Compulsory licensing and access to drugs*

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Abstract

Compulsory licensing allows the use of a patented invention without the owner's consent, with the aim of improving access to essential drugs. The pharmaceutical sector argues that, if broadly used, it can be detrimental for innovation. We model the interaction between a company in the North, that holds the patent for a certain drug, and a government in the South that needs to purchase it. We show that both access to drugs as well as pharmaceutical innovation depend largely on the Southern country's ability to manufacture a generic version. If the manufacturing cost is too high, compulsory licensing is not exercised. As the cost decreases, it becomes a credible threat forcing prices down, but reducing both access and innovation. When the cost is low enough, the South produces its own generic version, and access reaches its highest value, despite a reduction in innovation. The global welfare analysis shows that the overall impact of compulsory licensing can be positive, even when accounting for its impact on innovation. We also consider the interaction between compulsory licensing and the strength of IPRs, which can have global repercussions in other markets beyond the South.

Keywords: IPRs, pharmaceutical R&D, compulsory licensing, access to drugs, international exhaustion.

JEL classification: F13; L12; O34.

*We thank the Editor, two referees, Anton Giulio Manganelli, Marisa Miraldo, and participants to the 2013 CRESSE conference for useful comments.

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1 Introduction

Access to pharmaceutical drugs remains one of the greatest challenges of health policy around the world. Yet a number of developing countries lack both the manufacturing capability to develop new drugs as well as the negotiating power to buy them at affordable prices.

To address the issue, members of the World Trade Organization (WTO) signed in 2001 in Doha the Declaration of the Trade-Related Aspects of Intellectual Property Rights (TRIPs) which include considerations on public health. The Doha Declaration, as more commonly known, provided for the first time a strong negotiating tool to developing countries by allowing them to issue compulsory licensing of pharmaceuticals. A compulsory license is a non-voluntary authorization imposed by a government between the patent holder and a third party, by which the latter is allowed to use the patented invention without the patent owner's consent. Since the Doha Declaration, compulsory licensing has been exercised by a number of countries, including Thailand and Brazil.

The pharmaceutical industry argues that, if broadly used, compulsory licensing reduces its incentives to innovate (Rozek, 2000; Scherer and Watal, 2002). The interest of the pharmaceutical sector becomes more apparent in a world with weak protection of intellectual property rights (IPRs), which may have global repercussions. For instance, imagine international exhaustion of IPRs such that parallel trade is allowed (Danzon, 1997; Bale, 1998; Bennato and Valletti, 2011; Mantovani and Naghavi, 2012; Guo *et al.*, 2013), or a system of international reference pricing (Galizzi *et al.*, 2011; Garcia Mariñoso *et al.*, 2011). In both cases, if a drug becomes cheaper in the country that exercises a compulsory license, it will affect the firm's ability to set differential pricing in different countries.

Despite the intense policy debate on compulsory licensing and the role it may play in improving access to drugs, to the best of our knowledge, there exists no formal treatment in the health economics literature. The aim of this paper is to provide a theoretical framework that allows the analysis of the impact of compulsory licensing on access to essential drugs, and the possible long-term impact on pharmaceutical innovation and on welfare. Our contribution is also original in that we consider explicitly the cost of distributing the drug to the developing country. Evidence shows that these costs can be quite substantial (Pecoul *et al.*, 1999; WHO, 2002) and often determine whether a pharmaceutical product will reach remote rural areas or not (Chaudhuri *et al.*, 2006).

In our analysis, access to drugs depends not only on drug prices but also on the

number of people that can be reached.[1] Our findings show that the impact of compulsory licensing on key policy variables, such as R&D investment, access and welfare, first decrease and then jump up as compulsory licensing becomes a more credible threat. We also discuss how our results change when compulsory licensing interacts with other policy tools that affect the IPRs of the patent holder, in particular under a system of international exhaustion.

The paper is organized as follows. Section 2 reviews briefly a number of motivating cases where compulsory licensing has been used. Section 3 presents the model and section 4 develops it. Section 5 considers the interaction between compulsory licensing and international exhaustion of IPRs. Section 6 discusses the findings and concludes.

