College of Management of Technology

ÉCOLE POLYTECHNIQUE
FÉDÉRALE DE LAUSANNE

GAULE, Patrick; CONTI, Annamaria

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Patrick Gaulé & Annamaria Conti

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This paper seeks to add an economic contribution to the current debate on using university licensing contracts to improve access to medicines in developing countries. We build a simple model in which we have a university licensing out an academic invention to a profit-maximizing pharmaceutical company. We compare three different types of licensing contracts that the university might use to enhance access to pharmaceuticals in the South: (1) an exclusive license limited to the North; (2) an exclusive license worldwide with a price cap in the South; and (3) an exclusive license worldwide with a price cap in the South and a clause specifying that the licensee would lose its exclusivity in the South if it does not supply the Southern market. We show that in a simple model with asymmetric information on production costs the latter type of contract dominates the two others.

1   Introduction[1]

Many pharmaceutical products have their origins in research undertaken in Northern universities. According to Cockburn & Henderson (1999), 15 of the 21 of the most important drugs introduced between 1965 and 1992 were developed using knowledge and techniques from research financed by US public funding. The degree of public involvement may vary considerably but Kneller (2005) finds that of the 173 new chemical and biological entities approved by the US Food and Drug Administration (FDA) between 1998 and 2003, 26 had been described in patents applied for by universities. Thus, it is common for a pharmaceutical product to be discovered by academic researchers, patented by the university and transferred to a pharmaceutical company for further development and clinical trials. Several drugs of prime importance for the developing world have followed this model of pharmaceutical development. Famous examples include Stavudine (d4T), Abacavir and Lamivudine. These three antiretrovirals are listed in the World Health Organization (WHO) essential medicines list and were discovered at Yale, Minnesota University and Emory University respectively. In 2001, Stavudine received widespread publicity after pressure from students groups led Yale University to renegotiate with its licensee, Bristol-Myers Squibb, and to obtain a 30-fold price reduction for the drug in South Africa.

Our research question is the following: assuming that the university cares about access to its invention in developing countries (along with licensing revenues), what clauses should the university include in the licensing contract to reach its objective? We compare three different types of licensing contracts that the university might use to enhance access to pharmaceuticals in the South: (1) an exclusive license limited to the North so that in the South the licensee is subject to competition from generic producers ('equitable access license') ; (2) an exclusive license worldwide specifying a maximum price that the producer may charge in the South ('target'); and (3) a variant of the last contract where the licensee loses its exclusivity in the South if it does not supply the Southern market ('target with punishment'). We show that in a simple model with asymmetric information on production costs, the target with punishment dominates the two others.

Multiple scholars and groups have suggested that universities could and should play a role in access to pharmaceutical through their licensing contracts. In a *Science* editorial, Kapczynski, Crone & Merson (2003) argue that university research should consistently be used to advance the global public good through appropriate licensing policies. A special interest group, Technology Managers

for Global Health, has been formed within the Association of University Technology Managers to "enhance academic research translation (...) in a way that advances global health causes". Universities Allied for Essential Medicines, a group of students and faculty from US universities, advocates that universities make changes in both their principles and policies in order to improve access to medicines in poor countries (Chokshi 2006; Chokshi & Rajkumar 2007). Brewster, Chapman & Hansen (2005), from the American Association for the Advancement of Science, seek to raise awareness among public sector managers of the importance of managing intellectual property to facilitate humanitarian access to pharmaceutical innovation.

One of the recommendations of the WHO commission on Intellectual Property Rights, Innovation and Public Health is that "Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to R&D outputs relevant to the health concerns of developing countries and to products derived therefrom, are facilitated through appropriate licensing policies and practices." (WHO 2006a). The Strategic Advisory Group of Experts, WHO's advisory group for vaccine policy similarly recommended that "[t]o facilitate developing countries' access to new inventions, WHO should clearly articulate the responsibilities of both private and public-sector intellectual property owners to consider developing-country needs in the management of their intellectual property." (WHO 2006b)

The inclusion of clauses aiming at facilitating access is still very uncommon in academic licensing contracts. The Socially Responsible Program Licensing Program at the University of California, Berkeley, which aims at "widespread availability of technology and healthcare, including in the developing world" (Mimura, 2006) is a notable exception. However, many universities and academic institutions might be convinced to adopt humanitarian licensing policies for their health-related inventions. Universities technology transfer offices understand their mission as serving the public interest. For instance, MIT "supports efforts directed toward bringing the fruits of MIT research to public use and benefit". Similar language is used by the TTOs of Caltech and of the University of California which with MIT hold the three largest academic patent portfolios. Of great practical importance are the licensing policies of the National Institutes of Health (NIH) with its annual budget close to USD 30 billion. Given that the mission of the NIH is "support biomedical research to extend healthy life by reducing illness *worldwide*" (Salicrup et al.,2005, italics added) it is conceivable that the NIH might adopt licensing policies aimed at facilitate access to the results NIH-funded research in the developing world[2].

The paper is organized as follows. In section 2 we review the literature. In section 3, we present our basic model. In section 4, we explain the intuition

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[2] The office of technology transfer from the NIH has already made a number of non-exclusive technology transfer agreements in the field of vaccines (Salicrup et al., 2005). However, NIH's office of technology transfer only licenses inventions from NIH intramural research which is a small fraction of total NIH funding.

for two extensions of the basic model: asymmetric information about demand and uncorrelated draws between the production costs of the licensees and the production costs of generic producers. Section 5 concludes.

2 Literature review

2.1 Economic Literature

Our economic contribution draws mainly from the literature on the role of TTOs in the process of technology transfer. Siegel et al. (1999) underline the role of TTOs as bridge institutions between entrepreneurs and scientists, the two parties being animated by different interests and goals. Jensen et al. (2003) develop a theoretical model in which a TTO is both an agent for the university central administration and for the faculty. In this model the TTO plays a role of mediator between the interests of the central administration and that of the faculty.

Thursby et al. (2004) and Macho-Stadler et al. (2005) analyze the role of TTOs in resolving the problems of asymmetric information arising when scientists and firms are not equally informed on the quality of the inventions that are being commercialized and on the costs of commercializing these inventions. Thursby et al. (2004) find that milestone payments, annual payments and consulting "are common because moral hazard, risk sharing and adverse selection all play a role when embryonic inventions are licensed". Macho-Stadler et al. (2005) model the TTO as a technology seller who has an incentive to shelve some of the less-successful university inventions in order to induce the buyers to believe that university inventions are of high quality.

