Vanderbilt University Department of Economics Working Papers 17-00013

Price controls versus compulsory licensing: effects on patent-holders and consumers

Eric W Bond
Vanderbilt University

Kamal Saggi
Vanderbilt University

Abstract

We extend the model of Bond and Saggi (2014) in which a patent-holder chooses between direct entry and the voluntary licensing of its technology to a local firm in a developing country. We compare two scenarios: one where the country imposes a price control on the patent-holder and another where it issues a compulsory license to the local firm if the patent-holder decides to neither enter nor license its technology voluntarily. A price control makes entry less attractive to the patent-holder relative to voluntary licensing whereas the threat of compulsory licensing has the opposite effect. While a price control always makes the patent-holder worse off, the option of compulsory licensing can sometimes be to its advantage.

Price controls versus compulsory licensing: effects on patent-holders and consumers

Eric Bond[*]   and   Kamal Saggi[†]
Department of Economics
Vanderbilt University

Abstract

We extend the model of Bond and Saggi (2014) in which a patent-holder chooses between direct entry and the voluntary licensing of its technology to a local firm in a developing country. We compare two scenarios: one where the country imposes a price control on the patent-holder and another where it issues a compulsory license to the local firm if the patent-holder decides to neither enter nor license its technology voluntarily. A price control makes entry less attractive to the patent-holder relative to voluntary licensing whereas the threat of compulsory licensing has the opposite effect. While a price control always makes the patent-holder worse off, the option of compulsory licensing can sometimes be to its advantage.

Keywords: Patented Goods, Compulsory Licensing, Voluntary Licensing, Price Controls, Quality, Welfare. *JEL Classifications*: F13, F10, F15.

[*]E-mail: eric.bond@Vanderbilt.Edu; phone: (+1) 615-322-2388.
[†]E-mail: k.saggi@Vanderbilt.Edu; phone: (+1) 615-322-3237.

1 Introduction

When the Doha Round of trade negotiations was launched in 2001, there was an expectation among developing countries that their interests would figure prominently in the ensuing negotiations. Indeed, the Doha ministerial conference explicitly stated that since majority of the members of the World Trade Organization (WTO) were developing countries, the Doha work programme would seek to place their needs and interests at its core. This was a welcome development from the viewpoint of developing countries, many of whom viewed the Uruguay Round (1986-1993) as having bequeathed a bargain that was biased in favor of developed countries. Perhaps the most problematic outcome of the Uruguay Round from the perspective of developing countries was the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) – a multilateral agreement that requires all WTO members, regardless of their level of economic development, to grant certain minimum levels of protection to all major forms of intellectual property.

Of course, by their very nature, intellectual property rights (IPRs) create monopoly power for rights holders. For example, the holder of a patent over an invention has the right to exclude others from making, using, or offering the invention for sale. The expansion in the global reach of such monopoly power via the world-wide enforcement of IPRs can be rather problematic in the realm of patented pharmaceuticals, at least some of which are frequently needed for addressing significant public health concerns. While the issue of affordability of patented pharmaceuticals takes on a special urgency in the context of poor developing countries, it is also relevant within the developed world. It is no surprise then that governments across the world use price controls and other such regulations to combat the monopoly power of firms selling patented pharmaceuticals.[1]

As one might expect, price regulation in the pharmaceutical industry has important consequences for consumers. For example, in her structural study of 155 pharmaceutical products sold in India during 2001-03, Dutta (2011) found that consumers derived substantial benefits from price controls. Similarly, Chatterjee et al. (2013) argue that the removal of price controls in the oral anti-diabetic segment of the Indian pharmaceutical market would have significant negative repercussions for consumers. While appealing, the use of price controls can become counter-productive if foreign pharmaceutical companies refuse to sell their patented medicines in markets where they find such controls to be too stringent. In her large sample study spanning 68 countries over the time period 1982-2002, Lanjouw (2005) found that the presence of price regulations in countries delayed the introduction of new drugs by pharmaceutical companies into their markets. Similar results were found by Kyle (2005) in her study of the 28 largest pharmaceutical

---

[1]It is noteworthy that while TRIPS requires patented inventions to be protected from imitation for a duration of twenty years, it does not constrain countries from combating the market power of patent-holders by the use of price regulations.

markets in the world. Thus, while price controls can be effective in improving consumer access to patented pharmaceuticals conditional on local availability, they run the risk that patent-holders deliberately choose to make their products unavailable in countries that impose them.

An alternative strategy that governments can use for providing local consumers access to patented foreign pharmaceuticals that are not sold locally is to issue compulsory licenses for such products to local firms.[2] Multilateral rules governing the use of compulsory licensing (CL) by member countries of the WTO are contained in Article 31 of TRIPS. As per this Article, the use of CL is only justified if the entity seeking a compulsory license has failed to obtain a voluntary license from the patent-holder on "reasonable" commercial terms. Furthermore, the government issuing the compulsory license has to ensure that "adequate remuneration" is paid to the patent-holder in return for the right to produce its patented product locally.[3] While Article 31 requires that any sales under CL should be predominantly for the domestic market of the country issuing the license, the 2001 Doha Ministerial conference relaxed this rule by allowing compulsory licenses for patented foreign products to be issued to producers in third countries. The objective of this modification was to bring CL within reach of those countries that lacked the technological capability to produce patented pharmaceuticals and other necessary products locally.

Building on related previous work (Bond and Saggi, 2014), in this paper we contrast the roles of price controls and CL as alternative instruments for improving consumer access to patented foreign products in developing countries. In the model, a developing country (called South) sets the level of the price control while the patent-holder chooses between direct entry and the voluntary licensing (VL) of its technology to a local firm. The model assumes that while the fixed costs incurred under VL are relatively lower, so is the quality of production. We compare two scenarios: one where the South attempts to improve consumer access via the use of a price control and another where it resorts to CL if the patent-holder chooses to not work its patent locally. In accordance with the available case-study evidence pertaining to the implementation of CL in developing countries, we assume that the local firm's quality of production under CL is lower than that under entry.[4] For simplicity, we assume that there is no quality differential between the two types of licensing.

---

[2]As Saggi (2016) notes, the right to issue a compulsory license is perhaps the most important flexibility that is available to WTO members under TRIPS.

[3]Overall, Article 31 seems to grant a fair bit of discretion to countries seeking to use CL. For example, "reasonable commercial terms" remains undefined and open to different interpretations. Similarly, it is far from clear as to what level of remuneration to the patent-holder should be considered "adequate" in the event of CL.