2 Background and motivating cases

2.1 Background

The process of issuing a compulsory license is not undemanding. The TRIPs agreement (art. 31) states that before applying for a license, the person or company that has an interest in making use of a patented invention must first try to negotiate a voluntary license with the patent owner. If the negotiation fails, then a compulsory license can be delivered.

The adoption of compulsory licenses is not without cost either. It entails expensive legal and administrative costs for the government that has called for that exception. In addition, even when the non-voluntary license has been granted, other costs associated with its use would arise. These costs are related to reputational losses, sanctions and retaliation in response to a possible violation of international law.[2]

2.2 Motivating cases

Since the Doha Declaration in 2001, compulsory licensing has been used in a number of occasions. One of the most prominent cases comes from Thailand. The Thai Ministry of Health, with the aim to provide universal health care, has used compulsory licensing to import generic versions from countries where these drugs are not patented, or make use of the patented technology to produce it (NHSO, 2007; Steinbrook, 2007). In 2006, the Thai Ministry of Public Health announced the first compulsory license for the antiretroviral

[1] This is why the terms access and coverage are used interchangeably in this paper.

[2] Countries that do not meet their certain obligations are subject to trade penalties (Kerr and Gaisford, 2007).

drug Efavirenz, patented by Merck. A few months later, 66,000 bottles of a generic version were imported from India. By the end of 2007, Thailand announced compulsory licenses for more than 20 drugs for HIV/AIDS, cardiovascular conditions and cancer. One of them, Gleevec, for the treatment of cancer, was cancelled later on when the manufacturing company, Novartis, offered to provide it for free. In 2008, Thailand produced and delivered a generic version of Abbot's Kaletra, a drug for HIV. As a result, Abbott Laboratories announced they would withdraw their activities from Thailand and would not introduce any new medicines in the country (Lybecker and Fowler, 2009).

Along the lines of the Thai experience, other countries have followed a similar path, but obtaining different results. In August 2001, the Brazilian government announced it would issue a compulsory license for manufacturing the antiretroviral drug Nelfinavir, a generic version of Viracept by Roche, to a local pharmaceutical producer. Following the announcement and a series of negotiations, Brazil cancelled the compulsory license after Roche agreed to sell the drug in Brazil at a 40% discount (Cohen, 2006). In 2007 Brazil achieved another deep discount on the price of Sustiva, an antiretroviral drug, after threatening to issue a compulsory license for the use of Merck's patent on it (Cohen, 2007).[3] Although the use of discount exposes the monopolist to the risk that these lower prices may be used as external reference pricing in other markets, it also allows it to keep up its reputation at the international level, preserving at the same time its market shares in large markets such as Brazil.[4]

Rwanda made use of paragraph 6 of Doha Declaration requesting the manufacturing of Apo TriAvir from Canada. Indeed, in 2007 Canada manufactured and shipped copies of Apo TriAvir to Rwanda, becoming the first country to issue a compulsory license for exporting a generic drug to a third country (Reichman, 2009). Following Canada, a number of developed countries have also used compulsory licensing not only for exporting to poorer countries but also to stop anticompetitive actions (Coco and Nebbia, 2007; van Zimmeren and Requena, 2007). These examples, although of less relevance to our model, indicate the increasingly wider use of compulsory licensing.[5]

[3] For more details on the Brazilian case see, for instance, http://www.cptech.org/ip/health/c/brazil/

[4] Indonesia, India, Vietnam and South Korea have all threatened Roche with compulsory license for Tamiflu, a commonly used drug for the treatment of flu. Roche decided to manufacture the drug with partners from these four countries (van Zimmeren and Requena, 2007).

[5] Compulsory licenses are used in a wider variety of cases, in both the patent and copyright areas. In the U.S., National Public Radio and PBS have a license as non-commercial institutions to play music on public broadcasting. In the biotech industry, the U.S. government has granted a number of compulsory licenses on key patents to other biotech and pharmaceutical companies. The U.S. government also uses compulsory licenses of air-pollution technology to promote clean air, under the Clean Air Act. See http://www.cptech.org/ip/health/cl for more information and examples.