Thursby et al. (2004) and Macho-Stadler et al. (2005) assume that the TTO is a revenue-maximiser whose utility increases with the revenue generated by licensing contracts. Jensen et al. (2003) include in the objective function of the TTO an indicator variable that takes the value of one if a license is executed. In their model the TTO not only cares of licensing revenue but also of the number of licenses executed. Belenzon and Schankerman (2007) assume that the TTO has a dual objective of maximizing licensing revenue and local economic development.

2.2 Legal and medical literature

A growing number of papers are being written in the legal and medical literature on the role universities could play in access to medicines. These papers contain either advocacy only or combine advocacy for humanitarian licensing

4

with discussions of the appropriate type of contracts that universities should actually use. We focus on the discussions of the appropriate type of contracts.

One branch of the literature (Kapczynski et al. 2005, Chokshi.2006, Chokshi & Rajkumar 2007; Chaifetz et al., 2007) outlines 'the equitable access license' and advocates its use. The equitable access license aims to facilitate unfettered generic competition in poor countries (Kapczynski et al. 2005). Under the equitable access license, the contract offered by the university does not include exclusive rights for sales in the South (exclusivity is limited to high-income countries). The licensee is also required to grant back to the university associated rights, i.e. 'all potentially exclusive rights the company holds or acquires that could prevent a third party from producing or delivering an end product' (Chaifetz et al., 2007). The grant back is necessary because otherwise the university licensees might patent improvements that may effectively foreclose generic competition even though the licensee does not have exclusivity in the South on the initial university patent. Non-exclusive licenses for sales in the South to both the original university invention and the associated rights are automatically granted to generic producers upon notification. The equitable access license notifiers would be required to pay royalties in the range of 0 to 6%. This branch of the literature suggests that low monitoring and enforcement cost as well as greater clarity are the main advantages of the equitable access license.

The alternative which Brewster, Chapman & Hansen (2005) refer to as 'positive humanitarian conditionality' consists of including clauses in the licensing contract requiring the licensee to undertake certain steps to facilitate access to the final product in developing countries. Humanitarian clauses mentioned in the legal and medical literature include the following: (a) selling at a 'reasonable' price in developing countries where 'reasonable' is loosely defined or not all (b) selling at a reasonable price where price is defined as cost of production plus a small profit as percentage over cost (cost-plus pricing) (c) define a price ceiling (Eiss, Hanna & Mahoney 2007) d) selling a predefined volume (Oehler 2007) (e) request the licensee to undertake clinical trials in developing countries (Nelsen & Krattiger, 2007) (f) "create a worldwide marketing plan to licensed products, the implementation of which it monitors through agreed upon benchmarks" (Brewster, Chapman & Hansen 2005). The licensing contract could set various types of penalties if the licensee does not fulfill its obligation: temporary increases in royalties, loss of exlusivity in general or for a specific region or the payment of a fine (Oehler 2007).

3   Basic model

3.1   Setup of the model

Our model is a game-theoretic model of technology licensing with two active players: a licensor and a pharmaceutical company (consumers). The pharmaceutical company further develops and commercializes the invention made by the licensor. We proceed to describe the players and how they interact.

Consumers. Demand for the pharmaceutical product is given by a linear inverse demand schedule in both markets:

$$
\begin{aligned}
p_N &= a_N - q_N^C \\
p_S &= a_S - q_S^C
\end{aligned}
$$

where q_N^C and q_S^C are the quantities consumed in the North and the South and p_N, p_S are the prices prevailing in the North and in the South respectively. The choice of a specific functional form and specifically of linear demand is made for simplicity. The possibility of arbitrage between the two markets through parallel imports or other means is excluded. While parallel imports are an interesting issue in themselves, very substantial price differences are observed across pharmaceutical markets in the world and in particular between developed and developing countries[3]. The existence of these differences is certainly not consistent with widespread price arbitrage across markets. For the purpose of this paper the assumption of separate markets appears to be satisfactory.

Licensor. The licensor is a university technology transfer office whose task consists in commercializing a patented technology issued from its university. We define the objective function of the risk-neutral licensor as a weighted average of total licensing income and of the volume of sales.

$$
V(M, q_S; \theta) = M + \theta * q_S^C
$$

Where M is licensing revenues in the form of a fixed fee paid to the licensor, q_S^C is the quantity of output consumed in the South, and θ (≥ 0) is a parameter that reflects the intensity of the humanitarian component in the licensor objective function.

We think of the licensor as being interested in technology diffusion and in the number of consumers who have access to the final good. Therefore, we include output consumed in the South in the objective function of the licensor, along with licensing revenues. For simplicity, output in the South enters linearly in the utility function of the licensor. We do not include output consumed in the North in the utility function of the licensor because thanks to higher standards

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[3] For instance, hepatitis B vaccine is one hundred times more expensive in the United States in the private sector compared to prices obtained by UNICEF for low-income countries.

of living as well as health insurance and social security systems, few Northern consumers lack access to medicines.

Our model features fixed fees as the form of payment. In actual licensing contracts, *ad-valorem* royalties are the most commonly used form payments. In our model, the main difference between *ad-valorem* royalties and fixed fees is that *ad-valorem* royalties introduce a distorsion by creating a wedge between the producer real and perceived marginal cost (this distorsion is usually referred to as the double marginalisation problem). In this context, humanitarian policies such as limiting the exclusivity to the North or setting a lower price tends to have the beneficial effect of reducing double marginalisation. We use fixed fees rather than ad valorem royalties because this allows considerable gains in simplicity without altering the ranking between different types of contracts[4]. Moreover the distorsion introduced double marginalisation is probably quantitatively small in practice[5].

