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Compulsory licensing, price controls, and access to patented foreign products*

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Abstract

Motivated by existing multilateral rules regarding intellectual property, we develop a North-South model to highlight the dual roles price controls and compulsory licensing play in determining Southern access to a patented Northern product. The Northern patent-holder chooses whether and how to work its patent in the South (either via entry or voluntarily licensing) while the South determines the price control and whether to issue a compulsory license. The threat of compulsory licensing benefits the South and also increases global welfare when the North-South technology gap is significant. The price control and compulsory licensing are complementary instruments from the Southern perspective.

Keywords: Patented Goods, Compulsory Licensing, Price Controls, Quality, Welfare. *JEL Classifications*: F13, F53, O34.

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1 Introduction

Limited access to patented pharmaceuticals is a serious issue confronting developing countries. Since the ratification of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) by the World Trade Organization (WTO), this issue has acquired an even greater degree of urgency since local pharmaceutical industries in countries such as Brazil and India can no longer reverse-engineer patented foreign medicines and sell them at low prices in developing country markets.[1] Post TRIPS, government across the developing world have tried to improve consumer access to medicines sold by foreign pharmaceutical companies by imposing price controls on them. Indeed, such controls exist even in rich countries where the public sector plays an integral role in health care. However, a problem with using price controls to improve consumer access is that pharmaceutical companies with patented medicines may simply refuse to sell in markets where they find such controls to be too strict. When faced with no or limited access to a patented foreign product, a country may choose to engage in compulsory licensing, i.e., an authorization granted by a government to someone other than the patent-holder to produce the product without the patent-holder's consent.[2] Along with the freedom to allow parallel imports, the option to use compulsory licensing constitutes one of the major flexibilities available under TRIPS to member countries of the WTO – see Maskus (2000a and 2000b) for a detailed discussion of these TRIPS flexibilities.

This paper develops a North-South model to analyze the dual roles played by price controls and compulsory licensing in determining consumer access to patented foreign products in developing countries. In the model, the Southern government sets the level of price control on a Northern patent-holder who chooses between serving the Southern market by entering directly or by (voluntarily) licensing its technology to a local firm.[3] If the patent-holder fails to work the patent in the South, the government has the freedom to issue a compulsory license to the local firm, the quality of whose production is lower

[1] Existing studies indicate that the static welfare losses resulting from the TRIPS induced elimination of low price local sellers of pharmaceuticals can be quite significant – see, for example, Chaudhuri, Goldberg, and Jia (2006).

[2] Indeed, some observers have interpreted compulsory licensing as the "breaking of a patent" (Cahoy, 2011); what is broken is the right of a patent holder to exclude others.

[3] This aspect of our model is related to the literature that explores how the optimal entry strategy used by a firm to penetrate a foreign market depends upon the degree of IPR protection available in that market. See, for example, Ethier and Markusen (1996), Markusen (2001), and McCalman (2004).

than that of the patent-holder. As we explain below, this model is motivated by several recent case studies of compulsory licensing of pharmaceuticals and the ground rules established by TRIPS that govern the use of compulsory licensing by WTO members. The analysis addresses several inter-related questions: How does each instrument – i.e. a price control and the threat of compulsory licensing – affect the patent-holder's decision regarding its entry mode? What is the relationship between the two instruments? What are their respective welfare effects? Do price controls obviate the need for compulsory licensing?

At the time TRIPS was ratified (i.e. in 1995), approximately 100 countries already permitted some sort of compulsory licensing under their national rules and regulations pertaining to intellectual property, with requirements for use varying across countries (Lybecker and Fowler, 2009).[4] Article 31 of TRIPS (which pertains to "use without authorization of the right holder") lays down the set of conditions that govern the use of compulsory licensing by WTO members, the most important of which are the following:

(a) the entity (company or government) applying for a compulsory license should have been unable to obtain a voluntary licence from the right holder on "reasonable" commercial terms;

(b) if a compulsory license is issued, "adequate remuneration" must be paid to the patent-holder; and

(c) a compulsory license must be granted mainly to supply the domestic market.[5]

Exactly when a country can issue a compulsory license is not explicitly addressed by TRIPS although it does mention national emergencies, other circumstances of extreme urgency, and anti-competitive practices as possible grounds for compulsory licensing. Overall, it appears that countries seeking to use compulsory licensing have a fair bit

[4] Article 5 of the Paris Convention for the Protection of Industrial Property (commonly known as the Paris Convention), originally adopted in 1883, allowed signatories to adopt legislative measures "for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, *failure to work*" (Pozen, 2008). Thus, even as early as 1883, the non-working of a patent (equivalent to not supplying a patented medicine to a particular country in our context) was seen as justifiable grounds for compulsory licensing.

[5] The last requirement – i.e. production under a compulsory license must be sold only in the domestic market – was weakened in a landmark decision made by the WTO's TRIPS Council in 2003 under which it was decided that if a country lacked the ability to manufacture a drug locally (as is true for a large number of developing countries) it could import it from a third party under a compulsory license. This decision increases the options available to developing countries without affecting the patent holder's sales in other markets.

of discretion at their disposal, something that has been a source of major concern for pharmaceutical companies and other supporters of strong intellectual property rights. For example, it is far from clear as to what constitutes "reasonable commercial terms"? Similarly, how much remuneration to the patent-holder is "adequate"? Available evidence suggests that when compulsory licensing has occurred, patent holders have tended to receive fairly low royalty rates.[6]

Even though compulsory licensing is permitted under TRIPS, it has not been used that often by developing countries. Of course, for the option to invoke compulsory licensing to matter, compulsory licensing need not actually be used: the threat to issue a compulsory license can affect the behavior of patent-holders to the advantage of developing countries thereby making its use unnecessary. In this regard, it is useful to briefly discuss two prominent recent cases where compulsory licensing has been used by Thailand and Brazil. Both cases involved the compulsory licensing of HIV/AIDS drugs, although it seems that governments in these countries are likely to expand their reach to issue compulsory licenses for other essential medicines.

In a case that drew significant attention in the press, on January 2007 the government of Thailand issued a compulsory license for Kaletra, an AIDS drug, to the Government Pharmaceutical Organization (GPO) – a government owned Thai producer of medicines.[7] Regardless of one's views about compulsory licensing, one aspect of the Thai experience that is worrisome for all concerned is that the quality of the drug produced by GPO (called GPO-vir) was sub-par – an aspect of production under compulsory licensing that is central to the model that we develop below. Indeed, the Global Fund to Fight HIV/AIDS actually granted the GPO $133 million in 2003 so that it could upgrade its plant to meet international quality standards. However, the Fund withdrew its

[6] See Scherer and Watal (2002) for a discussion of a variety of contexts in which compulsory licensing has been used. They note that in most cases, the royalty rates paid to the patent holders have been quite low, often being under 5%.

[7] The decision to issue a compulsory license was made after a study funded by the World Bank and the health ministry in Thailand estimated that the compulsory license would save the government 100 billion bhat (roughly 3 billion USD) through 2025 and was explained by Dr. Mongkol, the Thai Health Minister, as follows: "We ask for the understanding of pharmaceutical companies. Much of our affected population cannot afford your drugs and we want people to have access to the medicines that they need." He also noted that there would be no need for compulsory licensing if pharmaceutical companies "would voluntarily reduce prices." (Baron, 2008). The Thai decision to issue a compulsory license was endorsed by the Clinton Foundation, 22 US Senators, the WHO, and UNAIDS – the United Nations agency responsible for coordination AIDS care and prevention in the world (Baron, 2008).

support in 2006 since the GPO failed to meet the World Health Organization's (WHO's) quality standards (Lybecker and Fowler, 2009).[8]

Following in Thailand's footsteps, in May 2007 Brazil decided to issue a compulsory license for Efavirenz, another patented AIDS drug, after price negotiations with the patent-holder (Merck) had broken down. Brazil had previously used the threat of compulsory licensing to pressure companies to lower prices of patented medicines, but Efavirenz was the first time a compulsory license was actually issued.[9] The price negotiations with Merck were partly induced by a steady increase in the market price of Efavirenz: the annual per-patient cost of treating patients with Efavirenz in Brazil had increased from $1336 in 2004 to $2500 in 2006 (Daemmrich and Musacchio, 2011). As in the Thai case, Merck offered a 30 percent price cut but Brazilian officials did not accept its offer and negotiations eventually bogged down culminating in the issuance of a five year compulsory license for Efavirenz with a royalty rate of 1.5% to Merck (Daemmrich and Musacchio, 2011).