2.3 Compulsory licensing and international exhaustion of IPRs

Originally, the TRIPs agreement, with the aim to protect the IPRs of the innovative firm, regulated an important exception about the international exhaustion of IPRs (art. 31(f)). Products made under compulsory licensing should be manufactured *mainly* for domestic use. However, this was weakened in a landmark decision made by the WTO in 2003: the so-called "Paragraph 6 problem" allowed the generic copy made under compulsory licenses to be exported to developing countries that lack production capacity. Indeed, in 2006 the European Parliament intervened in favor of 23 such countries, allowing the use of parallel trade to address public health problems.[6]

Since the TRIPs agreement has never defined an unambiguous solution for this problem, it may be possible to parallel trade those goods manufactured under a non-voluntary license (Matthews, 2004). As the price of a compulsory licensed drug will be lower than the price of the equivalent patented drug, there will be an incentive to export the cheaper drug into more expensive markets. To avoid this arbitrage, the patent holder will then have to reduce the price also in more expensive markets. Thus, compulsory licensing can have global effects that go well beyond the national boundaries (Maskus, 2000; Pecorino, 2002; Danzon and Towse, 2003; Ganslandt and Maskus, 2004; Danzon *et al.*, 2005; Valletti and Szymanski, 2006; Grossman and Lai, 2008; Morais, 2008).

Parallel trade is only one way of weakening IPRs, which will affect the ability of the drug manufacturer to sustain international price differences (Goroff and Reich, 2010). Similarly, one could argue that compulsory licensing could have country spillovers via international reference pricing (Brekke *et al.*, 2007; Miraldo, 2009; Bardey *et al.*, 2010), insofar as the price in one country affects the price in some other country.[7]

3 Model assumptions

There are two countries that we denote respectively as the North (N) and the South (S). In each country, there is a downward-sloping demand for a drug, generated by preferences *à la* Mussa and Rosen (1978). Specifically, consumers are heterogenous, and a consumer of type τ that buys a drug of product u at a price p_i in country i enjoys a net utility given by:

$$U(\tau) = \tau u - p_i,$$

[6] http://eur-lex.europa.eu/LexUriServ/ LexUriServ.do?uri=OJ:L:2006:157:0001:0007:EN:PDF

[7] There are many reasons that can weaken the ability of a drug company to adopt differential pricing globally. Even if parallel trade under compulsory licence is illegal, it does not mean it is not possible, especially if enforcement is weak. Hornbeck (2005) finds evidence of illegal international smuggling of expensive AIDS drugs from African countries to the US.

where τ measures the consumer's marginal valuation of quality. We account for differences in consumer preferences between the two countries in the following way. In the North, the taste parameter τ is distributed uniformly, with unit density, over the interval $\tau \in [0, 1]$. In the South, the taste parameter τ is distributed uniformly, with unit density, over the interval $\tau \in [0, a]$, where it is reasonable to assume $a \leq 1$. Note that a is a parameter that affects elasticity: the lower is a, the more elastic is demand in the South compared to the North. In the South, there is a total mass σ of potential consumers, where $\sigma \lesseqgtr 1$, as the South can be more or less populated compared to the North. In both countries, consumers can also decide not to buy any supplied good, and in this case they obtain their reservation utility, which is normalized to zero. Since the lowest type is 0, in both countries there will be always someone who does not buy any product, unless it is offered for free.[8]

North and South differ in three important respects. First, the good is supplied by the patent holder who is based in the North. This is the only firm authorized to provide the patented good, both in the North and in the South market. By spending resources on R&D, the monopolist can improve the quality of its drug, with the cost of quality, denoted as $C(u)$, increasing at an increasing rate, $C'(u) > 0$ and $C''(u) > 0$.[9] These costs are incurred only at the investment stage, while all other costs at the manufacturing stage are normalized to zero for simplicity.

The second difference between the North and South stems from distribution costs and access to health services. While the North has a system already in place for distributing, selling, and administering drugs at any location ("full coverage"), this does not hold for the South. In particular, we assume that, when a number x of locations is supplied in the South, there are some associated additional local costs defined as $H(x)$, increasing at an increasing rate, $H'(x) > 0$ and $H''(x) > 0$. To obtain closed-form solutions, we employ the following function:

$$H(x) = k\frac{x^2}{2},$$

where k is a parameter that allows us to describe how costly it is to supply the South. In the North there is a unit mass of customers, while in the South the mass of consumers

[8] Preferences of this kind have been employed to describe pharmaceutical markets by Wright (2004) and Valletti and Szymanski (2006), among others, and can also be interpreted as stemming from income heterogeneity. Notice that we are therefore assuming that there are disparities of income both in the North and in the South. We avoid any reference to co-payment mechanisms, as these preferences are simply meant to generate downward demands in both countries: if the price of a drug decreases, more people will have access to it (either by paying in part, or by having a health provider paying for it). Similarly, if the quality of a drug increases, ceteris paribus, there is a demand expansion effect.