Producer. We will occasionally refer to the producer as the licensee. The risk-neutral producer, a pharmaceutical company, seeks to maximize its total profits (which are its sales revenues minus its costs and the fixed fee to be paid to the licensor):

$$\Pi = p_N(q_N) * q_N + p_S(q_S) * q_S - C(q_N, q_S) - M$$

Producer costs are partly fixed (F) and partly variable with a constant marginal cost $C(q_N, q_S) = c * (q_N + q_S) + F$. The fixed cost F includes the cost of R&D needed to bring the product to the market (in particular the clinical trials, product registration, marketing) as well as all the non-variable costs of production (e.g. setting up the plant and quality assurance system). The marginal cost of production c includes the variable costs of production which we assume to be directly proportional to the number of units produced. Marginal cost can be either high c_H or low c_L $(c_H > c_L)$[6]. Whether the marginal cost is high or low is determined by Nature with the two states of the world $(s = H, L)$ occuring with equal probability.

Structure of the game. The *ex ante* distribution of costs is common knowledge; i.e. at the beginning of the game both parties know that the marginal cost of production may be either c_H or c_L with equal probability. The players of the game interact in the following way:

1. The licensor offers a contract to the producer.

---

[4] An earlier version of this paper was based on ad-valorem royalties but the use of fixed fees allows us to derive results analytically rather than numerically.

[5] For instance, examples of licensing contract renegotiation (such as a one time payment in exchange for the remaining royalty obligation dues) once the product of the market are on the market are rare . One would expect renegotiations to be frequent if double marginalisation was quantitatively important.

[6] We assume that c_H is not too large; specifically $c_H < a_S$ and $c_H < a_N$.

2. The producer may accept or decline the offer. If it refuses, the game ends; the producer receives an exogeneous reservation payoff of ν while the licensor receives 0. If it accepts it pays the fixed fee M to the TTO and the game proceeds.

3. Nature chooses the type of marginal cost. The producer privately learns whether its cost is c_H or c_L.

4. The producer chooses his level of output in the North and in the South, profits are realized.

| Licensor offers a contract to the producer | Producer accepts or rejects the contract | Nature chooses the type of marginal cost. Producer privately learns its type | Producer chooses his level of output in the North and in the South |
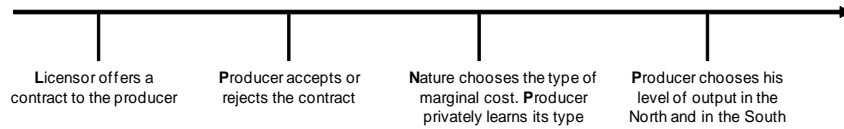
The key element of the basic model is asymmetric information on marginal cost. At the beginning of the game, the assumption is that neither party is informed about the type of marginal cost. This reflects the fact that the technology is embryonic as most university inventions are (Thursby, Jensen & Thursby, 2001). In the life science field, a typical university invention would be the knowledge that a certain substance has a certain therapeutic effect *in vitro* or in animals. By the time the product is brought to the market, the producer, but not the licensee, will have learned the marginal cost production. The type of marginal cost can neither be deduced by the licensor or be verified *ex post* so that it is not possible to write contracts contingent on the type of marginal cost.

Our model also features a take-it or leave-it offer by the licensor which is typical in the literature on university-industry patent licensing or on patent licensing more generally. The reservation payoff of the producer ν can be interpreted as the bargaining power of the producer.

3.2   The first-best

In this sub-section, we merge the two entities (licensor and producer) and find the quantities that maximises the sum their payoffs. We do not entertain such a merger as a realistic possibility but it allows us to abstract from the difficulties associated with contracting and to define a benchmark against which realistic contracts can be assessed. In line with the standard approach in contract theory, we will refer to the the quantities chosen by the merged entity and the associated utility levels as the first-best.

The merged entity maximises with respect to q_N and q_S the sum of the payoffs of both actors ($V = (a_N - q_N) * q_N + (a_S - q_S) * q_S - c_i * (q_N + q_S) - F -$

$\nu + \theta q_S^C$). The quantity consumed will be the same as the quantity produced by the merged entity so $q_S = q_S^C$. In its decision, the merged entity knows the type of marginal cost. The first-best level of output[7] are $q_{N(FB)} = \frac{a_N - c_H}{2}$ and $q_{S(FB)} = \frac{a_S - c_H + \theta}{2}$ in state H and $q_{N(FB)} = \frac{a_N - c_L}{2}$ and $q_{S(FB)} = \frac{a_S - c_H + \theta}{2}$ in state L. Plugging these quantities into the objective function of the merged entity yields the level of utility attained at the first best (see appendix).

3.3   The equitable access license

Under the "equitable access license", the university essentially limits the exclusivity of the license to the Northern market and will grant an unlimited number of licenses for sales in the South only (cf literature review for details). Since under this contract there is free entry in the South, we will assume that the price in the South, p_S, will drop to the marginal cost. The cost of generic production is perfectly correlated with the cost of production[8]. Thus under the equitable access license, the price in the South will drop to c_L in state of the world L and to c_H in state of the world H. The quantities consumed in the South increase to $q_S^C = a_S - c_L$ and $q_S^C = a_S - c_H$ respectively and the producer will not make any profit in the Southern market. Effectively, the contract offered to the firm is an exclusive license limited to the North.

Problem of the producer. To find the equilibrium of the game under this contract, we first consider the problem of the producer and solve the game backwards. In the North, the producer behaves as monopoly and puts the profit-maximising quantity $q_N = \frac{a_N - c_i}{2}$ on the market. The producer will be willing to accept the contract only if its expected profits is at least as high as its outside option ν: $\frac{(a_N - E(c))^2}{4} - F - M \geq \nu$

Problem of the licensor. The licensor can extract the rent of the producer by setting the fixed fee as $M_{EAL}^* = \frac{(a_N - E(c))^2}{4} - F - \nu$ and the expected utility of the licensor is $V_{EAL} = \frac{(a_N - E(c))^2}{4} - F - \nu + \theta * (a_S - E(c))$.

Proposition 1 *The Equitable Access License leads to a payoff lower than the level of utility attained at the first-best level except for one particular value of θ ($\theta = a_S - \frac{c_H + c_L}{2}$).*

Proof. See appendix ■

---

[7] To be complete, when θ is extremely high ($\theta \geq a_S + c_i$), the merged entity would like to set a price below which is not possible. In that case, the first best is to set a price equal to 0 so that the quantity is a_S.