[4]For a discussion of some of the relevant case studies, see Baron (2008), Lybecker and Fowler (2009), Daemmrich and Musacchio (2011), Bond and Saggi (2014), and Harris (2014).

The analysis in Bond and Saggi (2014) focused on the case where the licensee's fixed cost advantage is large relative to its quality disadvantage and it showed that, depending on parameter values, the patent-holder may choose to serve the Southern market by either VL or entry in the absence of price controls. In this paper we consider the case where the licensee's fixed cost advantage is small relative to its quality disadvantage. The present case is likely to arise for sophisticated production processes in which a potential Southern licensee faces a significant handicap when attempting to undertake local production of the patented product and/or where the patent-holder has a high degree of familiarity with the Southern market so that the fixed cost disadvantage of entry is small. We show that in such a case, in the absence of a price control, the patent-holder either directly enters the market or it stays out – i.e. VL does not emerge in equilibrium when monopoly pricing is permitted. However, it turns out that the use of a price control by the South tilts the patent-holder's choice in favor VL. Indeed, we find that there exists a range of price controls and fixed costs for which VL can end up emerging in equilibrium. Intuitively, due to the higher quality of production under entry, the monopoly price under entry exceeds that under VL so that a price control penalizes the profitability of entry to a relatively larger degree.

Due to the presence of mode-specific fixed costs, both entry and VL can be unprofitable for the patent-holder even when its pricing is completely unconstrained by the South. Clearly, in such a situation, Southern consumers obtain no access to the product and the South's price control policy is rendered inconsequential. If only entry is profitable, it is optimal for the South to set the price control ($\bar{p}$) at a level that allows the patent-holder to just break even (i.e. cover its fixed cost of entry) – anything more stringent simply results in complete loss of access to the product. A price control set at the break-even price hurts the patent-holder by driving its net profit to zero but it increases Southern welfare.

When both modes of supply are profitable, a given price control ($\bar{p}$) is more binding under entry relative to VL since the optimal monopoly price under entry is higher due to the lower quality of production under VL (i.e. $p_E^* \geq p_L^*$ since $q_E \geq q_L$). When the break-even price under entry ($\bar{p}_E$) is lower than that under VL ($\bar{p}_L$), it is optimal for the South to set the price control at $\bar{p}_E$ since entry is doubly preferable to VL: it not only offers a higher quality product, it does so at a lower price than VL. However, when $\bar{p}_L \leq \bar{p}_E$, the South has to decide whether to set a price control that just allows the patent-holder to break-even under VL (i.e. set $\bar{p} = \bar{p}_L$) or to set a sufficiently lax price control at which the patent-holder prefers entry: even though profits are positive under both modes, the entry inducing price control $\widetilde{p}$ is such that entry is marginally more profitable for the patent-holder. Setting the price control $\bar{p} = \bar{p}_E$ is not optimal when $\bar{p}_E \geq \bar{p}_L$ since doing so induces the patent-holder to choose VL (under which it earns positive profit). From the patent-holder's viewpoint, the scenario where $\bar{p} > \bar{p}_E$

4

is necessarily better but the South also prefers it when the quality of production under VL is fairly low.

Our analysis shows that the option to use CL ensures that at least a lower quality version of the patented good is available locally if the patent-holder decides not to work its patent in the South. However, the very possibility of CL also makes it less likely that the patent-holder chooses to sell in the South. The threat of CL reduces the patent-holder's profits under VL by lowering the fee that the local licensee is willing to pay. Similarly, since the royalty payments under CL provide the patent-holder a return from the Southern market if it chooses to stay out, entry becomes relatively less attractive as well. When CL *replaces* entry, it can lower Southern welfare because it not only delivers a lower quality product to consumers, it does so with some *delay.*

Overall, our results show that the social value of CL is very much context dependent. When the fixed cost of entry is high relative to the size of the Southern market, CL plays a socially useful role that can be to the advantage of both the South and the patent-holder since the South obtains access while the patent-holder receives royalties from a market in which it would not have entered in the absence of CL. On the other hand, when fixed costs are of an intermediate level such that the patent-holder prefers to wait for CL rather than entering itself, the South is made worse off by the option of CL. Finally, when fixed costs are so small that the patent-holder chooses to enter regardless of whether the South has the option to issue CL or not, the threat of CL does not affect market outcomes and welfare.

The rest of the paper is organized as follows. Section 2 introduces the model of the patent-holder's choice between VL and entry and identifies the fixed cost/product quality trade-off between the two modes of supply. Section 3 analyzes the effect of price controls on the entry/licensing decision of the patent-holder and derives the South's optimal price control. Section 4 considers the alternative case under which the South does not use a price control, but has the ability to issue a compulsory license that is consistent with the relevant WTO rules. Here, we also compare the effects of price controls and CL on the patent-holder's decision and on the welfare of the two parties. Section 5 provides some concluding remarks.

2   Model

Since the basic purpose of the paper is to complete the analysis of the model of price controls and CL introduced in Bond and Saggi (2014), we begin by describing the basic structure of this model. Consider a Northern firm (referred to as the "patent-holder")

that produces a good protected by a patent for T periods. There are a continuum of Southern consumers of measure 1, each of whom buys (at most) one unit of the product. If a consumer buys the good at price p, its utility is $U = \theta q - p$ where q measures quality and $\theta \geq 0$ is a taste parameter that captures the willingness to pay for quality. For simplicity, θ is assumed to be uniformly distributed over the interval [0,1]. Normalizing utility under no purchase to zero, the per-period demand in the South is $d(p,q) = 1 - p/q$.

If the patent-holder decides to enter the Southern market and produce the good itself then its quality level equals q_E. To be able to produce the good, the patent-holder has to incur the fixed entry cost φ. The parameter φ captures the costs of obtaining any necessary approval from local authorities as well as the costs of establishing an effective marketing and distribution network.

The patent-holder can also sell its product in the South by licensing its technology to a local firm. For simplicity, we assume that there is only a single local firm with sufficient capability to be an effective licensee. Since the purpose of the model is to analyze the role of compulsory licensing (CL), we refer to the patent-holder choosing to license on its own terms as voluntary licensing (VL). Since VL allows the patent-holder to use the local licensee's existing distribution and retail network, the fixed cost of VL is assumed to be lower than that of direct entry and is denoted by $\alpha\varphi$ where $0 < \alpha < 1$.[5] The parameter α captures the fixed cost savings of VL relative to entry. The disadvantage of VL is that the quality of production under it (q_L) is lower than under entry: $q_L = \gamma q_E$ and $\gamma < 1$ captures the quality disadvantage of VL relative to entry.