However, the story did not end with the issuance of the compulsory license. It turned out that Farmanguinhos – the leading government owned pharmaceutical manufacturer in Brazil – was unable to manufacture Efavirenz since it lacked the technological know-how to do so (Daemmrich and Musacchio, 2011). It eventually took Farmanguinhos two years to be able to supply Efavirenz to the local market (at an annual cost of $210 per patient).[10] In the meantime, Brazil had to resort to importing a generic version of the drug from India.

[8] A potentially lethal consequence of the sub-standard quality of GPO-vir was that almost a fifth of those taking the drug (roughly 20,000 HIV-positive people) quickly developed resistance to it (Baron, 2008), prompting Lynbecker and Fowler (2009) to assert that "the cheap GPO solution will unquestionably result in greater public health problems and more expensive therapies."

[9] For example, prior to the negotiations with Merck, Brazil had threatened to issue a compulsory license for Kaletra but did not actually do so since Abbott Laboratories agreed to lower the price of Kaletra to $1380 per year through 2011.

[10] The experience of Brazil and Thailand was observed carefully by other developing countries and could lead to an increase in the use of compulsory licensing. For example, Ecuadorian President Rafael Correa signed a decree on October 23, 2009 allowing compulsory licenses and the National Intellectual Property Office worked out a mechanism for issuing such licenses with the first such license being issued in April 2010. Referring to Article 31 of TRIPS, the Ecuadorian constitution, and the WTO Doha Declaration on TRIPS and Public Health, Correa declared access to essential medicines to be of public interest and argued that compulsory licensing was a tool for achieving general development goals, a position that plays to the worst fears of pharmaceutical companies and seems to stretch the manner in which compulsory licensing has been generally defined and utilized.

There are three common (and crucial) aspects of the experiences of Thailand and Brazil with compulsory licensing. First, price considerations were a major factor in prompting the use of compulsory licensing. Indeed, the governments seemed to have used their power to bargain down prices as well as the option to use compulsory licensing as tools for improving consumer access to foreign patented goods. Second, in both Thailand and Brazil, there was essentially a single local producer that had the competence to produce the relevant drug under a compulsory license. Third, in both instances, the local producer's quality was clearly inferior to that of the original patent-holder. We believe that these features capture important ground realities confronting the potential use of compulsory licensing in developing countries and the model that we develop below puts them at center stage.

In our model, while choosing its price control, the Southern government has to decide whether to impose a strict price control thereby inducing voluntary licensing (under which the local production is of low quality) or to set a more lax price control that is sufficient to cover the Northern patent-holder's fixed cost of entry. Indeed, when the local quality disadvantage is large, it is optimal for the South to not impose any price control at all.

While a stricter price control makes direct entry less attractive to the patent-holder relative to licensing, a more stringent compulsory licensing policy (i.e. one that results in a low licensing fee being paid to the Northern patent-holder) has the opposite effect on the patent-holder's entry mode decision. More importantly, while a price control improves consumer access by lowering price, it lowers the likelihood of the South obtaining access to the high quality good. Thus, the two policy instruments at the disposal of the government play rather different roles in affecting access to the patented foreign good.

Our analysis shows that the option to use compulsory licensing necessarily increases Southern welfare: it either lowers the licensing fee that is paid to the Northern patent-holder or it causes a switch from licensing to entry thereby improving the quality of the good available to Southern consumers. However, when the effect on the Northern patent-holder is taken into account, the effects of compulsory licensing are not always beneficial. In particular, while a relatively lax compulsory licensing policy (i.e. one that does not lower the fee paid to the patent-holder too much) increases world welfare, a stringent compulsory licensing policy can lower world welfare by inducing a suboptimal switch

from licensing to direct entry. Furthermore, the threat of compulsory licensing has no effect on world welfare when it leaves the patent-holder's entry decision unaffected.

The model is also able to shed light on the nature of interaction between a price control and compulsory licensing. We find that the two policy instruments are somewhat complementary from the Southern perspective: by shifting the patent-holder's preference in favor of entry, a stricter compulsory licensing policy allows the South to set a more stringent price control (under entry) which raises Southern welfare. Thus, even when the government can use a price control to improve consumer access, compulsory licensing plays a useful role for the South by making licensing less attractive to the patent-holder thereby allowing it to extract a greater share of the surplus. This result resonates well with Goldberg (2010) who has argued that price regulations might need to be complemented by compulsory licensing to ensure adequate access to medicines in developing countries.

We focus on the policy choices of the South and abstract from the repercussions of those choices in other markets. For example, Grossman and Lai (2008) have shown how the Southern price control can affect Northern policy regarding exhaustion of intellectual property rights which in turn determines prices and welfare in both regions. We also do not consider the dynamic consequences of compulsory licensing for the South. In this context, Moser and Voena (2012) have shown that compulsory licensing of nearly 130,000 German chemical inventions by the United States (US) after World War I under the Trading with the Enemy Act had a substantial positive effect on subsequent innovation by the US chemical industry. However, similar effects might not be as central to the types of compulsory licensing considered in our model. This is due to two reasons. One, a few isolated cases of compulsory licensing may not generate a substantial amount of knowledge transfer. Second, even if compulsory licensing could be mobilized on a large scale, many developing countries lack the technological capability necessary for making effective use of licensed foreign technologies as an input into domestic innovation.

2 Model

We consider the case of a Northern firm (referred to as the "patent-holder") that produces a good that is protected by a patent with a duration of T periods. We assume

that the patent-holder is able to segment markets internationally, so that profits in its home market are unaffected by its pricing decision in the South. There are a continuum of Southern consumers of measure A, each of whom buys (at most) one unit of the product. If a consumer buys the good at price p, its utility is given by $U = \theta q - p$ where q measures quality and $\theta \geq 0$ is a taste parameter that captures the willingness to pay for quality. For simplicity, we assume that with θ is uniformly distributed over the interval [0,1]. Assuming utility under no purchase equals zero, the per-period demand $d(p, q)$ for the product in the South is easily calculated: $d(p, q) = A\left(1 - \frac{p}{q}\right)$.

If the patent-holder decides to enter the Southern market and produce the good itself its quality level equals q^E and its marginal cost of production is normalized to zero. Production by the patent-holder also requires that it incur a fixed entry cost of φ.[11] We assume that the patent-holder faces a price ceiling, $\bar{p}$, when selling its product in the Southern market.

Letting β be the discount factor, the present value of profits (gross of entry costs) will be $\sum_{t=0}^{T} \beta^t Ap(1 - \frac{p}{q^E})$. Choosing units such that $A\left(\frac{1-\beta^{T+1}}{1-\beta}\right) = 1$, the present value of the maximum profits the patent-holder earns by selling in the South equals

$$\pi^E(\bar{p}) = \min[\bar{p}, \frac{q^E}{2}]\left(1 - \frac{\min[\bar{p}, \frac{q^E}{2}]}{q^E}\right) \tag{1}$$

where $\frac{q^E}{2}$ is the unconstrained monopoly price under entry. The absence of a price control is then equivalent to $\bar{p} \geq \frac{q^E}{2}$.

The patent-holder can also enter the South by licensing the technology to a local firm for the life of the patent. We assume that there is only a single local firm with sufficient capability to be an effective licensee. If there is no licensing, the local firm cannot produce the good. Under licensing, the local firm's quality equals $q^L = \gamma q^E$, where $\gamma \leq 1$ captures the quality gap between the licensee and the patent-holder. This quality differential can be interpreted as the Southern firm having a lower level of technological capability than its Northern counterpart, and thus not being able to produce a high quality product (as was evidenced by the experience of Thailand and Brazil). It may

[11] We do not distinguish between the Northern patent-holder entering the South via exporting or by establishing a foreign subsidiary. Either mode of entry would satisfy the condition for working the patent thereby preventing a compulsory license, and either would involve fixed entry costs. We assume the patent-holder chooses the entry mode that yields it higher profit.

also reflect the frictions associated with technology transfer, with more sophisticated products having a lower level of γ for the licensee.