[8] This assumption is relaxed in section 4.2 where we consider uncorrelated costs.

3.4 A price target in the South

In this sub-section, we consider the following contract to be offered by the licensor: a fixed fee and a maximum price t that can be charged in the South. While we are not aware of universities using such contracts, price targets are used in the field of neglected diseases. For instance, the Meningitis Vaccine Project has given funding, expertise and technology to Serum Institute of India, a vaccine producer based in India, for the development of a meningococcal A conjugate vaccine for use in African countries. In exchange, Serum Institute of India has committed itself to charge a maximum price of half a US dollar on the final product. The Medicines for Malaria Ventures, a not for profit group that support R&D for malaria drugs, typically requires its fundees to charge no more than one US dollar per tablet.

Problem of the producer. In the North, the producer profit maximising quantity is $q_N = \frac{a_N - c_i}{2}$ as in the equitable access license. In the South, two cases may happen. First, the target may be above the marginal cost ($t \geq c_i$, i=H,L), in that case the producer sells the quantity $a_S - t$ at price t. On the other hand, if the price is below the marginal cost ($t < c_i$, i=H,L), the producer will not want to sell anything in the Southern market. Thus, the reaction function of the producer in state of the world i is:

$$
\begin{aligned}
q_S^i(t) &= a_S - t &&\text{if } t \geq c_i \\
&= 0 &&\text{if } t < c_i
\end{aligned}
\tag{1}
$$

The participation constraint is different than under the equitable access license as the producer will typically be earning some profit from sales on the Southern market:

$$
\frac{(a_N - E(c))^2}{4} + (a_s - t)(t - E(c)) - F - M \geq \nu \qquad \text{if } t \geq c_H \tag{2}
$$

$$
\frac{(a_N - E(c))^2}{4} + \frac{1}{2}(a_s - t)(t - c_L) - F - M \geq \nu \qquad \text{if } c_H > t \geq c_L
$$

$$
\frac{(a_N - E(c))^2}{4} - F - M \geq \nu \qquad \text{if } t < c_L
$$

Problem of the licensor. The problem of the licensor is to choose the fixed fee and the target t so as to maximize its payoff subject to the participation constraint and the incentive compatibility constraints:

$$
\underset{M,t}{Max} \qquad M + \theta * q_S^C
$$

$$
\text{s.t. (2) and (1)}
$$

Since the producer is a monopolist on the Southern market, the quantity consumed in the South is the same as the quantity produced by the monopolist ($q_S^C = q_S(t)$).

Lemma 1 *It is never optimal for the licensor to set a target below c_L. Under very weak assumption on parameters, it is not optimal for the licensor to set a target below c_H.*

Proof. See appendix. ∎

The intuition for this lemma is clear: the licensor will never want to set a target below c_L because the Southern market would not be served in either states of the world and the producer would not make any profits in the South which could be extracted through the fixed fee. Similarly, he will not want to set a target below c_H (and above c_L) because with probably one half the Southern market would not be served and the producer would not make any profit in the South which could be extracted through the fixed fee. Since a target below c_H leads to a higher quantity in state of the world L, it is conceivable that this might offset both the loss in revenues and the fact that nothing is sold in the South in state of the world H. Very weak restrictions on parameters are sufficient to rule this possibility out (see proof of the lemma for details).

Lemma 1 implies that c_H is a lower bound on the price target. Clearly, the participation constraint will be binding at the optimum and we can rewrite the problem of the licensor as:

$$
\underset{t,t\geq c_H}{Max} \quad \frac{(a_N - E(c))^2}{4} + (a_s - t)(t - E(c)) - \nu - F + \theta * (a_S - t)
$$

Deriving the first order condition of the unconstrained problem and solving for t we find:

$$
t^* = \frac{a_S - \theta + E(c)}{2}
$$

The lower bound on the target becomes binding when $c_H = \frac{a_S - \theta + E(c)}{2}$ or when $\theta = a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$. The utility of the licensor under the target is indicated in the appendix.

Proposition 2 *If (and only if) $\theta \leq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, a contract with an appropriately defined price target yields the same expected utility to the licensor as the first best.*
Proof. *See appendix.* ∎

The first-best level of utility can be attained because the fixed fee allows the licensor to extract revenues from the licensee without distortion and, the desired lower price in the Southern market can be implemented through the target[9].

---

[9] The realized level of prices in the South deviate from the first-best level of prices because the licensor sets a single target whereas in the first best a different price is for the two states of nature. However, thanks to the linearity of q_S in the utility of the licensor the target leads to the same expected utility as the first best.

However, in setting the target, the licensor is constrained by the fact that if the target is too agressive, the producer will not supply in the South (at least when the cost is high). A licensor that would set a price lower than c_H in the first best cannot reach the desired level of prices with a target which causes a deviation from the first best.

Proposition 3 *If $\theta \leq a_S - \frac{1}{2}c_L - \frac{1}{2}c_H$, the price target yields a higher utility than the equitable access license to the licensor. If $\theta \geq a_S - \frac{1}{2}c_L - \frac{1}{2}c_H$, the equitable access license yields a higher utility to the licensor than the price target.*

Proof. See appendix. ■

3.5   A price target in the South with punishment

The idea developed in this paragraph is that it is possible to improve on the simple contract with a target discussed in the previous paragraph by imposing a due diligence clause. Specifically, the contract could specify that if the producer fails to supply the Southern market, the producer would lose its exclusivity in the South (but not in the North). The loss of exclusivity would then allow generic competition in the South as in the equitable access license. Thus, if the producer does not sell in the South, the quantity consumed is $q_S^C = a_S - c_L$ in state of the world L and $q_S^C = a_S - c_H$ in state of the world H.

Problem of the producer. The solution to the problem of the producer is exactly the same as under the target of the previous sub-section. The potential loss of exclusivity does not influence its behaviour. If the target is above its marginal cost, it will want to produce the same as before. If the target is below its marginal cost, it will rather lose its exclusivity than sell at a loss.

Problem of the licensor. From the licensor's perspective, the inclusion of a due diligence clause matters. When the licensor sets a target between c_L and c_H, the producer will not sell in the South in state H. Under the previous contract that meant that the South was not served at all in this state of the world. However under the present contract with a due diligence clause, the producer would lose its exclusivity in the South. Generic producers, which are not bound by the target would then supply the Southern market leading to a quantity consumed in the South of $q_S^C = a_S - c_H$.