[9] As it will become apparent below, the parameter restriction $\frac{k}{a^4\sigma^2} > \frac{1}{16C''}$ is needed for the second-order condition w.r.t. u to be always satisfied.

served varies in equilibrium with k. Hence the role of k is also to take into account differences in the market size of the North relative to the South: a small value of k corresponds to a "large" South relative to the North, and vice versa. In other words, to supply and administer drugs to more people in the South becomes progressively more expensive, as this involves the supply to the least accessible patients.[10]

In each market, there is thus a marginal type who is just indifferent between buying and not buying, defined as

$$\underline{\tau}_i = p_i/u,$$

where $i = N, S$. For future reference, it is convenient to define consumer surplus in both countries, which is respectively

$$\begin{aligned} CS_N &= \int_{\underline{\tau}_N}^{1} (\tau u - p_N) d\tau = \frac{(u - p_N)^2}{2u}, \\ CS_S &= x\sigma \int_{\underline{\tau}_S}^{a} (\tau u - p_S) d\tau = x\sigma \frac{(au - p_S)^2}{2u}. \end{aligned} \tag{1}$$

The third difference concerns the role of governments. We assume that the government in the North does not regulate any aspect of drug production and consumption. The North has adopted a strong regime of IPR that grants a patent to the monopolist for reasons that we do not model, but just take as given. In contrast, the South government can recur to compulsory licensing in the way we specify below. Cross-national drug price differentials may therefore be based not only on demand elasticity, but on differences between the interference of national governments by way of regulation of drug prices (Maskus, 2000; Pecorino, 2002; Jelovac and Bordoy, 2005). The strategic players in our model are the monopolist firm and the South government.

3.1 Compulsory licensing regime

We consider the following timing (see Figure 1). First, the monopolist decides on its R&D effort. In the second stage, the firm proposes a price p_S to the South government. If the offer is accepted, in the last stage the firm decides on the coverage x of the market

[10] One interpretation is the following. Imagine that, in the South, there is a certain mass of potential consumers who live in different locations, which are ordered according to a "distance" parameter x. This represents how easy or difficult it is to supply and market drugs at that location (e.g., geographic access). Consumers at $x = 0$ are those in the biggest city, where it is very easy to supply them (e.g., because basic services are already in place), while to reach, supply and administer drugs to more people in remote regions becomes progressively more expensive for the provider. The model will determine endogenously the equilibrium value of x, i.e., the coverage of those locations where people might have access to the drug.

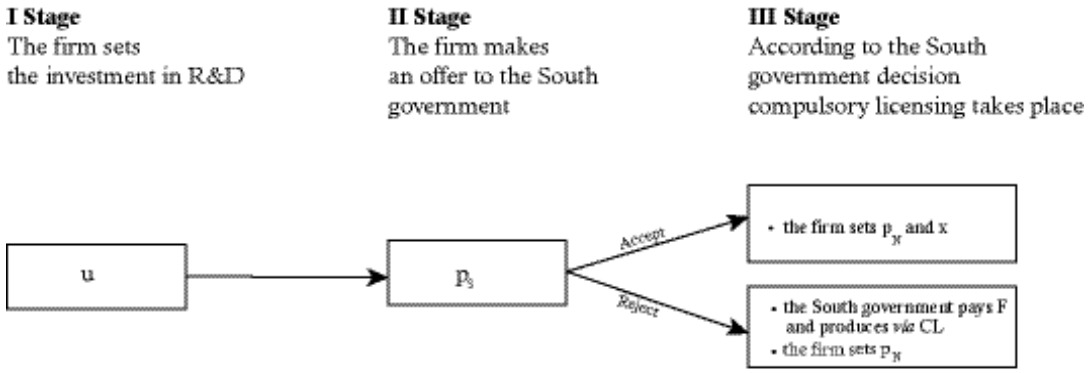

Figure 1: *Sequence of moves under compulsory licensing when parallel trade is banned*