Assuming a production cost of zero for the licensee, the maximum profits resulting from licensing over the life of the patent equal

$$\pi^L(\bar{p},\gamma) = \min[\bar{p}, \frac{\gamma q^E}{2}] \left(1 - \frac{\min[\bar{p}, \frac{\gamma q^E}{2}]}{\gamma q^E}\right) \tag{2}$$

where $\frac{\gamma q^E}{2}$ is the monopoly price for the licensee.

The welfare of the South equals the sum of the discounted sum of consumer surplus, $S(p,q) = \frac{q}{2}(1-\frac{p}{q})^2$, and the net profits of the local firm. The present value of Southern welfare under licensing is denoted W^L where

$$W^L(\bar{p},\gamma) = S(\min[\bar{p}, \frac{\gamma q^E}{2}, \gamma q^E) + \pi^L(\bar{p},\gamma) - f \tag{3}$$

and f is the licensing fee paid to the patent-holder. Southern welfare under direct entry is denoted W^E and it comprises solely of consumer surplus that accrues to the South:

$$W^E(\bar{p}) = S(\min[\bar{p}, \frac{q^E}{2}, q^E) \tag{4}$$

Thus, while licensing provides the South benefits in terms of the profits of the local firm (net of the license fee), these benefits come at the cost of receiving a lower quality product relative to entry.

The problem of the patent-holder is to decide how to serve the Southern market. We assume that the Southern government has two policy instruments via which it can influence the firm's entry and pricing decisions: compulsory licensing and a price control. We analyze the interactions between the patent-holder and the Southern government (referred to as simply "the government" from hereon) as a three stage game. In the first stage, the government chooses the price ceiling to be imposed on the product in the domestic market. The government is assumed to know the firm's entry cost, as well as the quality of the product that would be produced by the patent-holder or the licensee when making this decision. We also assume that once the price ceiling has been set, the government is committed to that price ceiling for the remainder of the game.

At the second stage of the game, the patent-holder decides whether to enter the market itself, to license the product to the local firm, or to not sell the product at all in

the South. We refer to a license negotiated with the Southern firm at the second stage as a *voluntary license*. The third stage of the game is the government's compulsory licensing decision. If the product has not been sold in the market in the second period, either because the patent-holder chose not to enter or was unsuccessful in negotiating a voluntary license, the government can choose to issue a compulsory license to the local firm. Under a compulsory license, the local firm produces the patented good as a licensee and pays a license fee equal to a share $\lambda \in [0, 1]$ of the profits that the patent-holder would have earned from its best use of the patent.

The structure of the entry game in our model is intended to capture actual features of the TRIPS agreement and the concerns of developing countries as identified in the case studies. The TRIPS requirement that applicants for a compulsory license should have been unable to obtain a voluntary license is reflected in the assumption that the third stage of compulsory licensing only arises if the patent-holder does not enter and there is no agreement on a voluntary license at the second stage. The share of profits received by the patent-holder, λ, is assumed to reflect the TRIPS requirement of a "adequate remuneration" to the patent-holder. As Scherer and Watal (2002) note in their discussion of what constitutes adequate remuneration for the patent holder: "since the purpose of virtually all known compulsory licensing schemes is to increase competitive supply and reduce prices, the 'profits lost' test cannot logically be the standard to be met in determining compensation for compulsory licensing." We interpret this as suggesting that in practice λ will be quite low, which seems consistent with the payments observed in practice. However, we also imagine that governments are not completely free in their choice of compensation, since choosing $\lambda = 0$ would almost certainly result in a complaint to the WTO. Thus, we interpret λ as a parameter that represents the minimum compensation that must be paid to the patent-holder without triggering a complaint on its part.[12]

The government's concern about availability of the product at a reasonable price is reflected in our assumption that it can set a price ceiling for sales in the local market.

[12] Tandon (1982) provides a model in which both the length of a patent as well as the royalty rate, given that the cost-reducing innovation is subject to compulsory licensing, are optimally determined. It should be noted that Tandon's definition of compulsory licensing differs from that applied by the WTO, in that he allows compulsory licenses to be granted even if the patent is being worked by the patent-holder. With a perfectly elastic supply of potential licensees, this yields a perfectly competitive industry equilibrium in the product market.

Since the patent-holder incurs a fixed cost of entry if it serves the market itself, there is a potential holdup problem if the government has the ability to alter the price ceiling once the patent-holder has made its entry decision. To avoid this issue, we assume that the government is able to commit to the price ceiling prior to the entry decision.

In the next section we present the analysis starting from stage two onward, which we refer to as the compulsory licensing game. In cases where the government does not have price ceilings available as a policy instrument or where the price ceiling has been set exogenously by a different government agency, there will be no first stage to the entry game. If the government does choose to impose a price ceiling, the compulsory licensing game is a proper subgame of the three stage game, given the price ceiling chosen at stage one. The analysis of the first stage, which endogenizes the price ceiling, is presented in section 4. This approach allows us to highlight the impact of compulsory licensing as a policy instrument for a given level of the price ceiling, and thus to contrast the effects of the compulsory license and price ceiling as alternative policy tools that affect Southern access to the patented Northern good.

3 The Compulsory Licensing Game

We solve the compulsory licensing game by backward induction. At stage three, the government must decide whether or not to grant a compulsory license if the product has not been sold in the market at stage two. We assume that stage two takes one period, so that a compulsory license granted at stage three provides the licensee with the right to produce the good for $T-1$ periods. The present value of profits earned by the licensee under a compulsory license is $\mu\pi^L(\bar{p},\gamma)$, where $\mu = \frac{1-\beta^T}{1-\beta^{T+1}} < 1$ is the discount applied to the licensee's profits due to the shortened horizon for the patent. Similarly, the patent-holder would earn a net return of $\mu\pi^E(\bar{p}) - \varphi$ from entering at the third stage of the game. Since under compulsory licensing the fee paid by the Southern firm/licensee is assumed to equal a share λ of the net profits that the latter would have earned in its most profitable use of the patent, the compulsory licensing fee is given by

$$f^{CL} = \lambda \max[\mu\pi^E(\bar{p}) - \varphi, \mu\pi^L(\bar{p},\gamma)] \tag{5}$$

A lower value of λ reflects a stricter compulsory licensing policy, in that it reduces the

compensation paid to the patent-holder.[13]

With the compulsory licensing fee given by (5), we can substitute into the Southern welfare function (3) to obtain the payoff to the government under compulsory licensing:

$$W^{CL} = \mu \left[S(\min[\bar{p}, \frac{\gamma q^E}{2}], \gamma q^E) + \pi^L(\bar{p}, \gamma) \right] - \lambda \max[\mu \pi^E(\bar{p}) - \varphi, \mu \pi^L(\bar{p}, \gamma)] \quad (6)$$

In order for compulsory licensing to be a credible threat in the voluntary licensing game, we require that the government prefers issuing a compulsory license to the outcome that would occur if no compulsory license were offered. We assume that the government believes that if it does not give a compulsory license, the product will not be offered in the market, in which case Southern welfare equals zero. This implies that compulsory licensing is a credible threat whenever $W^{CL} > 0$.

If $\varphi \geq \mu \left(\pi^E(\bar{p}) - \pi^L(\bar{p}, \gamma) \right)$, then the profits of the licensee exceed the licensing fee under compulsory licensing and $W^{CL} > 0$. If $\varphi^{CL} < \mu \left(\pi^E(\bar{p}) - \pi^L(\bar{p}, \gamma) \right)$, it is possible that the cost of the compulsory license exceeds the profits that earned by the license. Compulsory licensing is still possible in this case as long as the losses of the licensee are less than the amount of consumer surplus generated by the compulsory license (where we assume the government subsidizes the local firm to ensure participation if $\mu \pi^L(\bar{p}, \gamma) - f^{CL} < 0$). Since $\lim_{\gamma \to 0} S(\min[\bar{p}, \frac{\gamma q^E}{2}], \gamma q^E) + \pi^L(\bar{p}, \gamma) = 0$, there exists γ sufficiently small such that the total surplus generated for Southern consumers and the licensee is insufficient to cover the fee paid to the patent-holder. Thus, compulsory licensing fails to be a credible threat for some levels of the fixed cost φ if the South's product quality is so low that $W^{CL} < 0$. We can thus define

$$\varphi^{CL} \equiv \max[\arg \min_{\varphi} W^{CL} \geq 0, 0] \quad (7)$$

to be the threshold value of the entry cost above which the government issues the compulsory license if the patent-holder fails to work the patent locally.[14] The following

[13] The nature of our results would not be affected if compensation under compulsory licensing is specified as a minimum royalty rate per unit that must be paid to the patent-holder. Since the primary role of compensation under compulsory licensing is to serve as a threat point in the bargaining game under voluntary licensing, what matters in terms of equilibrium outcomes is the total payment that is received by the patent-holder in the event of licensing.