If θ is low ($a_S - \frac{1}{2}c_L - \frac{3}{2}c_H \geq \theta$), the price target with and without punishment are identical since punishment never occurs. The solution of the game is the same as for the price target without punishment.

If $a_S - \frac{1}{2}c_L - \frac{3}{2}c_H \leq \theta$, the optimal policy for the licensor is to set a target below c_H, in which case the producer sells in the South only in state of the world L. In state of the world H, generic production occurs instead.

Lemma 2 *Under the contract specifying a target and with a due diligence clause, it is optimal for the licensor for certain parameter values to set a target below c_H. Specifically, the optimal target is (1) $t = \frac{a_S + E(c) - \theta}{2}$ if $\theta \leq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$ (2) $t = \frac{a_S + c_L - \theta}{2}$ if $a_S - c_L \geq \theta \geq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$ (3) $t = c_L$ if $\theta > a_S - c_L$.*

Proof. See appendix. ∎

As before, the licensor will not want to set a target below c_L, because the Southern market would never be served or able to generate profits that can be recovered through the fixed fee. Whereas in the target without punishment, setting a target strictly below c_H (and above c_L) was not attractive because the licensor would risk that the Southern market would not be served should state of the world H occur. This is no longer the case now and it becomes attractive to set a target in the range between $[c_L, c_H[$ when the humanitarian component in the licensor's objective function has a relatively high weight.

Proposition 4 *The payoff of the licensor is as least as good with the target with punishment as with the target without punishment for all parameter values and strictly better for $\theta \geq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$.*

Proof. See appendix ∎

Proposition 5 *The payoff of the licensor is as least as good with the target with punishment as with the equitable access license for all parameter values and strictly better for $\theta < a_S - c_L$.*

Proof. See appendix. ∎

3.6   Summary of results of the basic model

Table 1 summarizes the results of the basic model. For low values of θ (zone A, $\theta \leq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$) the optimal policy is a target, with or without punishment. Since the quantity of output in the South has a low weight in the objective function of the licensor, the desired level of output can (in expectation) be induced by the licensor through an appropriately defined target without being constrained by the fact that the producer may not find optimal to supply the Southern market at all. This constraint becomes very relevant for medium, high and very high values of θ (zone B, C and D, $\theta > a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$) when the licensor would like to induce its licensee to produce a higher level of output through a price target set at a low level. For medium, high and very high values of θ (zone B, C and D, $\theta > a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$), the licensor finds it optimal to set a target at exactly c_H to induce the licensee to supply the Southern market in both states of the world. A higher quantity can be reached with the equitable

license since generic competition drives prices to marginal cost in both states of the world. As a consequence, when the humanitarian component has a high or very high weight ($\theta > a_S - c_L$; zone C and D) in the objective function of the licensor, it is better for the licensor to use the equitable access license rather than a target (without punishment).

However, the target can be improved by including a due diligence clause that specifies that if the Southern market is not served, the licensee will lose its exclusivity in the South. When the contract includes such a 'punishment', the licensor is not longer constrained by the fact that the licensee may not supply the Southern market if the target is set too low. This is because generic competition would step in to supply the Southern market thanks to the loss of exclusivity. Therefore, for medium and high values of θ ($\theta > a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, zone B and C), the target with punishment strictly dominates the other types of contracts. For very high values of θ ($\theta > a_S - c_L$), the target with punishment and the equitable access license lead to the same outcome. The main result of the basic model is thus that the target with punishment is at least as good as the other types of contracts for all parameters values and strictly better for some parameter values.
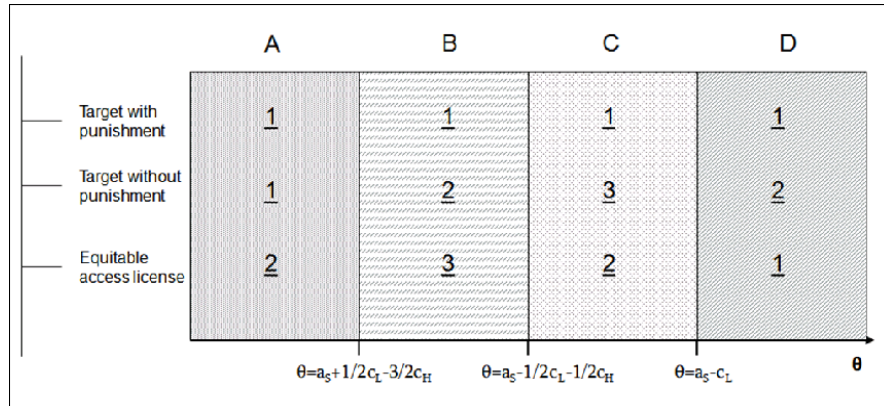

Figure 1: ranking of contracts in the basic model

4   Extensions of the basic model

4.1   Demand asymmetry

In the basic model, we have considered asymmetric information on the level of marginal cost. An alternative would be to consider instead asymmetric information on the demand. It seems reasonable that the demand may not be known when the contract is signed and that subsequently the firm may have better information on the demand function. In the case of demand asymmetry,

the setup of the model is the same as with cost asymmetry except that now the marginal cost is always c and the demand parameters a_N and a_S can take the values a_N^L and a_N^H: a_S^L and a_S^H respectively in states of the world L and H. The simplest and most natural is to assume that when demand is low in the South, demand is also low in the North. As in the basic model with cost asymmetry, the type of demand is privately revealed to the producer after the signature of the contract.

With the equitable access license, the solution of the game is essentially identical to that of the model with cost asymmetry. However, demand asymmetry leads to qualitatively different results under the target. Since there is a single marginal cost level c, the choice of the TTO is limited to setting the target above c, equal to c or below c (in the basic model it was also necessary to consider a target between the two cost levels). Setting the target below c is never optimal for the TTO because the Southern market would not be served. The optimal target is to choose the price that implements the first best in expectation unless the lower bound c is binding in which case the optimal target is c. Since the target is never set below the marginal cost level, the producer will serve the South in both states of Nature and a due diligence clause is never triggered in equilibrium. Therefore, it does not matter whether the target is with punishment or without.