in the South, and simultaneously sets the price p_N in the North. If the offer is not accepted, the government of the South can resort to compulsory licensing, and the firm still sets the price of the patented good in the North. The use of compulsory licensing implies that the government of the South has the ability to serve domestic consumers (i.e., by choosing x) at the same production cost as the monopolist (here, normalized to zero), but it incurs a positive fixed cost F.

In other words, the issuing of compulsory licensing gives autonomy to the South, but comes at a cost (i.e., legal, administrative and reputational costs). The idea is that it would be cheaper for the South to regulate the price of the drug than to engage in a complicated WTO procedure for the license. Also, it is cheaper to produce the existing drug in the North than to have it licensed by the South, as marginal cost is the same in both regions, but there is no fixed cost (of compulsory licensing) in the North. As such, compulsory licensing is not efficiency-enhancing *per se*. The fixed cost F could also be reinterpreted as the loss in consumer surplus to the South when producing the drug itself, but with an inferior quality to that of the original patent holder.

We develop our analysis assuming a regime in which North and South are completely separate, i.e. parallel trade is banned. However, as argued in Section 2.3, parallel trade may be possible and therefore, in section 5, we will also consider the case where parallel trade is applicable to drugs manufactured under compulsory licensing.

4 Analysis

In order to set a benchmark, we start by characterizing the unregulated equilibrium when compulsory licensing is ruled out. Both in the domestic and in the foreign market, the patent holder behaves as a monopolist. After R&D investment is sunk, the monopolist

sets a price p_N in the North and a price p_S in the South to maximize its profits

$$\begin{aligned}\pi_N + \pi_S &= \int_{\underline{\tau}_N}^{1} p_N d\tau + x\sigma \int_{\underline{\tau}_S}^{a} p_S d\tau - H(x) \\ &= p_N(1 - p_N/u) + p_S(a - p_S/u)x\sigma - kx^2/2.\end{aligned}$$

It follows immediately that optimal prices are set as follows

$$\begin{aligned}p_N &= p_N^* = \frac{u}{2}, \\ p_S &= p_S^* = \frac{au}{2}.\end{aligned}$$

Profits differ in each country also due to coverage differences. Indeed, in the North the monopolist makes a profit equal to $\pi_N = \frac{u}{4}$ and in the South its profits are $\pi_S = \frac{a^2 u}{4}\sigma x - k\frac{x^2}{2}$. The optimal coverage of the South is also immediately derived and equal to

$$x = \frac{ua^2\sigma}{4k}, \tag{2}$$

which is increasing in quality (u), as gross profits at each location also increase in quality, as well as in the willingness to pay (a), and in the potential population (σ) of the South.

When choosing R&D, the patent holder maximizes its global profits

$$\Pi = \pi_N + \pi_S - C(u) = \frac{u}{4} + \frac{u^2 a^4 \sigma^2}{32k} - C(u).$$

The monopolist thus offers both in the North and in the South a good having the same optimal quality u^*, implicitly defined by

$$\frac{1}{4} + \frac{u^* a^4 \sigma^2}{16k} = C'(u^*). \tag{3}$$

The resulting coverage follows from (2), with $x^* = u^* a^2 \sigma/(4k)$.

It is also useful to define what would happen if the monopolist completely ignored the South, obtaining profits only in the North (autarky). In this case, quality would be $u^N < u^*$, defined by $1/4 = C'(u^N)$.

Compulsory licensing (CL) Imagine first that the South accepts the offer p_S of the monopolist. As R&D costs are sunk at this stage, coverage in the South is still decided

by the monopolist from maximizing $\pi_S = p_S(a - p_S/u)\sigma x - kx^2/2$, that gives

$$x = p_S \frac{au - p_S}{ku}\sigma, \tag{4}$$

which, from (1), ensures a welfare in the South which coincides with its consumer surplus

$$CS_S = \frac{(au - p_S)^3 p_S}{2ku^2}\sigma^2, \tag{5}$$

since there is yet no compulsory licensing, and F is therefore not spent. Notice that this expression is maximized for $0 < p_S = au/4 < p_S^*$, trading off between cheaper prices and the monopolist incentive to supply coverage.