[14] An alternative assumption would be that the government believes that if it does not issue a compulsory license, the patent-holder chooses its profit maximizing mode of entry. Under this assumption, $\varphi^{CL} = \mu(\pi^E(\bar{p}) - \pi^L(\bar{p}, \gamma))$. The qualitative nature of our results does not depend on which of these assumptions is used.

result can now be stated:

Lemma 1: *If the product is not supplied to the South as a result of the stage two negotiations, the government issues a compulsory license to the local firm iff* $\varphi > \varphi^{CL}$ *where* φ^{CL} *is given by (7) and* $\varphi^{CL} < \mu\left(\pi^E(\bar{p}) - \pi^L(\bar{p},\gamma)\right)$. *If compulsory licensing occurs, the patent-holder receives the license fee given in (5).*

3.1 The Firm's Decision

We now turn to stage two where the patent-holder makes its decision on how to utilize the patent in the South market. If the patent-holder enters the Southern market, it earns a return of $\pi^E(\bar{p}) - \varphi$. If it chooses to license the product to the Southern firm, it engages in a bargaining game with the Southern firm to determine the size of the license fee f^{VL} that it receives. Given these payoffs, the patent-holder's optimal decision is as follows:

(i) enter if $\pi^E(\bar{p}) - \varphi \geq \max[0, f^{VL}]$;

(ii) choose voluntary licensing if there is a licensing fee that is acceptable to the Southern firm and the fee satisfies $f^{VL} > \max[0, \pi^E(\bar{p}) - \varphi]$; and

(iii) not work the patent in the South otherwise.

We assume that the bargaining game for licensing is one in which the patent-holder makes a take it or leave it offer to the Southern firm. If the offer is accepted then the Southern firm acts as a licensee and pays the fee f^{VL}. If the offer is rejected then the Southern firm can request a compulsory license from its government in the next period. In the absence of compulsory licensing or if the Southern government were choose not to grant a compulsory license in response to a request from the South firm, the Southern firm earns zero profits if it rejects the patent-holder's offer of a license. The maximum license fee that the patent-holder can earn is $f^{VL} = \pi^L(\bar{p},\gamma)$, which drives the Southern firm to zero profits. When the threat of compulsory licensing is credible (i.e. $\varphi \geq \varphi^{CL}$ from Lemma 1), the best the patent-holder can do in the voluntary licensing game is to make the Southern firm indifferent between paying f^{VL} and waiting to obtain a compulsory license in the next period. The present value payoff to the Southern firm in the event of compulsory licensing will be $(1-\sigma)\pi^L(\bar{p},\gamma)$ where $\sigma \equiv 1 - \beta\mu(1-\lambda))$, so the maximum fee that the patent-holder can charge under voluntary licensing is

$f^{VL} = \sigma\pi^L(\bar{p}, \gamma)$.

Given that the threat of compulsory licensing is credible, the condition for the patent-holder to prefer voluntary licensing (with the fee f^{VL}) to entry is

$$\varphi > \Delta\pi^E(\bar{p}, \gamma, \sigma) \equiv \pi^E(\bar{p}) - \sigma\pi^L(\bar{p}, \gamma). \tag{8}$$

When compulsory licensing is not a credible threat, the patent-holder captures all of the licensee's profits and it prefers entry to licensing if $\varphi > \Delta\pi^E(\bar{p}, \gamma, 1)$. Using (8) and Lemma 1, we have the following chain of inequalities:

$$\Delta\pi^E(\bar{p}, \gamma, \sigma) > \Delta\pi^E(\bar{p}, \gamma, 1) \geq \mu\left(\pi^E(\bar{p}) - \pi^L(\bar{p}, \gamma)\right) > \varphi^{CL}$$

These inequalities can be interpreted as follows. Since $\sigma < 1$, when compulsory licensing is a credible threat the patent-holder captures only a share of the profits under licensing and thus finds entry relatively more attractive. The second inequality simply says that, given that compulsory licensing is credible, if the patent holder prefers licensing to entry in the second period then it also prefers it in the first period.

By lemma 1, if the patent-holder prefers licensing in the second period then it is optimal for the government to issue a compulsory license so as to lower the rent transferred to the patent-holder. Foreseeing this, the patent-holder chooses voluntary licensing in the first period with a fee of $f^{VL} = \sigma\pi^L(\bar{p}, \gamma)$ for $\varphi > \Delta\pi^E(\bar{p}, \gamma, \sigma)$. For $\varphi \in [\varphi^{CL}, \Delta\pi^E(\bar{p}, \gamma, \sigma)]$, the patent-holder opts for entry in the first period: in this region, the threat of compulsory licensing serves to lower the fee that the patent-holder can potentially collect under voluntary licensing. Finally, for $\varphi < \varphi^{CL}$ compulsory licensing is not credible. The patent holder's entry costs are sufficiently low in this region that it prefers entry even though it can extract all of the licensee's profits under voluntary licensing. Thus, *the patent holder necessarily prefers entry when compulsory licensing is not credible.*

These arguments establish the following result:

Proposition 1*: In the compulsory licensing game, the patent-holder enters at the first stage if* $\varphi < \Delta\pi^E(\bar{p}, \gamma, \sigma)$ *whereas it issues a voluntary license with the license fee* $f^{VL} = \sigma\pi^L(\bar{p}, \gamma)$ *if* $\varphi \geq \Delta\pi^E(\bar{p}, \gamma, \sigma)$ *where* $\sigma = (1 - \beta\mu(1 - \lambda))$.

Under our assumptions, compulsory licensing is not observed in equilibrium since the equilibrium involves either entry or the issuance of a voluntary license at the first

stage. In other words, by working the patent, the patent-holder preempts the use of compulsory licensing by the government. However, the possibility of compulsory licensing strengthens the bargaining position of the Southern firm for all values of the entry cost φ for which the government's threat to issue a compulsory license is credible. In addition, the existence of compulsory affects the entry decision of the patent-holder by altering the range of entry costs over which it chooses to grant a voluntary license.

We can use Proposition 1 to derive results for the effect of changes in σ and other parameter changes on the patent-holder's entry decision. Using (1) and (2), this profit differential can be expressed as

$$\Delta\pi^E(\bar{p},\gamma,\sigma) = \begin{cases} \frac{(1-\gamma\sigma)q^E}{4} & \bar{p} \geq \frac{q^E}{2} \\ \bar{p}(1-\frac{\bar{p}}{q^E}) - \frac{\sigma\gamma q^E}{4} & \frac{\gamma q^E}{2} < \bar{p} < \frac{q^E}{2} \\ \bar{p}(1-\sigma) + \frac{\bar{p}^2}{q^E}\left(\frac{\sigma-\gamma}{\gamma}\right) & \bar{p} < \frac{\gamma q^E}{2} \end{cases} \tag{9}$$

Differentiation of (9) yields the following result:

Corollary 1*:*

(a) As the price control becomes more lax (i.e. $\bar{p}$ increases) for $\bar{p} < \frac{q^E}{2}$, the threshold value of the entry cost φ above which voluntary licensing is preferred to entry by the patent-holder increases ($\frac{\partial\Delta\pi^E(\bar{p},\gamma,\sigma)}{\partial\bar{p}} > 0$).

(b) As the share of licensee profits captured by the patent holder in a voluntary license (σ) increases, the threshold above which licensing is preferred decreases, ($\frac{\partial\Delta\pi^E(\bar{p},\gamma,\sigma)}{\partial\sigma} < 0$).

(c) As the quality of the licensee's product (γ) increases, the threshold above which licensing is preferred decreases ($\frac{\partial\Delta\pi^E(\bar{p},\gamma,\sigma)}{\partial\gamma} < 0$).