Normalizing the cost of production under VL to zero, the monopoly price for the licensee equals $p_L^* = q_L/2$. The maximum gross profits accruing to the licensee over the life of the patent when facing the price control $\bar{p}$ are given by:

$$v_L(\bar{p}, q_L) = (1 + \Omega)\pi_L(\bar{p}, q_L) \text{ where } \pi_L(\bar{p}, q_L) \equiv \min[\bar{p}, p_L^*]\left(1 - \frac{\min[\bar{p}, p_L^*]}{q_L}\right) \quad (1)$$

where $\Omega = \sum_{t=1}^{T} \beta^t$ converts future flow profits to present value and $0 < \beta \leq 1$ is the per period discount factor.[6]

---

[5] Chatterjee et. al. (2013) discuss how Novartis decided to license vildagliptin (an ant-diabetic drug) to a local Indian firm called USV in order to take advantage of its established presence and reach in the market. A similar strategy was used by Merck to sell sitagliptin in India. Thus, one advantage of VL is that it allows patent-holders to utilize the established marketing and distribution networks of their local licensees.

[6] The distinction between first period and subsequent returns plays an important role in the analysis of compulsory licensing in Section 4, since we interpret the first period as the waiting period required before a compulsory license can be imposed by the South. This period is intended to capture the time window granted by TRIPS for the patent-holder to have an adequate opportunity to work its patent in the South.

Assuming that the marginal cost of production under entry is the same as that under VL, the present value of the maximum gross profits the patent-holder earns by selling in the South via direct entry when facing the price control $\bar{p}$ equals

$$v_E(\bar{p}) = (1 + \Omega)\pi_E(\bar{p}) \text{ where } \pi_E(\bar{p}) \equiv \min[\bar{p}, p_E^*]\left(1 - \frac{\min[\bar{p}, p_E^*]}{q_E}\right) \qquad (2)$$

where $p_E^* = q_E/2 > p_L^*$ is the unconstrained monopoly price under entry. The absence of a price control is then equivalent to $\bar{p} \geq p_E^*$.

Southern welfare under VL equals

$$W_L(\bar{p}, q_L) = (1 + \Omega)S(\min[\bar{p}, p_L^*], q_L) + \pi_L(\bar{p}, q_L)] - \alpha\varphi - f \qquad (3)$$

where f denotes the licensing fee paid to the patent-holder and $S(p, q_L) = (q_L/2)(1 - p/q_L)^2$ measures consumer surplus at price p and quality q_L. Southern welfare under entry (W_E) consists (solely) of consumer surplus that accrues to the South over the life of the (higher quality) product sold by the patent-holder:

$$W_E(\bar{p}, q_E) = (1 + \Omega)S(\min[\bar{p}, p_E^*], q_E) \qquad (4)$$

Thus, while VL has the potential to provide the South some benefits in terms of the profits of the local firm (net of the license fee), these benefits come at the cost of having a lower quality product relative to entry. If the market is not served, the South receives a payoff of 0.[7]

We begin with the benchmark case where the only instrument available to the South for improving consumer access is the price control $\bar{p}$. Then, we allow the South to use CL in the event the patent-holder does not work its patent in the South.

3   Price controls and consumer access

In what follows, we first analyze interaction between the patent-holder and the Southern government (referred to as simply "the South" from hereon) in a two stage game in which the South does not have the option to use CL if the patent-holder refrains from selling locally.

---

[7]Our analysis implicitly assumes that once the patent expires, the product is supplied by competitive generic producers so that Southern welfare equals the consumer surplus associated with the generic version of the product. We assume that the payoff following the expiration of the patent is independent of whether the product is supplied to the South as well as of the mode (entry or VL) via which it is supplied during the period when it is still under patent. This assumption allows us to simplify exposition by dropping the welfare accrued after the expiration of the patent from the South's payoff function.

In the first stage of the game, the South chooses its price control $\bar{p}$. To avoid any hold-up problem, we assume that once the price control has been set, the South is committed to it for the remainder of the game. Given the price control set by the South, the patent-holder chooses between entry, VL, and not selling in the South. Under VL, the patent-holder makes a take it or leave it offer to the Southern firm. If the Southern firm accepts the offer, it acts as a licensee and transfers the present value of its product market profit stream to the patent-holder as the licensing fee $f_L(\bar{p})$. This is because if it rejects the offer, the Southern firm earns zero profits since it lacks the right to produce the patented product independently.

3.1 Patent-holder's decision

To determine how the patent-holder's choice between VL and entry depends upon the price control $\bar{p}$, first note that since $p_E^* > p_L^*$ a given price control either (i) binds under neither entry nor VL (i.e. $\bar{p} = p_E^*$); (ii) binds only under entry (i.e. $p_L^* \leq \bar{p} < p_E^*$); or (iii) binds under both modes (i.e. $\bar{p} < p_L^*$).

Denote the present value of the patent-holder's payoff under monopoly pricing by v_Z^* where $Z = L$ or E. The present value differential between the two modes as a function of the price control $\bar{p}$ can be written as:

$$
\Delta v(\bar{p}) \equiv v_E(\bar{p}) - v_L(\bar{p}) =
\begin{cases}
\Delta v^* = v_E^* - v_L^* = \frac{q_E(1+\Omega)(1-\gamma)}{4} & \bar{p} \geq p_E^* \\[2mm]
\Delta v_1(\bar{p}) = (1+\Omega)\left[\bar{p}(1 - \frac{\bar{p}}{q_E}) - \frac{q_L}{4}\right] & p_L^* \leq \bar{p} < p_E^* \\[2mm]
\Delta v_2(\bar{p}) = (1+\Omega)\frac{\bar{p}^2}{q_E}\left(\frac{1-\gamma}{\gamma}\right) & \bar{p} < p_L^*
\end{cases}
\tag{5}
$$

Direct calculations establish the following:

Lemma 1: *(i)* $\frac{\partial \Delta v(\bar{p})}{\partial \bar{p}} > 0$ *for* $p < p_E^*$; *(ii)* $\frac{\partial \Delta v^*}{\partial \bar{p}} = 0$; *(iii)* $\frac{\partial^2 \Delta v_1(\bar{p})}{\partial^2 \bar{p}} < 0$; *and (iv)* $\frac{\partial^2 \Delta v_2(\bar{p})}{\partial^2 \bar{p}} > 0$.

Part (i) of Lemma 1 simply says that as the price control becomes less stringent, the present value differential between entry and VL increases for any price at which the control is binding for at least one mode of serving the market. For $\bar{p} \in (p_L^*, p_E^*)$, VL becomes relatively more attractive because the price control only binds under entry. For $\bar{p} < p_L^*$ a more stringent price control lowers profitability under both modes, but it is *more binding under entry* since $p_E^* > p_L^*$.