Instead, the South government could opt for a non-voluntary license, and pay the corresponding costs. Under the compulsory licensing regime, in the last stage of the game the South government optimally sets the price of the drug to zero (the marginal production cost), and also sets the market coverage to maximize welfare

$$W_S = x\sigma \int_{\underline{\tau}_S}^{a} (\tau u) d\tau - k\frac{x^2}{2} - F,$$

which is the consumer surplus in the South minus the coverage costs and the fixed cost. Since $\underline{\tau}_S = 0$, it follows that the optimal coverage is

$$x = \frac{ua^2\sigma}{2k},$$

which identifies the welfare of the South achievable under compulsory licensing as

$$W_S^{CL} = \frac{u^2 a^4 \sigma^2}{8k} - F. \tag{6}$$

Comparing (6) and (5), if $\frac{Fk}{\sigma^2} < \frac{a^4u^2}{8} - \frac{(au-p_S)^3 p_S}{2u^2}$ the offer is rejected and compulsory licensing is preferred, otherwise the government of the South accepts the offer made by the monopolist. To conclude the characterization of the third stage, the price in the North is always set at $p_N = p_N^* = u/2$.

In the second stage, the monopolist makes its take-or-leave-it offer, subject to the foreign government's ability to recur to compulsory licensing. If the offer is rejected, the monopolist's profits are zero in the South, and $\pi_N = u/4$ in the North. If accepted, profits are still $\pi_N = u/4$ in the North, and $\pi_S = \frac{[\sigma p_S(a - p_S/u)]^2}{2k}$ in the South.

We can easily establish some limiting cases. First, if the monopolist was uncon-

strained, the profits in the South would be maximized for $p_S = p_S^* = u/2$, from which it follows a consumer surplus of $CS_S = u^2a^4\sigma^2/32k$ for the South. This value is better than the welfare under the outside option (i.e., making use of the compulsory licensing) if F is high enough, and therefore the offer is always accepted in this range of values of F. Second, if the monopolist acted in the best interest of the South maximizing CS_S from (5) instead of its profits, we established that it would offer a price $p_s = au/4$. At this price, the corresponding consumer surplus is $CS_S = 27u^2a^4\sigma^2/512k$, which is worse than the welfare of the South under the outside option if F is low enough, hence any offer would be rejected in this range of values of F. Third, for intermediate values of F, the price p_S comes from the binding outside option, $CS_S = W_S^{CL}$.

Consequently, the optimal solution takes the following form

$$p_S(u) = \begin{cases} \frac{au}{2} \quad \text{if } \frac{Fk}{a^4\sigma^2} > \frac{u^2}{8} - \frac{u^2}{32} = \frac{3u^2}{32}, \\ \frac{(au-p_S)^3 p_S \sigma^2}{2ku^2} = \frac{u^2a^4\sigma^2}{8k} - F \quad \text{if } \frac{37u^2}{512} \leq \frac{Fk}{a^4\sigma^2} \leq \frac{3u^2}{32}, \\ \text{offer rejected} \quad \text{if } \frac{Fk}{a^4\sigma^2} < \frac{u^2}{8} - \frac{27u^2}{512} = \frac{37u^2}{512}. \end{cases} \tag{7}$$

Moving back to the first stage, the monopolist chooses the level of investment in R&D looking ahead and anticipating the strategy chosen by the foreign government. Its maximization problem amounts to

$$\max_u \ \Pi(u, p_S(u)) = \pi_N + \pi_S - C(u), \tag{8}$$

where $\pi_N = u/4$ and the value of π_S depends on the value taken by the fixed cost, as expressed by (7). We are now in a position to prove our first result.[11]

