posting the monopoly price $P_M^H(N) = P_{CL} + C^W$ and the government will accept it. The government expected utility is: $U_G^W(N) = \left[P_{int} - \left(P_{CL} + C^W\right)\right]$. If the government uses the threat, the lab will post the price $P_M^H(T) = P_{CL} + C^W - c$. Thus the government reaches the surplus: $U_G^W(T) = P_{int} - (P_{CL} + C^W - c) - c$, and the government is indifferent between the two options, i.e. $U_G^W(N) = U_G^W(T)$.

For both type of governments there is no strict preference between the two Threats options, no government finds optimal to deviate from the equilibrium strategy. This hybrid equilibria is therefors feasible under condition $q < q_2$ and with the degenerated Lab's strategy $L_3'()$.

In this equilibrium, the CL Threat is only used by Weak governement but the signal is not credible. The Lab therefore answers by posting the monopoly price.