Comparing the equitable access license and the target, there are only two ranges of parameter values to consider. For a low θ ($\theta \leq E(a_S) - c$), the first-best level of utility can be reached with the target but not with the equitable access license. For a high θ ($\theta \leq E(a_S) - c$) the first-best level of utility can no longer be reached. The target and the equitable access license lead to exactly the same outcome.

Rather than considering demand asymmetry instead of cost asymmetry, we could consider demand asymmetry on top of cost asymmetry. This is probably the most realistic case: when the contract is signed, neither party has good information on the demand and production cost; thereafter, the producer has better information on the demand and cost level than the licensor. When demand asymmetry is combined with cost asymmetry, the results are essentially identical to the basic model with expectations on the demand parameters replacing the demand parameters. The comparison between the equitable access license, the target with punition and the target without punishment yields the same results as the basic model.

4.2 Generic production costs uncorrelated with production costs

Another extension to the basic model is to assume that that the costs of generic production are independent of the cost of the producer (licensee). As before,

generic production is characterised by either high marginal cost or a low marginal cost, depending on the state of nature. When the licensee has a certain marginal production cost however, is it equally likely that marginal cost of generic production is low or high. Thus, four cases occur with equal probability: (1) the licensee has cost c_H and generic production is at cost c_H (2) the licensee has cost c_H and generic production is at cost c_L (3) the licensee has cost c_L and generic production is at cost c_H (4) the licensee has cost c_L and generic production is at cost c_L. It is assumed that the licensing knows the type of generic production cost.

In this setup, the equitable access license has a sampling effect. Sampling effects refer to the fact that when production costs are not perfectly correlated among producers, competition between suppliers makes it more likely that one of the competing producers has a low production cost (Armstrong & Sappington, 2006). Here, generic producers have the same costs among themselves; however, beneficial effects of sampling emerge through competition between the licensee and generic producers. In expected values, the quantity in the South is the same as with perfectly correlated cost. However with uncorrelated costs and under the equitable access license, the licensee can sometimes make a profit from sales in the Southern market which was not the case in the basic model. Specifically, when the licensee is of type L and generic production is of type H, the licensee can charge slightly below c_H making a positive profit on sales to the Southern market. At the equilibrium, the expected value of this profit is captured by the licensor through the fixed fee.

The target without punishment leads to the same outcome with perfect cost correlation or without, because generic production never occurs in either case. The target with punishment however becomes even more attractive than in the basic model because it is now associated with a potential sampling effect. If the target is set between the two cost levels (i.e. between c_L and c_H), the due diligence is triggered when the licensee is of type H. When that happens and the costs are uncorrelated, the price in the South is either c_L or c_H with equal probability. In the basic model the price was always c_H when the due diligence cause was triggered. The licensor will be tempted to set a target between the two cost levels to take advantage of this sampling effect. For this reason, c_H is never an optimal target.

With uncorrelated costs, the quantity with the target may be strictly larger than with the equitable access. To see this, consider a target set at c_L. In the state of the world where the licensee has cost L and the generic production is of type H, the quantity consumed in the South is $a_S - c_L$ under the target (the licensee finds it optimal to serve the Southern market at the target price). In the same state of the world under the equitable access license, the licensee sells at price slightly below c_H leading to a quantity slighly above $a_S - c_H$ (the licensee is not constrained by any target but by the potential competition of generic producers). In other states of the world the target and the equitable

access license leads to the same quantities. The broader point is that if the costs of the licensee are (sometimes or always) below the costs of generic production, it is possible with a target with punishment to exploit this to achieve a greater quantity than the quantity under equitable access license.

4.3 Other extensions

The basic model could be extended in various other ways that are not particularly interesting in terms of insights gained but could nevertheless have important implications for the comparison between the three types of contract.

First, marginal costs may not be the same for generic producers and for the licensee not only in the values they take *ex post* (as in section 4.2) but also in expectation *ex ante*. For instance, it could be that the marginal cost of production tends to be lower for generic competitors based in the South because they face lower input costs. Generic producers may also have greater incentives to invest in cost-reducing technology to improve their price-cost margin. Conversely, if marginal cost was not constant but decreasing, the licensee would enjoy economies of scale. It is also possible that original producers use superior production techniques thanks to their R&D intensive orientation. Thus, it is unclear whether production costs are lower for original producers or for generic producers. In the basic model we took a middle road by assuming that production costs of the licensee and of generic production are the same. If the generic production costs were deemed to be lower (in expectation) than the production costs, that would favor the equitable access license over target and vice versa.

Second, reverse engineering may involve substantial costs for generic producers. High reverse engineering costs could make both the equitable access license and the threat of generic competition ineffective leaving the licensor with a simple target as the only viable option (among those considered in this paper). The costs of reverse engineering are probably very low for small molecule drugs as evidenced by the rapid entry of generic producers after patent expiry. However, they can be high in in the case of biologicals and vaccines due to the importance of know-how in vaccine production (Milstien, Gaule & Kaddar, 2007).

Third, entering into the Southern market may involve a fixed cost for the producer (for instance clinical trials may have to be repeated). In that case, the producer would find it profitable to supply the Southern market only if if its profits in the South exceed the the cost to enter the Southern market. That would further constrain the licensor in setting a price target and increase the importance of including a due diligence clause in the licensing contract.

5 Concluding remarks

Access to pharmaceuticals in developing countries depends on many factors and in particular on the quality of local health systems. Nevertheless, the price of pharmaceuticals is certainly an important determinant of access; and patent protection often has a significant effect on prices. In compliance with the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), developing countries have strenghtened their intellectual property laws (except least developed countries). This implies in effect that generic competition will no longer be possible for new pharmaceutical products. There are few prospects of the TRIPS agreement being substantially changed to address the problem of access to pharmaceuticals. While the relevant international legal framework may not change, the behaviour of individual actors within the intellectual property system may change. The adoption by Northern universities of humanitarian licensing policies may help solve the problem of access to pharmaceuticals in developing countries.