Proposition 1 *(i) When $Fk/(a^4\sigma^2) \geq 3(u^*)^2/32$, compulsory licensing (CL) is not a credible threat and the equilibrium is the same as in the benchmark: $u^{CL} = u^*$, $p_S^{CL} = p_S^*$, $x^{CL} = x^*$. (ii) When $L < Fk/(a^4\sigma^2) < 3(u^*)^2/32$, with $L < 37(u^N)^2/512$, CL is a credible threat but the South is still supplied by the monopolist: $u^{CL} < u^*$, $u^{CL}/4 < p_S^{CL} < p_S^*$, $x^{CL} < x^*$, where $u^{CL} < u^N$ when Fk approaches L. (iii) When $Fk/(a^4\sigma^2) \leq L$, CL is exercised along the equilibrium path: $u^{CL} = u^N$, $p_S^{CL} = 0$, $x^{CL} > x^N$, where also $x^{CL} > x^*$ if k is large enough.*

We comment on our findings also with the help of Figure 2, where the curves in bold depict the equilibrium as a function of the cost of compulsory licensing.[12] The top

[11] All proofs are in the Appendix, where also the expressions for L are provided.

[12] In Figure 2, we use a quadratic cost function $C(u) = u^2/2$, and set $k = 1, a = 1, \sigma = 1$. While we frame the discussion in terms of F, one could similarly refer, e.g., to the equilibrium size of the South

and middle panels describe respectively the invested quality, and coverage in the South. Starting from the right with high values of F (region (iii)), obviously, the recourse to a compulsory license is useless due to its high costs, thus the monopolist still asks for the unconstrained monopoly price, and we fall back to the unregulated benchmark. The more interesting cases arise for intermediate and low fixed costs, which make compulsory licensing a credible threat. We emphasize how both investment and coverage are non-monotonic with respect to F: starting from high levels of F, a better outside option (via a lower value of F) leads first to a decrease both in u and x. As F is further decreased, they both increase when the South government starts manufacturing via the compulsory license, and in fact x can even become higher than the benchmark.

For intermediate values of F (region (ii)), despite the low bargaining power of the foreign government, a compulsory licensing regime implies that the monopolist cannot act in an unconstrained manner and, to avoid a rejection, it has to take into account the welfare of the South when making an offer. Compulsory licensing is a credible threat but it is not played along the equilibrium path: it simply causes the firm to offer its drug at a cheaper price in the South. This price cut directly reduces both the incentives to invest in R&D, causing u to decrease, as well as diminished incentives to supply coverage x. In this intermediate range, the South government benefits in aggregate from compulsory licensing compared to the benchmark, since it is able to obtain a better price. We emphasize, however, that this improvement for the South comes essentially from a price effect: conditional on being supplied, more people can afford the drug; however the firm is less motivated to supply coverage precisely because of the cheaper drug price, so that fewer remote areas end up being covered.

For lower values of F, the monopolist, when choosing its R&D investment, would not make any profits in the South, if the South recurs to compulsory licensing. Instead of losing the South market entirely, the monopolist prefers to expand the intermediate region (ii) where the outside option just binds: it does so by actually offering fairly *low* levels of u which can be matched by a small increase in the price p_S. The monopolist goes even *below* the level u^N it would choose if it simply made monopoly profits only in the North market, and zero in the South (autarky). This is not a paradoxical result but comes from the fact that an increase in quality improves the outside option (6) relatively more than CS_S as given by (5). By providing a low quality, the monopolist is not forced to offer a big price reduction, and nonetheless have this price accepted by the South. The monopolist thus "stretches" the validity of the intermediate region (ii) in order to

relative to the North, as described by k, after having fixed a value for the other parameters. What matters to distinguish the three regions of Proposition 1 is in fact simply the term $Fk/(a^4\sigma^2)$.

still have some sales in the South, until it finds it optimal to give up the South market entirely.

When F is very low (region (i)), the outside option is now taken in equilibrium. The foreign government acts independently and is able to supply the unbranded good to a large part of its population, reaching also rural areas which the unregulated monopolist is not willing to cover. This is when there is an upward "jump" in x. The market coverage of the South can even be larger than x^* in the unregulated (unconstrained) benchmark: this is certainly the case in Figure 2. As we show in the proof, this is always true, more in general, for high enough values of k.[13] This explains a fundamental difference between relatively small countries and larger ones. For very large countries (low values of k), even if compulsory licensing is relatively cheap (low values of F), the ability to improve access to drugs will be severely undermined by the reduction in the quality of the drug, as the large South country has a big impact on the global profits of the drug manufacturer. Lower quality reduces willingness to pay and coverage. Instead, if the South is small relatively to the North (large k), but still has the ability to recur to compulsory licensing, its impact on global investment is negligible, and will benefit from the ability of basing access to drugs according to national welfare, instead of having to rely on private supply and delivery.