8

Part (*ii*) notes that if the price control lies above the optimal price under entry, the present value differential is independent of the price control since the patent-holder is free to charge its optimal price under both modes of supply. Parts (*iii*) and (*iv*) say that if the price control binds only under entry then the present value differential between entry and VL is concave in the level of the price control, whereas it is convex when it binds under both modes.

We now utilize the present value differential in (5) to derive the patent-holder's optimal decision. We begin with the case where the price control is so lax that the patent-holder can charge its optimal monopoly price under direct entry and VL (i.e. $\bar{p} \geq p_E^*$). The patent-holder prefers entry to VL iff $v_E^* - \varphi \geq f_L(p_L^*) = v_L^* - \alpha$ which implies that entry is preferred by the patent-holder iff

$$\varphi \leq \tilde{\varphi} \equiv \Delta v^*/(1 - \alpha) \tag{6}$$

Furthermore, each mode of selling in the South is profitable iff the fixed cost of each mode lies below the present value of the respective profit stream:

$$\varphi \leq \varphi_E \equiv v_E^* \text{ and } \varphi \leq \varphi_L \equiv v_L^*/\alpha \tag{7}$$

The patent-holder's choice between entry and VL depends on the following trade-off. Though the fixed cost of VL is lower than that of entry (since $\alpha < 1$), the revenue earned by the licensee is smaller due to the lower quality of its product (i.e. $q_L = \gamma q_E$ where $\gamma < 1$). When $\gamma \leq \alpha$, the fixed cost saving under VL is dominated by the product quality advantage of entry and the break-even level of fixed cost for entry is lower than that for VL. Since the case where $\gamma > \alpha$ has been analyzed exhaustively in Bond and Saggi (2014), through-out the rest of the paper we assume that the cost advantage of licensing is dominated by its quality disadvantage:

Assumption 1: $\gamma \leq \alpha$.

Note that Assumption 1 implies that $\varphi_L \leq \varphi_E$ – i.e. VL is profitable over a smaller range of fixed costs than entry. In other words, whenever entry is unprofitable for the patent-holder so is VL. Using inequalities (6) and (7) we can show the following:

Proposition 1: *Given Assumption 1 ($\gamma \leq \alpha$), the patent-holder chooses to enter for all $\varphi \in [0, \varphi_E]$ whereas it does not work its patent in the South for all $\varphi > \varphi_E$.*

In other words, when the patent-holder is free to charge its optimal monopoly prices under both modes, VL does not occur in equilibrium. However, it is still interesting to analyze VL since, as we will see below, the use of a price control by the South tilts the patent-holder's choice between entry and VL in such a way that VL can arise in equilibrium due to the imposition of a price control.

9

We are now ready to consider the case where the South imposes a price control that binds on the patent-holder. It is useful to define the break-even price for entry $\bar{p}_E(\varphi)$ as the solution to $v_E(\bar{p}) = \varphi$. It is clear that $\bar{p}_E(\varphi)$ is continuous and increasing over $[0, v_E^*]$. Since there is no price at which the patent-holder can break even for $\varphi > v_E^*$, we set $\bar{p}_E(\varphi) = \infty$ for $\varphi > v_E^*$. Similarly the break-even price for VL is denoted by $\bar{p}_L(\varphi)$, which is continuous and increasing on $[0, v_L^*]$ and equal to ∞ for $\varphi > v_L^*$.

It is obvious that the patent-holder does not serve the Southern market if $\bar{p} < \min[\bar{p}_L(\varphi) < \bar{p}_E(\varphi)]$. If $\bar{p}_E(\varphi) \leq \bar{p}_L(\varphi)$, Lemma 1(i) ensures that entry is more profitable for the patent-holder than VL for all price controls for which it is profitable (i.e. $\bar{p} \geq \bar{p}_E(\varphi)$). If $\bar{p}_L(\varphi) < \bar{p}_E(\varphi)$, then entry is the more profitable mode if

$$\Delta v(\bar{p}) \geq (1 - \alpha)\varphi \tag{8}$$

If $\bar{p}_L(\varphi) < \bar{p}_E(\varphi)$ and $\varphi \leq \tilde{\varphi}$, there exists a price $\tilde{p}(\varphi)$ at which

$$\Delta v(\bar{p}) = (1 - \alpha)\varphi = 0$$

We refer to $\tilde{p}(\varphi)$ as the *entry-inducing* price, since the patent-holder prefers entry to VL if $\bar{p} \geq \tilde{p}(\varphi)$.[8]

We can show the following:

Proposition 2: *For all price controls $\bar{p} \in [0, p_E^*)$, there exists a threshold level of fixed cost $\varphi_0 \in (0, \varphi_L]$ such that the following hold:*
(i) For $\varphi \in (0, \varphi_0)$ we have $\bar{p}_L(\varphi) < \bar{p}_E(\varphi) < \tilde{p}(\varphi)$ and the patent-holder opts for VL if $\bar{p}_L(\varphi) \leq \bar{p} < \tilde{p}(\varphi)$; it enters if $\bar{p} \geq \tilde{p}(\varphi)$; and does not serve the Southern market otherwise.
(ii) For $\varphi \in (\varphi_0, \varphi_L]$, we have $\bar{p}_E(\varphi) \leq \bar{p}_L(\varphi)$ and the patent-holder enters if $\bar{p} \geq \bar{p}_E(\varphi)$ whereas it does not serve the market otherwise.
(iii) The threshold value φ_0 has the property that $\frac{\partial \varphi_0}{\partial \alpha} < 0 < \frac{\partial \varphi_0}{\partial \gamma}$.

The intuition underlying this result follows from Lemma 1(i): as the price control $\bar{p}$ becomes more stringent, the profit advantage of entry over VL is reduced. Therefore, the fixed cost advantage of VL starts to become more important as $\bar{p}$ falls so that VL becomes a viable option over some range of fixed costs – i.e. for $\varphi \in (\varphi_0, \varphi_L]$ – when $\bar{p}$ is sufficiently low. The threshold value of the fixed cost (φ_0) below which VL is a viable option is higher if the licensee enjoys a greater fixed cost advantage and a smaller quality disadvantage.