The intuition for why entry becomes more likely as the price control becomes more lax is quite straightforward: a price control is more binding under entry since the optimal price under entry is relatively higher. Figure 1 illustrates the relationship between $\Delta\pi^E(\bar{p},\gamma,\sigma)$ and $\bar{p}$ for $\gamma = .5$ and $\sigma \in \{.3,.7,1\}$. For $\bar{p} < \frac{\gamma q^E}{2}$, the price control binds for both the licensee and the entrant. Over this range, increases in the price control raise the profits of entry more than those for licensing for all $\gamma < 1$ due to the entrant's

higher volume of sales. For $\frac{\gamma q^E}{2} < \bar{p} \in [\frac{\gamma q^E}{2}, \frac{q^E}{2})$, the price control binds for the entrant but not the licensee. Relaxing the price control increases the profit under entry in this region but has no effect on licensing profits since the price control exceeds the optimal price of the licensee. For $\bar{p} \geq \frac{q^E}{2}$, the price control does not bind for either the licensee or the entrant. As a result, the range over which the threat of compulsory licensing induces a switch from licensing to entry on the part of the patent-holder shrinks as the price control becomes tighter. An important implication of this is that while a price control can improve access by lowering price, it cannot induce a switch to direct entry on the part of the patent-holder and cannot therefore increase the likelihood of the local economy obtaining access to the high quality good. This suggests that the two instruments (compulsory licensing and price controls) play rather different roles in affecting access to patented goods in developing countries – a theme to which we return later. Furthermore, as we noted earlier, the low quality of licensed production is indeed an important practical consideration for developing countries and stringent price controls work against the objective of improving the quality of drugs available to local consumers.

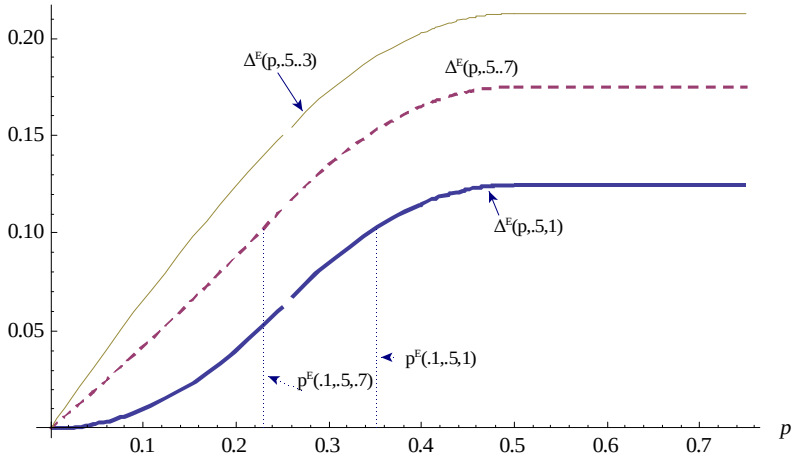

Figure 1: Profit Differential Between Entry and Licensing

An increase in the patent holder's share of licensing profit that accrues to the patent-holder under the shadow of compulsory licensing, σ, or an increase in the quality of the licensee's product, γ, will make licensing more makes licensing more attractive and raise the entry threshold. The effects of changes in σ on the licensing threshold are

illustrated in Figure 1. The parameter σ captures two features of the rules regarding compulsory licensing that affect the licensee's return through its impact on the threat value of compulsory licensing. One is the level of compensation that must be paid to the patent holder, because a lower λ reduces the equilibrium license payment under voluntary licensing. The second feature is the delay required before compulsory licensing can be enforced. Greater delay results in a lower value place on future returns, β, as well as a shorter horizon over which returns can be earned from the patent (i.e. lower μ). Each of these aspects of delay reduces the value to the licensee of waiting for a compulsory license, and thus reduces the equilibrium license payment.

3.2 Welfare

Proposition 1 can be used to evaluate the impact of introducing the option to issue a compulsory license on the welfare of the South and of the world as a whole. First consider Southern welfare. For $\varphi \geq \Delta\pi^E(\bar{p}, \gamma, \sigma)$, the South is better off when it can use compulsory licensing. In this range licensing occurs with or without compulsory licensing, but the credible threat of compulsory licensing shifts profits from the patent-holder to the licensee by lowering the licensing fee f^{VL} by the amount $(1-\sigma)\pi^L(\bar{p}, \gamma)$. For $\varphi < \Delta\pi^E(\bar{p}, \gamma, 1)$, compulsory licensing has no effect on Southern welfare because the Northern patent-holder enters with or without compulsory licensing. For $\varphi \in [\Delta\pi^E(\bar{p}, \gamma, 1), \Delta\pi^E(\bar{p}, \gamma, \sigma))$, the threat of compulsory licensing causes the entrant to switch from voluntary licensing to entry. Since the licensee obtains no surplus in the absence of compulsory licensing, we have from (3) and (4) that the effect of this switch on South welfare equals

$$S(\min[\bar{p}, \frac{q^E}{2}], q^E) - S(\min[\bar{p}, \frac{\gamma q^E}{2}], \gamma q^E) > 0$$

The South benefits from the switch from licensing to entry on the part of the patent-holder because consumers obtain greater consumer surplus from the higher quality of the entrant. Thus, we obtain the result that the South is at least as well off under compulsory licensing for all values of φ.

Proposition 2*: The ability to use compulsory licensing increases Southern welfare for all levels of entry costs at which licensing occurs, and also for all entry costs for which compulsory licensing induces the patent-holder to switch from licensing to entry.*

Consider world welfare next. Since the licensing fee is merely a transfer profit from the local Southern firm to the patent-holder, aggregate world welfare equals the sum of the patent-holder's profit and Southern consumer surplus. For $\varphi \geq \Delta\pi^E(\bar{p}, \gamma, \sigma)$, world welfare is unaffected by compulsory licensing because it merely transfers a share of σ of the profit from the patent-holder to the local licensee. The existence of compulsory licensing also has no effect on world welfare for $\varphi < \Delta\pi^E(\bar{p}, \gamma, 1)$ because it does not alter the patent-holder's entry decision.

For $\varphi \in [\Delta\pi^E(\bar{p}, \gamma, 1), \Delta\pi^E(\bar{p}, \gamma, \sigma))$, the patent-holder switches from voluntary licensing to entry with the introduction of a compulsory licensing regime. The difference between world welfare under compulsory licensing and world welfare without compulsory licensing is

$$\begin{aligned} WW(\bar{p}, \gamma, \sigma) - WW(\bar{p}, \gamma, 1) &= \left[S(\min[\bar{p}, \frac{q^E}{2}], q^E) - S(\min[\bar{p}, \frac{\gamma q^E}{2}], \gamma q^E)\right] \\ &\quad + \left[\Delta\pi^E(\bar{p}, \gamma, 1) - \varphi\right] \end{aligned} \tag{10}$$

Equation (10) identifies two conflicting effects of compulsory licensing on world welfare in this interval. The first term must be positive for $\gamma < 1$ and reflects the fact that increased entry under compulsory licensing raises consumer welfare by providing consumers with a higher quality product. The second term is non-positive on $\varphi \in (\Delta\pi^E(\bar{p}, \gamma, 1), \Delta\pi^E(\bar{p}, \gamma, \sigma))$ because the switch by the patent-holder from licensing to entry in the compulsory licensing regime lowers its profits. The former effect necessarily dominates for entry costs sufficiently close to $\Delta\pi^E(\bar{p}, \gamma, 1)$. However, there exists a critical value of the entry cost, which we denote by φ^G, such that (10) is negative for $\varphi > \varphi^G$. Therefore, if $\Delta\pi^E(\bar{p}, \gamma, \sigma) > \varphi^G$, the existence of compulsory licensing reduces world welfare when the entry cost satisfies $\varphi \in (\varphi^G, \Delta\pi^E(\bar{p}, \gamma, \sigma)]$.

The following proposition, proven in the Appendix, establishes conditions under which world welfare may decline for some levels of fixed costs under compulsory licensing.

Proposition 3: *Compulsory licensing has no effect on world welfare when it does not affect the patent-holder's decision regarding its mode of entry into the Southern market. For $\varphi \in [\Delta\pi^E(\bar{p}, \gamma, 1), \Delta\pi^E(\bar{p}, \gamma, \sigma))$, there exists a $\sigma^*(\bar{p}, \gamma) \in [0, 1)$ such that:*

(a) if $\sigma \geq \sigma^*(\bar{p}, \gamma)$, compulsory licensing increases world welfare for all values of entry costs in the interval and

(b) if $\sigma < \sigma^*(\bar{p}, \gamma)$*, there exists a* $\varphi^G \in (\Delta\pi^E(\bar{p}, \gamma, 1), \Delta\pi^E(\bar{p}, \gamma, \sigma))$ *such that compulsory licensing increases world welfare for* $\varphi \in [\Delta\pi^E(\bar{p}, \gamma, 1), \varphi^G)$ *whereas it decreases world welfare for* $\varphi \in (\varphi^G, \Delta\pi^E(\bar{p}, \gamma, \sigma)]$.