Which type of humanitarian licensing policies is most appropriate is still an open question. This paper sought to bring an economic contribution to the debate. Arguably one of the main problem in setting a maximum price (price target) in advance is that the licensor does not know enough about the cost of production or the demand. Our model takes this into account by assuming that both the licensor and the producer are not well informed about costs when the contract is signed and that afterwards the producer knows his costs but not the licensee. The problem of the price target under these conditions is that the licensor cannot set a target too low because the producer would not produce if its cost of production turns out to be higher than the target. The equitable access license (which roughly amounts to granting non-exclusive licenses for sales in the South) is better than the target when the university places a relatively high importance on the access objective because it leads to higher quantities. However, the target can be improved by a due diligence clause that specifies that the licensee would lose its exclusivity in the South if it does not supply the Southern market. This allows the licensor to set a lower target because if the costs of production turn out to be higher than the target, the licensee will not supply the South but generic producers will. We showed that in our simple model the target with the due diligence clause was at least as good as the two other contracts for some parameter values and strictly better for others. The main message of the paper is thus that the threat of generic competition may be stronger than its actual implementation.

6 Appendix

6.1 Utility attained by the licensor under different types of contracts

Utility at the first best $V_{FB} = \frac{(a_N - E(c))^2}{4} + \frac{(a_S - E(c))^2 - \theta^2}{4} - F - \nu + \theta * \frac{a_S - E(c) + \theta}{2}$
Utility under the equitable access license $V_{EAL} = \frac{(a_N - E(c))^2}{4} - F - \nu + \theta * (a_S - E(c))$
Utility under the target with or without punishment when $\theta \leq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$ $\frac{(a_N - E(c))^2}{4} + \frac{(a_N - E(c))^2 - \theta^2}{4} - F - \nu + \theta * \frac{a_S + \theta - E(c)}{2}$
Utility under the target without punishment when $\theta > a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$ $\frac{(a_N - E(c))^2}{4} + \frac{1}{2}(a_S - c_H)(c_H - c_L) - F - \nu + \theta(a_S - c_H)$
Utility under the target with punishment when $a_S - c_L > \theta > a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$ $V_{\text{punishment}} = \frac{(a_N - E(c))^2}{4} + \frac{(\frac{a_S + c_L - \theta}{2} - c_L)(a_S - \frac{a_S + c_L - \theta}{2})}{4} - F - \nu + \theta * \frac{a_S + \theta - E(c)}{2}$
Utility under the target with punishment when $\theta > a_S - c_L$ $V_{\text{punishment}} = \frac{(a_N - E(c))^2}{4} - F - \nu + \theta * (a_S - E(c))$

6.2 Proof of proposition 1

In section 3.2, we found that the utility at the first best is:
$V_{FB} = \frac{(a_N - E(c))^2}{4} + \frac{(a_S - E(c))^2 - \theta^2}{4} - F - \nu + \theta * \frac{a_S - E(c) + \theta}{2}$

In section 3.3, we found that the utility of the licensor under the equitable access license is: $V_{EAL} = \frac{(a_N - E(c))^2}{4} - F - \nu + \theta * (a_S - E(c))$

Substracting V_{EAL} to V_{FB} we obtain: $V_{FB} - V_{EAL} = \frac{(a_S - E(c))^2 - \theta^2}{4} + \theta * \frac{a_S - E(c) + \theta}{2} - \theta * (a_S - E(c))$ which can rewritten as $\frac{1}{4}(a_S - E(c) - \theta)^2$.

This expression is strictly positive unless $\theta = a_S - E(c)$ in which case it is exactly 0. Thus the equitable access license does not reach the first best except when $\theta = a_S - E(c)$.

6.3 Proof of lemma 1

First, we show that it is never optimal to set a target below c_L. Setting a target below c_L yields a payoff of $\frac{(a_N-E(c))^2}{4} - F - \nu$ to the licensor which is strictly lower than then the payoff from a target set at c_H ($\frac{(a_N-E(c))^2}{4} + \frac{1}{2}(a_S-c_H)(c_H-c_L) - F - \nu + \theta(a_S-c_H)$).

Second, we show that it is not optimal to set a target below c_H. When choosing a target between c_H and c_L, the best the licensor can do is to set a target equal to $\frac{a_S+c_L-\theta}{2}$ (which yields the first-best level of output in state of the world L). The utility of the licensor is then $\frac{(a_N-E(c))^2}{4} - F - \nu + \frac{1}{2}\frac{(a_S-c_L)^2-\theta^2}{4} + \frac{1}{2}\theta * \frac{a_S-c_L+\theta}{2}$. This utility is strictly lower than the payoff from a target set at c_H ($\frac{(a_N-E(c))^2}{4} + \frac{1}{2}(a_S-c_H)(c_H-c_L) - F - \nu + \theta(a_S-c_H)$) under the following two conditions: a) $c_H - c_L < 2(a_S - c_H)$ i.e. the difference between the two cost levels must not exceed twice the difference between the intercept and c_H and b) $\theta < 3a_S - 4c_H + c_L + 2((a_S-c_H)(2a_S-3c_H))^{1/2}$ which is a very large of θ (at this value of θ the first-best is to set a price equal to zero in the South in both states of the world).

6.4 Proof of proposition 2

The utility at the first best is:
$$V_{FB} = \frac{(a_N-E(c))^2}{4} + \frac{(a_S-E(c))^2-\theta^2}{4} - F - \nu + \theta * \frac{a_S-E(c)+\theta}{2}$$
When $\theta \leq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, the utility under the target is $\frac{(a_N-E(c))^2}{4} + \frac{(a_N-E(c))^2-\theta^2}{4} - F - \nu + \theta * \frac{a_S+\theta-E(c)}{2}$ which is the same as the first-best. When $\theta > a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, the difference between the utility at the first best and the utility under the target is: $V_{FB} - V_{\text{target}} = \frac{(a_S-E(c))^2-\theta^2}{4} + \theta * \frac{a_S-E(c)+\theta}{2} - \frac{1}{2}(a_S-c_H)(c_H-c_L) - \theta(a_S-c_H)$ which simplifies to $\frac{1}{4}(a_S - \frac{3}{2}c_H + \frac{1}{2}c_L - \theta)^2$ which is strictly positive.

6.5 Proof of proposition 3

If $\theta \leq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, the target reaches the level of utility of the first best while the equitable access license does not (see previous proofs). Thus the price target dominates the equitable access license over this range of parameter values.