---

[8]Of course, if $\bar{p}_L(\varphi) < \bar{p}_E(\varphi)$ and $\varphi > \tilde{\varphi}$, no entry inducing price will exist. As with the break-even prices, we define $\tilde{p}(\varphi) = \infty$ in this case.
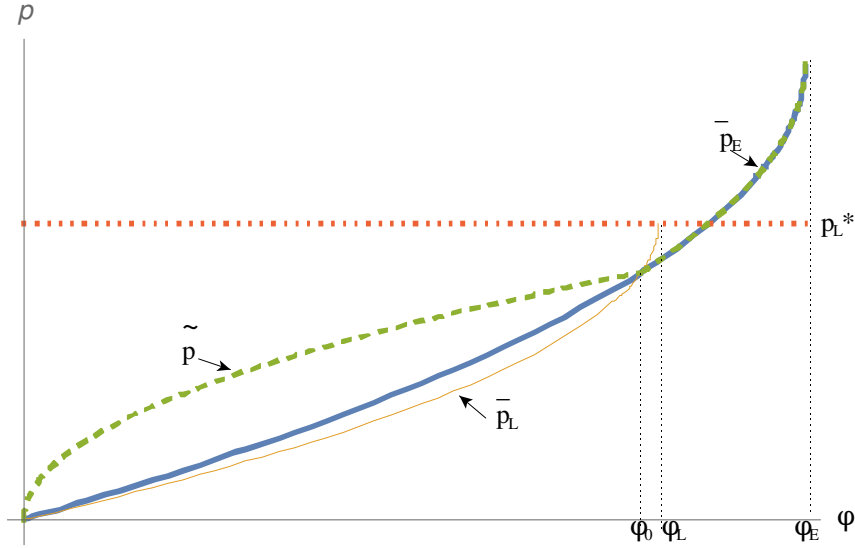
Figure 1: Price Control Thresholds

Figure 1 shows the relationship between the fixed cost parameter φ and the relevant prices under the two modes for a specific example. For $\varphi > \varphi_E$, neither entry nor VL is profitable and the market is not served. When $\varphi \in (\varphi_L, \varphi_E)$, fixed costs are sufficiently high that VL is not profitable at any price. Entry is the only possible mode of serving the market over this interval and it is chosen by the patent-holder as long as the price control is no less than $\bar{p}_E(\varphi)$. The example in Figure 1 illustrates a case in which $\bar{p}_E(\varphi_L) < p_L^*$, so that there exists an interval of fixed costs $[\varphi_0, \varphi_L]$ for which $\bar{p}_E(\varphi) < \bar{p}_L(\varphi)$. Although there are prices at which both VL and entry are profitable over this interval, the patent-holder always earn higher profits under entry. For $\varphi \in [0, \varphi_0]$ both VL and entry are profitable and entry is chosen by the patent-holder iff the price control exceeds the entry inducing price $\tilde{p}(\varphi)$.[9]

An interesting insight provided by a comparison of Propositions 1 and 2 is that *the use of a price control by the South can make VL arise in equilibrium.* Given Assumption 1, in the absence of a price control, the patent-holder either chooses entry or stays out whereas in the presence of a price control, it chooses VL when $\varphi \in (0, \varphi_0)$ and $\bar{p} \in (\bar{p}_L(\varphi), \tilde{p}(\varphi)]$. The intuition for this result comes from Lemma 1: whereas a price control reduces profitability under both entry and VL, it is more binding under entry since $p_L^* < p_E^*$. As a result, when $\varphi \in (0, \varphi_0)$, for any price control $\bar{p} \in (\bar{p}_L(\varphi), \tilde{p}(\varphi)]$, the

---

[9]If $\bar{p}_E(\varphi_L) \geq p_L^*$, then $\varphi_0 = \varphi_L$ and the break-even price for VL is lower than that for entry for all $\varphi < \varphi_L$. The threshold level φ_0 decreases as the licensee's quality disadvantage increases compared to its fixed cost advantage. In either case, there can be only one such reversal of advantage in break-even prices for VL and entry.

patent-holder ends up choosing VL whereas it never does so when the South allows it to charge its optimal monopoly prices under the two modes.

3.2 Optimal price control

We now derive the South's optimal price control assuming its objective is to maximize local welfare. Since the patent-holder extracts all rents under VL, the comparison between entry and VL is determined solely by consumer surplus. It is obvious that if $\varphi > \varphi_E$ then the patent-holder finds neither entry nor VL worthwhile and the price control is irrelevant since the patent-holder stays out of the Southern market no matter what its level.

Next suppose $\varphi_L \leq \varphi < \varphi_E$. Since only entry is profitable over this range, the optimal policy calls for the South to set the price control equal to the break even entry price $\overline{p}_E$. Now consider the scenario where both modes of supply are profitable for the patent-holder i.e. $\varphi < \varphi_L$. Here, first suppose that $\overline{p}_E \leq \overline{p}_L$ – which happens when $\varphi \in (0, \varphi_0)$. Under this scenario, if the South were to set $\overline{p} = \overline{p}_E$ then the patent-holder would choose entry since VL does not break even at this price. Since quality is superior under entry and the price needed to induce entry is lower than that required for VL, the South's optimal policy is to set $\overline{p} = \overline{p}_E$ whenever $\overline{p}_E \leq \overline{p}_L$. Consider now the case where $\overline{p}_E > \overline{p}_L$. Here, to be able to induce entry, the South has to set the price control at the entry inducing price $\widetilde{p}$. Of course, it can alternatively set $\overline{p} = \overline{p}_L$ (the break-even price under VL) thereby inducing VL. Thus, the trade-off facing the South is clear: entry offers a higher quality product but also requires a more lax price control. Thus, when $\overline{p}_E > \overline{p}_L$, the South prefers the entry inducing price $\widetilde{p}$ to the break-even VL price $\overline{p}_L$ iff

$$S(\widetilde{p}, q) \geq S(\overline{p}_L, \gamma q) \tag{9}$$

We summarize the optimal price control policy below:

Proposition 3: *The South's optimal price control policy is as follows:*
(i) For $\varphi \in [\varphi_0, \varphi_E]$ the optimal price control equals the break-even entry price $\overline{p}_E$.
(ii) For $\varphi < \varphi_0$, the optimal price control equals the entry inducing price $\widetilde{p}$ if inequality (9) holds and the break even licensing price $\overline{p}_L$ if it does not.

When both modes of supply are profitable for the patent-holder and the break-even price for VL is higher, the South's choice between the two modes is clear cut: entry is strictly preferable to VL since it offers a better product at a lower price. However, when $\overline{p}_E > \overline{p}_L$ whether entry is preferable to VL depends upon how large a price premium is required to induce it. Further insight into this trade-off can be gained by solving for the price at which $S(p, q) = S(\overline{p}_L, \gamma q)$. This equation yields the highest price $p_S(\gamma)$ that the

South is willing to pay to induce entry when VL can be induced at its break-even price. We have:

$$p_S = q_E(1 - \sqrt{\gamma}) + \frac{\overline{p}_L(\gamma)}{\sqrt{\gamma}} \tag{10}$$

where $p_S \geq \overline{p}_L$ since $\gamma \leq 1$.