The intuition for this result is simple. As compulsory licensing becomes more stringent the firm is more prone to choosing entry as established in Proposition 1. However, the threshold φ^G below which entry is more desirable than licensing from a global welfare perspective is independent of σ because σ merely determines how profits are shared between the patent-holder and the licensee. If the compulsory licensing regime is not too strict, in the sense that $\sigma \geq \sigma^*(\bar{p}, \gamma)$, it results in a welfare improvement for all φ at which the patent-holder switches from voluntary licensing to entry. However, if $\sigma^*(\bar{p}, \gamma) > 0$, there exist compulsory regimes sufficiently strict that world welfare is reduced by the switch from entry to voluntary licensing. The impact of various parameters on this threshold value of σ is given in:

Proposition 4: *The critical value* $\sigma^*(\bar{p}, \gamma)$ *above which compulsory licensing increases world welfare over* $\varphi \in [\Delta\pi^E(\bar{p}, \gamma, 1), \Delta\pi^E(\bar{p}, \gamma, \sigma))$ *has the following properties:*

(a) $\frac{\partial\sigma^*}{\partial\bar{p}} \geq 0$ *with strict inequality for* $\sigma^*(\bar{p}, \gamma) \in (0, 1)$ *and* $\bar{p} \in (0, \frac{q^E}{2})$.

(b) $\frac{\partial\sigma^*}{\partial\gamma} \geq 0$*, with* $\sigma^*(\bar{p}, \gamma) = 0$ *for* $\gamma \leq \frac{1}{3}$ *and* $\sigma^*(\bar{p}, 1) = 1$.

Part (b) shows that compulsory licensing is more likely to be damaging to world welfare for some values of φ in cases where the licensee produces a high quality product. This can be illustrated using the case where the price ceiling does not bind, which yields $\sigma^*(\bar{p}, \gamma) = \min[\frac{3}{2} - \frac{1}{2\gamma}, 0]$. For $\gamma \leq \frac{1}{3}$, the licensee is so inefficient relative to the patent-holder that the switch from licensing to entry induced by the existence of compulsory licensing must raise world welfare. The large quality gap means that the effect of entry on consumer surplus must dominate any loss in firm profits. For $\gamma > \frac{1}{3}$, on the other hand, the quality of the licensee's product is sufficiently high that entry occurs for some $\varphi > \varphi^G$ when $\sigma < \frac{3}{2} - \frac{1}{2\gamma}$. The fact that the threshold σ^* equals unity when there is no North-South technology gap (i.e. $\gamma = 1$) means that the inequality $\sigma \leq \sigma^*(1)$ is necessarily satisfied and the firm chooses entry over the range $\varphi \in [\varphi^G(1), \Delta\pi^E(1, \sigma))$ whereas licensing is globally optimal for any positive φ. Part (a) shows that a stricter price control makes it less likely that compulsory licensing is damaging to world welfare.

This occurs because a stricter price control raises consumer surplus relatively more under entry than for licensing due to the larger output sold by the patent-holder.

4 Endogenous Price Ceiling

We now extend the analysis by allowing the government to choose the price ceiling $\bar{p}$. We assume that the government can commit to a price ceiling prior to the entry decision of the patent-holder, so that the price ceiling decision is modeled by augmenting the compulsory licensing game with a stage 0 in which the government chooses $\bar{p}$.[15] In making its pricing decision, the government takes into account the impact of the price control on the entry decision of the patent-holder in the compulsory licensing game. If follows from Corollary 1 that for $\varphi \in (0, \Delta\pi^E(\frac{q^E}{2}, \gamma, \sigma))$, there exists a reservation price, p^E, at which the patent-holder is indifferent between entry and licensing. This reservation price is the solution to $\varphi = \Delta\pi^E(p^E, \gamma, \sigma)$. Corollary 1 also ensures that for entry costs in this interval, we can use the implicit function theorem to obtain $p^E(\varphi, \gamma, \sigma)$, which has the following properties:

Lemma 2: *The reservation price $p^E(\varphi, \gamma, \lambda)$ above which the patent-holder prefers entry to licensing is increasing in φ, γ, and σ for $\varphi \in (0, \Delta\pi^E(\frac{q^E}{2}, \gamma, \sigma))$.*

Intuitively, factors that increase the attractiveness of licensing, such as an increase in entry cost, a decline in the stringency of compulsory licensing policy, or an increase in the productivity of the licensee, raise the reservation value for entry because the patent-holder has to be compensated for foregoing the voluntary license. The effect of an increase in σ on the reservation value is illustrated in Figure 1. Proposition 1 establishes that the patent-holder enters if $\bar{p} \geq p^E(\varphi, \gamma, \sigma)$ which means that Southern welfare equals $S(\bar{p}, q^E)$ for $\bar{p} \in [p^E(\varphi, \gamma, \lambda), \frac{q}{2}]$. Since consumer surplus is decreasing in the price ceiling, setting $\bar{p} = p^E(\varphi, \gamma, \sigma)$ maximizes Southern welfare over the set of price controls for which the firm enters.

[15] It should be noted that, in this model, the patent-holder would never enter the South in the absence of such a commitment, because the government's welfare would be maximized by setting $\bar{p}$ equal to the entrant's marginal cost if it made the decision post entry. Indeed, as the available case study evidence suggests, price negotations generally tend to occur prior to entry/licensing decisions of patent holders.

For $\bar{p} \in [0, p^E(\varphi, \gamma, \sigma))$ or $\varphi > \Delta\pi^E(\frac{q^E}{2}, \gamma, \sigma)$, the patent-holder chooses licensing and Southern welfare is given by

$$S(\min[\bar{p}, \frac{\gamma\bar{q}}{2}], \gamma\bar{q}) + (1-\sigma)\pi^L(\bar{p}, \gamma)$$

Since the sum of consumer surplus and firm profits is maximized at marginal cost, $\bar{p} = 0$ maximizes Southern welfare over the set of price controls for which the firm chooses licensing. This discussion implies that the government's optimal policy is either to choose a price of 0 and obtain a product with quality γq^E from the licensee or to choose a price equal to the patent-holder's reservation price $p^E(\varphi, \gamma, \sigma)$ and obtain a higher quality product. This policy results in entry with price equal to the firm's reservation price when $\varphi \leq \Delta\pi^E(\frac{q^E}{2}, \gamma, \sigma)$ and licensing at $\bar{p} = 0$ otherwise. The former yields a surplus of a surplus $S(p^E, q^E)$ while the latter yields $S(0, \gamma q^E) = \frac{\gamma q^E}{2}$. A comparison of these outcomes yields the optimal decision rule for the government regarding price controls:

Proposition 5*: If the reservation price for entry by the patent-holder, $p^E(\varphi, \gamma, \sigma)$, is no greater than $p^S(\gamma) \equiv q^E(1-\sqrt{\gamma})$, the government chooses $\bar{p} = p^E(\varphi, \gamma, \sigma)$. If $p^E(\varphi, \gamma, \sigma) > p^S(\gamma)$, the government sets the price control to the licensee's break even price (which is zero) and the firm chooses licensing.*

If $\gamma \leq 1/4$, then $p^S(\gamma) \geq \frac{q^E}{2}$. Over this range the quality of the licensee's product is so low that the government does not impose any price control on the entrant since it is never optimal to induce licensing. As a result, the market outcome coincides with that which obtains in the absence of a price control. For $\gamma \in (1/4, 1]$, we have $p^S(\gamma) \in [0, \frac{q^E}{2})$. Here, the technology disadvantage suffered by the local producer is not so large that entry is always preferable from the South's viewpoint. Entry occurs with a binding price control at the entrant's reservation price $p^E(\varphi, \gamma, \sigma)$ when $\varphi \leq \Delta\pi^E(p^S(\gamma), \gamma, \sigma)$ and licensing at $\bar{p} = 0$ otherwise.