If $\theta \geq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, we compare the payoff of the licensor with a target equal to c_H to the payoff of the licensor with the equitable access license: $V_{\text{target}} - V_{EAL} = \frac{1}{2}((a_S - E(c))^2 - \theta^2) + \theta(\frac{a_S+\theta-E(c)}{2} - a_S - E(c)) =$

$(a_S - E(c)) * (a_S - E(c) - \theta)$. Since $a_S - E(c)$ is always posititive, the last expression is positive for $a_S - E(c) \geq \theta$ and negative otherwise.

6.6 Proof of lemma 2

If $\theta \leq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, the first best can be reached with the same target as without punishment $(t = \frac{a_S + E(c) - \theta}{2})$.

If $\theta > a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, the licensor might want to (i) set a target at c_H or (ii) a target between c_H and c_L First, we compute the optimal target if the licensor chooses option (ii). This amounts to $\underset{t, t < c_H}{Max} \quad \frac{(a_N - E(c))^2}{4} + \frac{1}{2}(a_s - t)(t - c_L) - \nu - F + \theta * \frac{1}{2}(a_S - t)$ and the solution is target $t^* = \frac{a_S - \theta + c_L}{2}$. The utility of the licensor with this target is:

$$V_{t < c_H} = \frac{(a_N - E(c))^2}{4} + \frac{(\frac{a_S + c_L - \theta}{2} - c_L)(a_S - \frac{a_S + c_L - \theta}{2})}{4} - F - \nu + \theta * \frac{a_S + \theta - E(c)}{2}$$

whereas the utility with a target at c_H is $V_{t = c_H} = \frac{(a_N - E(c))^2}{4} + \frac{1}{2}(a_S - c_H)(c_H - c_L) - F - \nu + \theta(a_S - c_H)$. The difference $V_{t < c_H} - V_{t = c_H}$ simplifies to $\frac{1}{8}(a_S - 2c_H + c_L - \theta)^2$ which is always strictly positive ($\theta \geq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$ implies $.a_S - 2c_H + c_L - \theta > 0$). Consequently, the optimal target when $a_S - c_L > \theta > a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$ is $t^* = \frac{a_S - \theta + c_L}{2}$.

When $\theta > a_S - c_L$ the optimal target is c_L. This target c_L is optimal in a weak sense because any price below c_L including $t = \frac{a_S - \theta + c_L}{2}$ (which is below c_L when $\theta > a_S - c_L$) leads to the same payoff. In fact, when the price is below c_L it is generic producers rather than the licensee that supply the South. In fact the target with punishment amounts to an equitable access license since both parties know that the due diligence clause will be triggered in any state of the world if the target is set below c_L. As shown in proposition 5, the equitable access license and the target with punishment yield exactly the same payoff when $\theta > a_S - c_L$ (the quantities in the South in the respective states of the world are the same and the licensing revenues are equal $\frac{(a_N - E(c))^2}{4} - \nu - F$ to in both cases).

6.7 Proof of proposition 4

Case 1: $\theta \geq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, the due diligence clause is never triggered and the optimal target is the same with or without punishment $(t = \frac{a_S + E(c) - \theta}{2})$. The two contacts are identical.

Case 2: $a_S - c_L \geq \theta \geq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$. Without punishment the optimal target for these parameter values is $t = c_H$ (see lemma 1) $V_{\text{no punishment}} = \frac{(a_N - E(c))^2}{4} + \frac{1}{2}(a_S - c_H)(c_H - c_L) - F - \nu + \theta(a_S - c_H)$. With punishment the

optimal target for these paramater value is $t = \frac{a_S + c_L - \theta}{2}$ (see lemma 2) and the utility of the licensor is $V_{\text{punishment}} = \frac{(a_N - E(c))^2}{4} + \frac{(\frac{a_S + c_L - \theta}{2} - c_L)(a_S - \frac{a_S + c_L - \theta}{2})}{4} - F - \nu + \theta * \frac{a_S + \theta - E(c)}{2}$. The difference $V_{\text{punishment}} - V_{\text{no punishment}}$ can be rewritten as $\frac{1}{8}(a_S - 2c_H + c_L - \theta)^2$ which is always strictly positive ($\theta \geq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$ implies $.a_S - 2c_H + c_L - \theta > 0$)

Case 3: $\theta > a_S - c_L$. Without punishment the optimal target and utility for these parameter values is the same as in case 2. With punishment the optimal target for these paramater value is $t = \frac{a_S + c_L - \theta}{2}$ (see lemma 2) and the utility of the licensor is $V_{\text{punishment}} = \frac{(a_N - E(c))^2}{4} - F - \nu + \theta * (a_S - E(c))$. The difference $V_{\text{punishment}} - V_{\text{no punishment}}$ can be rewritten as $\frac{1}{2}(c_H - c_L) * (\theta + c_H - a_S)$. This expression is strictly positive since $\theta > a_S - c_H$ is implied by $\theta > a_S - c_L$.

6.8   Proof of proposition 5

For values of θ such that $\theta \leq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, the target with punishment yields the first-best level of utility while the equitable access license does not (see propositions 1, 2 & 4).

For values of θ such that $a_S - c_L > \theta \geq a_S + \frac{1}{2}c_L - \frac{3}{2}c_H$, the utility of the licensor with the target is $V_{\text{target}} = \frac{(a_N - E(c))^2}{4} + \frac{(\frac{a_S + c_L - \theta}{2} - c_L)(a_S - \frac{a_S + c_L - \theta}{2})}{4} - F - \nu + \theta * \frac{a_S + \theta - E(c)}{2}$. The utility of the licensor with the equitable access license is $V_{EAL} = \frac{(a_N - E(c))^2}{4} - F - \nu + \theta * (a_S - E(c))$. The difference $V_{\text{target}} - V_{EAL}$ simplifies to: $\frac{1}{8}(a_S - c_L - \theta)^2$.

For values of θ higher than (or equal to) $a_S - c_L$, the equitable access license and the target with punishment yield exactly the same payoff (the quantities in the South in the respective states of the world are the same and the licensing revenues are equal $\frac{(a_N - E(c))^2}{4} - \nu - F$ to in both cases).

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