Differentiation of (10) establishes that

$$\frac{\partial p_S(\gamma)}{\partial \gamma} < 0$$

i.e. the maximum price that the South is willing to pay to induce entry declines as the quality disadvantage of licensing decreases. Indeed, as $\gamma \to 1$, $p_S \to \overline{p}_L$ so that the South becomes unwilling to offer any price premium for entry and the patent-holder ends up choosing VL. Further note that p_S increases in α, i.e., the Southern tolerance for a higher entry price increases when the cost advantage of VL declines.[10]

It is clear that the Southern price control necessarily makes the patent-holder worse off: for $\varphi_L \leq \varphi < \varphi_E$, its net payoff from entry is driven all the way to zero. For $\varphi < \varphi_L$, it does earn some positive profits when the South chooses to implement the entry inducing price $\widetilde{p}$ but these profits are always lower than what it earns in the absence of the price control since $\widetilde{p} < p_E^*$. As we will see below, unlike a price control, the use of CL does not always make the patent-holder worse off.

4   Compulsory licensing

We now examine how granting the South the option of using CL along the lines sanctioned by TRIPS affects the patent-holder and Southern consumers. We do so by considering the following game. In the first stage, the patent-holder chooses between VL and entry. Next, if the patent-holder neither enters nor grants a voluntary license to the local firm, the South issues a compulsory license to the local firm who produces the product for the duration of the patent. In return for the right to grant a compulsory license to the local firm, the South pays the per-period royalty R to the patent-holder.

The TRIPS requirement that applicants for a compulsory license should have been unable to obtain a voluntary license on "reasonable commercial terms" is reflected in the assumption that the second stage of the game arises only if the patent-holder neither

---

[10]If the Southern government has the ability to set two different price controls (one for entry and another for VL), it does not have to pay a premium to induce entry since it can drive the patent-holder's net payoff under VL to zero by setting the price control under VL at $\overline{p}_L^C(\varphi, R)$. The abiltiy to set two different price controls makes entry more attractive to the South.

enters nor issues a voluntary license to the local firm at the first stage. The per-period royalty R received by the patent-holder captures the TRIPS requirement of providing "adequate remuneration" to the patent-holder.

If the patent-holder does not sell in the South in the first period, the South must decide whether or not to grant a compulsory license. A compulsory license granted at stage two provides the licensee with the right to produce the good for $T - 1$ periods and delays incurring the fixed cost by one period. We assume that the quality of the product produced by the Southern firm under CL is the same as that under VL, as is the required fixed cost. Thus, from a technological perspective, the two types of licensing are identical.[11] We allow the South to compensate the local licensee for any losses that it might suffer under CL. With these assumptions, the welfare of the South under CL equals:

$$W_{CL} = \Omega \left[S(p_L^*, q_L) + \pi_L(p_L^*, q_L) - R \right] - \alpha\beta\varphi \tag{11}$$

In order for CL to be a credible threat we need that $W_{CL} > 0$, which basically requires that the quality of production under CL not be so low that the total surplus generated in the South ends up being insufficient to cover the royalty payment made to the patent-holder.

We denote the maximum level of fixed costs at which CL is a credible threat as

$$\varphi_C^m(R) = \frac{\Omega \left[S(p_L^*, q_L) + \pi_L(p_L^*, q_L) - R \right]}{\alpha\beta}$$

4.1 Supply mode

Given that CL is a credible threat, we are now ready to consider the patent-holder's decision regarding whether and how to utilize its patent in the South. Under entry, the patent-holder earns a return of $v_E^* - \varphi$. Under VL, the patent-holder's payoff equals its licensing fee f_L^C and it is determined as follows. We assume that the patent-holder makes a take it or leave it offer to the Southern firm. If Southern firm rejects the VL offer and the patent-holder does not enter directly then the Southern firm's outside option is no longer zero profits since the government grants it a compulsory license in the next period while paying the per period royalty R to the patent-holder, the present value of which equals ΩR. Under CL, the licensee earns a return with a present value of $\max[\Omega\pi_L(p_L^*, q_L) - \alpha\beta\varphi, 0]$.

The highest fee that the patent-holder can charge under VL is one that makes the Southern firm indifferent between agreeing to a VL in the first period and waiting for a

---

[11]Intuitively, we are assuming that the quality of production under either type of licensing reflects the technological capability of the local firm and that this capability is unaffected by whether the patent-holder grants a license voluntarily or is forced to do so by the South.

compulsory license in the next period, which yields:

$$f_L^C = v_L^* - \alpha\varphi - \max\left\{\Omega\pi_L(p_L^*, q_L) - \beta\alpha\varphi, 0\right\}. \qquad (12)$$

When $\Omega\pi_L(p_L^*, q_L) > \alpha\beta\varphi$, the possibility of CL induces "profit-shifting" from the patent-holder to the local licensee since it reduces the license fee the patent-holder can earn under VL. Note from above that $f_L^C \leq f_L(p_L^*)$: i.e. if production under CL is profitable for the local firm, the threat of CL lowers the patent-holder's payoff from VL; otherwise it does not affect it.

Given these payoffs, in the first period the patent-holder has to choose between the following options:
(i) enter with a return of $v_E^* - \varphi$;
(ii) issue a VL to collect the fee f_L^C; and
(iii) not work its patent and wait for CL which yields royalties worth ΩR.