Combining these results, the maximum level of entry costs at which the firm enters under compulsory licensing and the South's optimal price control is given by

$$\Phi(\gamma, \sigma) = \Delta\pi^E(\min[p^S(\gamma), \frac{q^E}{2}], \gamma, \sigma)$$

Using (9), we obtain

$$\Phi(\gamma,\sigma)=\begin{cases}\frac{(1-\gamma\sigma)q^E}{4} & \gamma\leq\frac{1}{4}\\ q^E\left(\sqrt{\gamma}-\gamma\left(1+\frac{\sigma}{4}\right)\right) & \frac{1}{4}<\gamma\leq 2(2-\sqrt{3})\\ \frac{q^E}{\gamma}\left(\sigma-2\sqrt{\gamma}\sigma+\gamma^{3/2}(1+\sigma)-\gamma^2\right) & \gamma>2(2-\sqrt{3})\end{cases} \tag{11}$$

This relationship is illustrated in Figure 2. Entry occurs for values of the fixed cost φ lying below the $\Phi(\gamma,\sigma)$ curve, and licensing for values above it. As compulsory licensing becomes stricter, the threshold level of fixed cost below which entry occurs increases.

Increases in the technology gap γ have two effects on the entry threshold under an optimal price control. The direct effect is to make raises the profitability of licensing for a given $\bar{p}$. The second effect, which arises if $\gamma>\frac{1}{4}$, is to lower the maximum price ceiling the government is willing to allow for an entrant. Both of these effects work in the direction of reducing the maximum value of φ below which the patent-holder prefers entry to licensing, so the $\Phi(\gamma,\sigma)$ locus must be downward sloping as illustrated in Figure 2. Increases in σ raise the attractiveness of licensing, leading to a downward shift in the locus.

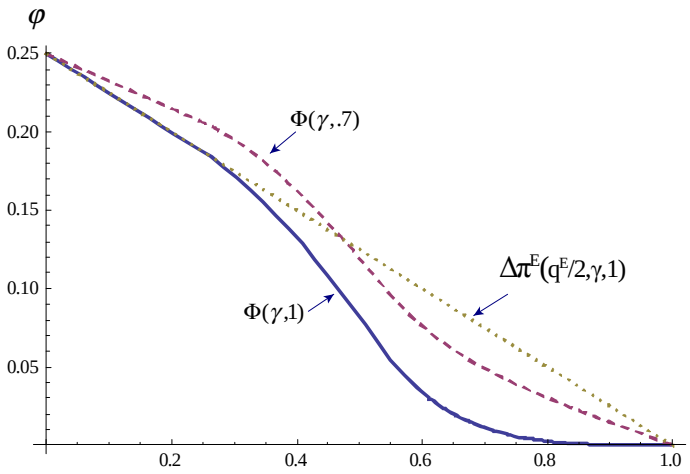

Figure 2: Threshold for Licensing with Price Controls

4.1 Price Controls, Compulsory Licensing, and Entry

Proposition 1 established that in the absence of compulsory licensing or price controls, a stricter compulsory licensing regime expands the range of entry costs over which the

patent-holder enters, since $\Delta\pi^E(\frac{q^E}{2},\gamma,\sigma)$ is decreasing in σ. The corollary to Proposition 1 showed that stricter price controls reduce the profits from entry relatively more than those from voluntary licensing, leading to a reduction in the range of entry costs for which the firm enters. These results indicate that introducing price controls and compulsory licensing have conflicting effects on entry. This raises the question of whether the introduction of compulsory licensing and price controls together leads to more or less entry than would have occurred without either policy instrument being employed.

The threshold under entry without compulsory licensing or price controls is $\Delta\pi^E(\frac{q^E}{2},\gamma,1) = \frac{(1-\gamma)q^E}{4}$, which as illustrated by the dotted line in Figure 2. The threshold with price controls and compulsory licensing is $\Phi(\gamma,\sigma)$, so the combined policies yield greater entry if $\Phi(\gamma,\sigma) > \Delta\pi^E(\frac{q^E}{2},\gamma,1)$. For $\gamma \leq \frac{1}{4}$, the government is willing to allow a price control of up to $\frac{q^E}{2}$ to ensure entry of the patent-holder, so $\Phi(\gamma,\sigma) - \Delta\pi^E(\frac{q^E}{2},\gamma,1) = \frac{\gamma(1-\sigma)q^E}{4}$. Price controls and compulsory licensing yield a higher level of entry for all $\sigma < 1$ and $\gamma \leq \frac{1}{4}$. In this case the technology gap is sufficiently large that the government is willing to forego restrictions on prices for the marginal entrant, so the increase in bargaining power of the licensee due to compulsory licensing expands the range of entry costs over which the firm prefers to enter. For $\gamma > \frac{1}{4}$, on the other hand, the technology gap is smaller and price controls bind for the marginal entrant. For $\sigma = 1$ and $\gamma > \frac{1}{4}$, we have less entry with price controls because $\Phi(\gamma,1) < \Delta\pi^E(\frac{q^E}{2},\gamma,1)$ as illustrated in Figure 2. It then follows that the combined use of compulsory licensing and price controls leads to less entry for σ sufficiently close to 1.

As compulsory licensing becomes stricter, the $\Phi(\gamma,\sigma)$ locus shifts upward in Figure 2 and the range of values of γ for which compulsory licensing and price controls lead to greater entry expands. This is illustrated by the comparison of the $\Phi(\gamma,.7)$ locus and the $\Delta\pi^E(\frac{q^E}{2},\gamma,1)$ line in Figure 2 – the threshold that determines the firm's choice between entry and licensing in the absence of either instrument. Furthermore, we can establish that the combined policies of compulsory licensing and price controls lead to more entry for σ sufficiently small. Using (11), $\Phi(\gamma,0) - \Delta\pi^E(\frac{q^E}{2},\gamma,1) = \frac{q^E}{4}(4\sqrt{\gamma} - 3\gamma - 1) > 0$ for $\gamma \in (\frac{1}{4},1)$. Therefore, $\Phi(\gamma,\sigma) - \Delta\pi^E(\frac{q^E}{2},\gamma,1) > 0$ for all $\gamma \in [0,1)$ for σ sufficiently close to 0.

4.2 Welfare Effects of Compulsory Licensing and Price Controls

The ability to vary the level of the price control provides a second instrument for the government. Proposition 2 shows that for a given level of λ it is in the interest of the government to reduce the price to the minimum level consistent with the desired entry/licensing outcome, so that the use of price controls yields a higher welfare level than can be obtained with compulsory licensing alone.

Price controls have two features that make them a useful instrument for the government. One is that they affect Southern welfare whether the patent-holder chooses entry or licensing. This contrasts with compulsory licensing, which does not affect the payoff of patent holders who would enter even in the absence of compulsory licensing when the price control is exogenous. A second feature is that price controls can be negotiated on a case by case basis, so that the government can tailor the control to maximize the surplus for a given entry cost.

A natural question to ask is whether the ability of the government to set a price control makes compulsory licensing a redundant policy instrument. To address this question, consider the effect of a change in σ on the payoff to the government for a case with $\varphi < \Phi(\gamma, \sigma)$, which is $S(p^E(\varphi, \gamma, \sigma), q^E)$. A stricter compulsory licensing policy lowers the entry threshold of the patent-holder, since $p^E(\varphi, \gamma, \sigma)$ is increasing in σ. This results in an increase in Southern welfare due to the reduced price. Note, however, that compulsory licensing still plays a useful role for the government because it makes licensing less attractive to the firm, which allows the South to extract greater surplus from an entering firm. Thus, compulsory licensing and price controls are *complementary instruments* from the point of view of the government.