Recall from Proposition 1 that due to Assumption 1, absent the threat of CL, the patent-holder necessarily prefers entry to VL. Note further that this conclusion remains unchanged when CL is an available option since the threat of CL *further lowers* the payoff from VL. This means that the only remaining question is whether the patent-holder prefers entry to CL or not. The patent-holder prefers entry to CL iff

$$v_E^* - \varphi \geq \Omega R$$

which yields:

Proposition 4: *The patent-holder chooses entry if $\varphi \in [0, \varphi_E^C]$ where $\varphi_E^C \equiv v_E^* - \Omega R$ where $\varphi_E^C < \varphi_E$ for all $R > 0$; it does not work its patent otherwise and the South resorts to CL in the second period.*

Figure 2 illustrates Proposition 4. A comparison of Propositions 1 and 4 shows that the possibility of CL causes two types of switches in the patent-holder's preferred mode of serving the Southern market. For $\varphi \in [\varphi_E^C, \varphi_E]$, the patent-holder switches from entry to not serving the market in order to obtain royalty payments under CL. This outcome represents a scenario where the patent-holder's return from entry is dominated by the present value of royalty payments it receives under CL. For $\varphi \in [\varphi_E, \varphi_C^m]$, CL results in the patented product being produced locally whereas the South would not have been served otherwise. As is clear from Figure 2, the threat of CL expands the range of parameters for which Southern consumers enjoy access to the patented good while *simultaneously* reducing the range of fixed costs for which the patent-holder chooses to enter the Southern market.
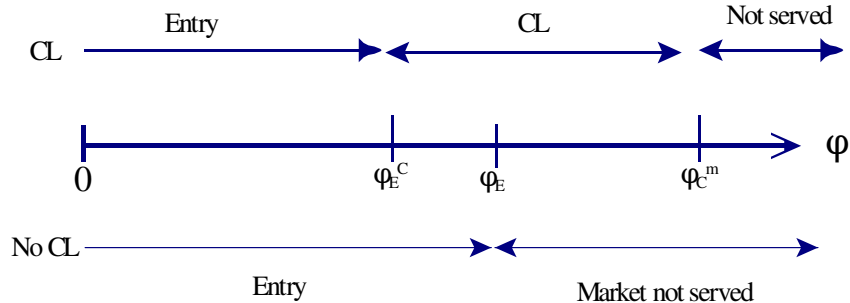
Figure 2: Effect of CL on Market Outcomes

Thus, CL is similar to a price control in the sense that *both instruments reduce the absolute attractiveness of entry* for the patent-holder. But the two instruments differ in two fundamental ways. One, unlike a price control, by reducing the fee paid to the patent-holder under VL the threat of *CL makes VL less attractive to the patent-holder relative to entry.*[12] Second, if the patent-holder chooses to stay out when facing a stringent price control it earns no return from the Southern market whereas it earns a strictly positive return when it decides to stay out and the South resorts to CL.

4.2   Welfare under CL

We now analyze the effect that the option to use CL has on Southern welfare and patent-holder. Figure 2 illustrates that three types of outcomes can obtain when CL is a credible threat: the patent-holder enters with or without CL for $\varphi \leq \varphi_E^C$, the patent-holder switches from entry to waiting for the occurrence of CL for $\varphi \in [\varphi_E^C, \varphi_E]$, and the Southern market is served by the local firm acting as a licensee under CL for $\varphi \in [\varphi_E, \varphi_C^m]$.

Clearly, neither party is unaffected by the threat of CL for $\varphi \leq \varphi_E^C$. Now consider $\varphi \in [\varphi_E^C, \varphi_E]$. For this range of fixed costs, the possibility of CL *induces* the patent-holder to not enter. As a result, Southern consumers experience a switch from consuming

---

[12]Beall and Kuhn (2012) provide an overview of international episodes of CL observed during 1995-2011. All in all, during this time period there were 24 episodes where CL was either publicly considered or actually implemented by governments of developing countries. VL was the end result in only 3 of these episodes; CL resulted in 12 of them; and the patent-holders agreed to sell their products at reduced prices in the other cases.

a product of quality q_E at its monopoly price of p_E^* to a lower quality product (of quality γq_E) at the price p_L^* (where $p_L^* = \gamma p_E^*$) with a delay of one period. These changes necessarily reduces the joint welfare of the two parties because not only is the quality of the product under CL lower than that under entry, it also becomes available after a one period delay. The switch from entry to CL necessarily raises the welfare of the patent-holder because the only reason it decides not to enter is that the royalty payments under CL offer a higher return than that which it can obtain under entry. Furthermore, since joint welfare decreases and the patent-holder gains from its decision to not enter and wait for CL, the South necessarily loses from this switch. Thus, the mere observance of CL does not imply that the country using it is better off relative to a scenario where it does not have the option to use CL.

When $\varphi \in [\varphi_E, \varphi_C^m]$, both the South and the patent-holder gain: here, CL grants access to a product that would otherwise not be sold in the South and the South gets consumer surplus and profits of the licensee while the patent-holder obtains royalty payments. Thus, over this range of fixed costs, the threat of CL yields a Pareto improving outcome – something that is not possible with a price control.

These results are summarized as:

Proposition 5: *The threat of CL affects equilibrium outcomes and welfare of each party as follows:*

(i) For $\varphi \in [\varphi_E, \varphi_C^m]$ the Southern market is served by the local firm under CL whereas it would not be served without the threat of CL. As a result, the payoff to both the South and the patent-holder increase due to the option of CL.

(ii) For $\varphi \in [\varphi_E^C, \varphi_E]$, CL occurs whereas the Southern market would have been served by entry if CL were not possible. In this case, the South loses, the patent-holder gains, and joint welfare declines due to the option of CL.

5 Conclusion

Both price controls and CL have been used to improve consumer access to patented pharmaceuticals in developing countries. In this paper, we have extended the analysis of Bond and Saggi (2014) to provide a comparison of the two instruments from the viewpoint of patent-holders as well as consumers in developing countries. While the TRIPS agreement of the WTO is silent on the subject of price controls, it does lay down some clear conditions that a country seeking to use CL must satisfy. Our model is designed to capture actual WTO rules pertaining to the use of CL quite closely. In particular, the South is allowed to use CL only if the patent-holder fails to work the patent locally via either entering directly or licensing its technology voluntarily to a local

firm. It follows then that the patent-holder can preempt CL by choosing to license its product or by entering the Southern market itself.

The model provides four main insights. First, from the perspective of the patent-holder, the use of price controls increases the attractiveness of VL relative to entry because the optimal monopoly price under VL tends to be lower. Second, the optimal price control of the South needs to account for the fixed cost of the two modes as well as the quality difference between them: while the patent-holder's break-even price under VL tends to be lower relative to entry, so does the quality of production under it. Thus, it is sometimes worthwhile for the South to allow a higher price in order to ensure the patent-holder chooses entry over VL. The third insight provided by the model is that while the option of CL reduces the attractiveness of VL (by lowering the fee that the local licensee is willing to pay) relative to entry, it also makes staying out of the market more attractive to the patent-holder since it can collect royalties under CL that results from its decision to not work its patent in the South. Fourth, CL ensures that local consumers have access to (a lower quality version of) the product when the patent-holder finds it unprofitable to sell locally. Indeed, it is possible that both the patent-holder and the South are made better off by the option of CL. However, as we show in the paper, when the option of CL induces the patent-holder to not enter, the South loses while the patent-holder benefits.

References

[1] Baron, David, 2008. "Compulsory Licensing, Thailand, and Abbott Laboratories." Stanford Graduate School of Business Case P-66.

[2] Beall, Reed and Randall Kuhn, 2012. "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis." PLos Medicine 9(1),1-9.

[3] Bond, Eric and Kamal Saggi, 2014. "Compulsory Licensing, Price Controls, and Access to Patented Foreign Products." Journal of Development Economics 109: 217-228.

[4] Chatterjee, Chirantan, Kensuke Kobe, and Viswanath Pingali, 2013. "The Welfare Implications of Patent Protection, Pricing, and Licensing in the Indian Oral Anti-Diabetic Drug Market." Indian Institute of Management Working paper No. 408.

[5] Daemmrich, Arthur A., and Aldo Musacchio, 2011. "Brazil: Leading the BRICs." Harvard Business School Case 9-711-024.

[6] Dutta, Antara, 2011. "From Free Entry to Patent Protection: Welfare Implications for the Indian Pharmaceutical Industry." The Review of Economics and Statistics 93(1): 160-178.

[7] Goldberg, Pinelopi. K., 2010. "Intellectual Property Rights Protection in Developing Countries: the Case of Pharmaceuticals." Journal of the European Economic Association 8, 326-53.

[8] Kyle, Margaret, 2007. "Pharmaceutical Price Controls and Entry Strategies." The Review of Economics and Statistics 89(1): 88-99.

[9] Lanjouw, Jean, 2005. "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry." NBER Working paper 11321, Cambridge, MA.

[10] Lybecker, Kristina M., and Elisabeth Fowler, 2009. "Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules." Journal of Law, Medicine & Ethics, Spring, 222-239.

[11] Saggi, Kamal, 2016. "Trade, Intellectual Property Rights, and the WTO," in the Handbook of Commercial Policy, edited by Kyle Bagwell and Robert W. Staiger, Elsevier.

6 Appendix

Proof of Proposition 1

The break-even price under VL is the solution to $\pi(p, \gamma q_E)(1 + \Omega) - \alpha\varphi = 0$ which yields

$$\bar{p}_L(\varphi) = \frac{\gamma q_E}{2}\left(1 - \left(1 - \frac{\alpha\varphi}{v_L^*}\right)^{1/2}\right) \text{ for } \varphi \in \left[0, \frac{v_L^*}{\alpha}\right] \tag{13}$$

where $v_L^* \equiv \gamma q_E(1 + \Omega)/4$. We set $\bar{p}_L(\varphi) = \infty$ for $\varphi > v_L^*$, since fixed costs exceed monopoly profits and the licensee cannot earn zero profits at any price. Under entry we have:

$$\bar{p}_E(\varphi) = \frac{q_E}{2}\left(1 - \left(1 - \frac{\varphi}{v_E^*}\right)^{1/2}\right) \text{ for } \varphi \in [0, v_E^*] \tag{14}$$

where $v_L^* = \gamma v_E^*$ and $\bar{p}_E(\varphi) = \infty$ for $\varphi > v_E^*$. It is straightforward to establish that the respective break-even prices are increasing and convex in φ, with $\bar{p}_L(\varphi) = \bar{p}_E(0) = 0$.

Since $\gamma \leq \alpha$, we have $v_L^*/\alpha \leq v_E^* \leq \Delta v^*/(1 - \alpha)$. To prove Proposition 2(i), we show that there exists a unique $\varphi_0 \in (0, v_L^*/\alpha]$ such that $\bar{p}_L(\varphi) < \bar{p}_E(\varphi_0)$ for $\varphi \in (0, \varphi_0)$

19

and $\bar{p}_L(\varphi) \geq \bar{p}_E(\varphi_0)$ for $\varphi \in (\varphi_0, v_E^*]$. Differentiating (13) and (14) and evaluating at $\varphi = 0$ yields $\bar{p}_E'(\varphi) - \bar{p}_L'(\varphi) = (1 - \alpha)/(1 + \Omega)$, which ensures that $\bar{p}_L(\varphi) < \bar{p}_E$ in the neighborhood of $\varphi = 0$. Evaluating the break-even functions at v_L^*/α yields $\bar{p}_L(v_L^*/\alpha) > \bar{p}_E(v_L^*/\alpha)$ iff $\gamma < 2 - 1/\alpha$.

We then have two cases to consider (a) $\gamma < 2 - 1/\alpha$ and (b) $\gamma \geq 2 - 1/\alpha$. First consider case (a). If $\gamma < 2 - 1/\alpha$ then $H(\varphi) = \bar{p}_E(\varphi) - \bar{p}_L(\varphi)$ is a continuous and differentiable function for $\varphi \in [0, v_L^*/\alpha]$ with $H(0) = 0$, $H'(0) > 0$, and $H(v_L^*/\alpha) < 0$. By the continuity of $H(.)$, there exists a $\varphi_0 \in (0, v_L^*/\alpha]$ such that $\bar{p}_L(\varphi) = \bar{p}_E(\varphi)$. Solving this equation yields the unique solution

$$\varphi_0 = \frac{\gamma q(1 - \gamma)(1 - \alpha)(1 + \Omega)}{(1 - \alpha\gamma)^2} \in (0, v_L^*/\alpha) \text{ for } \gamma < 2 - 1/\alpha \tag{15}$$

For this range of parameter values, $\bar{p}_E(\varphi) > \bar{p}_L(\varphi)$ for $\varphi \in (0, \varphi_0)$ and $\bar{p}_E(\varphi) < \bar{p}_L(\varphi)$ for $\varphi \in (\varphi_0, v_L^*/\alpha)$. The fact that $v_L^*/\alpha < \Delta v^*/(1-\alpha)$ ensures that Lemma 1(iii) applies in the latter range.

Now consider case (b). For $\gamma \in [2 - 1/\alpha, \alpha]$, $H(v_L^*/\alpha) \geq 0$ and there is no solution for $H(\varphi) = 0$ on $(0, v_L^*/\alpha)$. Since $v_L^*/\alpha < \Delta v^*/(1 - \alpha)$, Lemma 1(iii) applies and we have $\tilde{p}(\varphi) > \bar{p}_E(\varphi) > \bar{p}_L(\varphi)$ for $\varphi \in (0, v_L^*/\alpha)$. For $\varphi \in (v_L^*/\alpha, v_E^*]$, the licensee cannot break even at any price and Lemma 1(i) applies.

(iii) This result follows from straightforward differentiation of the expression for φ_0 in equation (15) with respect to α and γ respectively.$\|$