From the perspective of world welfare, a change in $\bar{p}$ affects welfare through two channels. The first channel is the effect of a change in $\bar{p}$ on consumer surplus and the patent-holder's profits for a given production mode. Since an increase in the price ceiling reduces consumer surplus by more than the increase in profits, the imposition of price controls raises welfare for all values of φ so long as the mode of entry does not change. The second channel is the effect of the price control on the entry decision of the marginal patent-holder, which is given by $\frac{\partial \Delta \pi^E(\bar{p}, \gamma, \sigma)}{\partial \bar{p}} > 0$ in Proposition 1. A switch from licensing

to entry raises consumer surplus by the amount

$$S(\min[\bar{p}, \frac{q^E}{2}], q^E) - S(\min[\bar{p}, \frac{\gamma q^E}{2}], \gamma q^E)$$

while the impact on profits is given by $\Delta\pi^E(\bar{p}, \gamma, 1) - \varphi$. Since the marginal firm earns a profit of $\Delta\pi^E(\bar{p}, \gamma, \sigma)$, a switch from entry to licensing reduces worldwide profits by $(1-\sigma)\pi^L(\bar{p}, \gamma)$. Therefore, a switch from entry to licensing as a result of an increase in $\bar{p}$ raises world welfare if

$$\left(S(\min[\bar{p}, \frac{q^E}{2}], q^E) - S(\min[\bar{p}, \frac{\gamma q^E}{2}], \gamma q^E)\right) + (\sigma - 1)\pi^L(\bar{p}, \gamma q^E) > 0$$

which is equivalent to the requirement that

$$\sigma > \sigma^*(\bar{p}, \gamma)$$

Thus, a reduction in the price ceiling causes the marginal patent-holder to switch from entry to voluntary licensing, which has a favorable effect on world welfare iff $\sigma < \lambda^*(\bar{p}, \gamma)$. Proposition 3 established conditions under which the use of compulsory licensing caused a suboptimal switch from voluntary licensing to entry. Since the price ceiling has the opposite effect on the marginal patent-holder's decision (i.e. causes a switch from entry to voluntary licensing), the effect of this switch on world welfare is positive.

5 Conclusion

High prices or outright unavailability of patented foreign goods (such as pharmaceuticals) often prompt governments to undertake policies that can potentially improve consumer access. The two types of policies that have been used frequently in this context are price controls and compulsory licensing. To the best of our knowledge, there exists no formal analysis of the role these policies play in improving consumer access to patented foreign goods as well as of their welfare effects more generally. Given the human welfare cost at stake, it is imperative that our understanding of these policies be improved. Motivated by the rules specified in the TRIPS agreement and the actual experience of several developing countries with compulsory licensing, this paper develops a model that sheds light on the effects of compulsory licensing as well as its interaction with price controls.

The model is designed to capture actual WTO rules quite closely. In particular, the Southern government is allowed to use compulsory licensing only if the Northern firm/patent-holder fails to work the patent locally. However, since monopoly pricing by the patent-holder can erode consumer access, we also allow the South to impose a price control on the patent-holder. The analysis provides several insights. First, the two instruments play rather different roles in terms of how they affect the patent-holder's decision to work the patent in the South: while the threat of compulsory licensing encourages entry, the use of a price control encourages voluntary licensing. This difference matters in our model because, consistent with the available case study evidence on compulsory licensing, the quality of production of the Southern licensee is below that of the patent-holder if it chooses to enter directly. Our results not only point to some clear distinctions between the two types of policy instruments, they also expose their limits in terms of improving consumer access to patented foreign goods. After all, if local technological capability is substantially lacking, too stringent a price control on the part of a developing country can simply prompt the patent-holder to not work the patent at all. Similarly, if local production suffers from too large a quality gap, the threat of compulsory licensing loses bite.

An important, albeit somewhat straightforward, result is that the option to use compulsory licensing benefits the South by either improving the terms at which voluntary licensing occurs or by causing the Northern patent-holder to switch from licensing to entry. The first channel implies that the South earns some rents from the licensing contract while the second channel leads to an improvement in the quality of the good available to local consumers. However, the effects of compulsory licensing on global welfare are not always sanguine: while a relatively lax compulsory licensing policy increases world welfare, too strict a compulsory licensing policy can lower it by inducing a suboptimal switch from licensing to entry. Finally, we show that a price control and compulsory licensing are complementary policy tools for the South: a stricter compulsory licensing policy makes it possible for the South to lower the price control under entry thereby improving consumer access.

6 Appendix

Proof of Proposition 3: Since (10) is decreasing in φ, compulsory licensing raises world welfare for all $\varphi \in (\Delta\pi^E(\bar{p},\gamma,1), \Delta\pi^E(\bar{p},\gamma,\sigma))$ if (10) is non-negative when evaluated at $\varphi = \Delta\pi^E(\bar{p},\gamma,\sigma)$. Therefore, compulsory licensing raises welfare for all values of φ at which patent holders switch from licensing to entry if

$$\left(S(\min[\bar{p}, \frac{q^E}{2}], q^E) - S(\min[\bar{p}, \frac{\gamma q^E}{2}], \gamma q^E)\right) + (\sigma - 1)\pi^L(\bar{p}, \gamma q^E) > 0 \qquad \text{(A1)}$$

The first term in parentheses is positive for $\gamma \in [0,1)$ as established in the text, so (A1) must be satisfied for $\sigma = 1$. Since (A1) is decreasing in σ, then $\sigma^*(\bar{p},\gamma)$ is the infimum over $\sigma \in [0,1]$ such that (A1) is satisfied. World welfare will be increased as a result of compulsory licensing for all $\varphi \in (\Delta\pi^E(\bar{p},\gamma,1), \Delta\pi^E(\bar{p},\gamma,\sigma))$ if $\sigma \geq \sigma^*$, which establishes (a). For $\sigma^*(\bar{p},\gamma) > 0$, $\varphi^G = \Delta\pi^E(\bar{p},\gamma,\sigma^*(\bar{p},\gamma))$. If $\sigma < \sigma^*$, welfare will decrease as a result of compulsory licensing for $\varphi \in (\varphi^G, \Delta\pi^E(\bar{p},\gamma,\sigma))$.||

Proof of Proposition 4: For $\bar{p} \geq \frac{q^E}{2}$, (A1) simplifies to $\frac{q^E}{8}\left(1 + 2\tilde{\lambda} - 3\gamma\right) > 0$. This yields $\sigma^*(\frac{q^E}{2},\gamma) = \min[\frac{3}{2} - \frac{1}{2\gamma}, 0]$, which is independent of $\bar{p}$ and non-decreasing in γ, with $\sigma^*(\bar{p},\gamma) = 0$ for $\gamma \leq \frac{1}{3}$ and $\sigma^*(\bar{p},1) = 1$.

(a) Effect of $\bar{p}$ on $\sigma^*(\bar{p},\gamma)$ for $\bar{p} < \frac{q^E}{2}$: The first term in parentheses is (A1) is decreasing in $\bar{p}$ because $\frac{\partial S(\bar{p},,q^E)}{\partial \bar{p}} - \frac{\partial S(\min[\bar{p},\frac{\gamma q^E}{2}],\gamma q^E)}{\partial \bar{p}}$ equals $-d(\bar{p},q^E) < 0$ for $\bar{p} \in (\frac{\gamma q^E}{2}, \frac{q^E}{2})$ and $-\left(d(\bar{p},q^E) - d(\bar{p},\gamma q^E)\right) < 0$ for $\bar{p} \in (0, \frac{\gamma q^E}{2})$. Since licensee profits are increasing in $\bar{p}$, (A1) is decreasing in $\bar{p}$. Therefore, $\sigma^*(\bar{p},\gamma)$ is increasing in $\bar{p}$ for $\sigma^*(\bar{p},\gamma) \in (0,1)$. Note that the limit of the first term in (A1) as $\bar{p} \to 0$ is strictly positive for $\gamma < 1$, whereas $\lim_{\bar{p}\to 0} \pi^L(\bar{p},\gamma) = 0$. Therefore, there will exist some $\bar{p} > 0$ such that $\sigma^*(\bar{p},\gamma) = 0$ for all $\gamma \in [0,1)$.

(b) Effect of γ on $\sigma^*(\bar{p},\gamma)$ for $\bar{p} < \frac{q^E}{2}$: The first term in parentheses is (A1) is decreasing in γ because consumer surplus for the licensee's product increases with quality. Licensee profits are increasing in γ, so (A1) is decreasing in γ and hence $\sigma^*(\bar{p},\gamma)$ is increasing in γ for $\sigma^*(\bar{p},\gamma) \in (0,1)$. Since $\sigma^*(\frac{q^E}{2},\gamma) = 0$ for $\gamma \leq \frac{1}{3}$, it follows from part (a) that the same result holds for $\bar{p} < \frac{q^E}{2}$. that $\sigma^*(\bar{p},\gamma) = 0$ for all $\bar{p} > 0$. For $\gamma = 1$, the first term in (A1) is 0 and $\pi^L(\bar{p},1) > 0$, so $\sigma^*(\bar{p},1) = 1$. ||

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