Before turning to the welfare analysis of compulsory licensing, we briefly discuss some of our assumptions and their implications. First, when the South government recurs to compulsory licensing, it sets the welfare maximizing price of the drug to zero. This assumes that the South government can fund the coverage costs with no other distortions, i.e., from international donations or from non-distortionary taxation. Alternatively, one could posit that the South government does not have such funds, and hence has to break even overall. The main thrust of the results would go through also under this alternative specification, which would however reduce the range of values of F such that compulsory licensing results in a credible threat. Analytically, expressions would be more complex.[14]

Second, a key role is played by our assumption that the monopolist can make a take-it-or-leave-it offer only based on price, but not on coverage. When the offer is rejected, the South government can decide on the coverage itself. It is this assumption that, when F is low enough, makes the South reject any offer and act on its own. If instead one postulated that the monopolist could make contractible offers based *both* on price

[13] Under a quadratic cost function $C(u) = \frac{u^2}{2}$, it is $u^* = \frac{4k}{16k - a^4\sigma^2}$ and $u^N = \frac{1}{4}$. Hence $x^{CL} = \frac{u^N a^2 \sigma}{2k} > x^* = \frac{u^* a^2 \sigma}{4k}$ for all values $k > \frac{a^4\sigma^2}{8}$.

[14] Instead of (6), the value of the outside option would now be $W_S^{CL} = \frac{\sigma^2(a^2u^2 - p_S^2)^2}{8ku^2} - F$, where p_S is the solution to the break-even condition in the South $\frac{\sigma^2(au - p_S)^2(3p_S - au)(p_S + au)}{8ku^2} - F = 0$.

and coverage, then clearly the monopolist could match any outside option of the South (because the monopolist saves F), and compulsory licensing would never occur along the equilibrium path. Our assumption is justifiable insofar as the contract between the firm and the South government is incomplete, because some aspects of the delivery contract are uncertain and cannot be fully contracted upon.

4.1 Welfare analysis

In the previous sections we examined the impact of compulsory licensing separately on access to drugs and pharmaceutical innovation. We now take a look at the overall welfare effects of compulsory licensing.

Welfare is the sum of consumer surplus in both countries and the firm's profit. This is a standard notion of welfare that is particularly appropriate in our context where R&D happens in the North, while CL might be exercised in the South. In case compulsory licensing is exercised, also the additional costs of manufacturing in the South have to be accounted for. Hence, in regions (ii) and (iii) welfare is

$$\begin{aligned} W &= CS_N + CS_S + \Pi \\ &= \frac{u}{2}\left\{1 - \left(\frac{p_N}{u}\right)^2 + x\sigma\left[a - \left(\frac{p_S}{u}\right)^2\right]\right\} - C(u) - H(x). \end{aligned} \tag{9}$$

In region (iii) instead it is

$$W^{CL} = CS_N + CS_S + \Pi - F. \tag{10}$$

By making use of the bottom panel of Figure 2, we assess welfare against the absence of compulsory case, in which case the benchmark arises (region (i) would apply everywhere). By allowing compulsory licensing, as the cost of manufacturing for the South goes down in region (ii), so does the overall welfare effect. This is due to the fact the monopolist's profits are reduced since it cannot act in an unconstrained manner anymore, lowering consequently its coverage and investment. Consumer surplus is also lowered overall (consumers in the South, in particular, get a cheaper drug, but they also get a lower-quality drug, which is supplied to fewer areas). While compulsory licensing does not emerge along the equilibrium path, it does have real effects as it changes the monopolist's behavior.

However, when F gets low then welfare can increase with compulsory licensing, even significantly, reaching levels higher than in the benchmark case. There are three forces at work in region (iii). The positive effect on welfare is due to the better access that the

South achieves. This has to be contrasted with the inefficiencies due to manufacturing in the South (F), though these will be low in region (iii), as well as with the reduction in R&D. The overall welfare effect will then possibly depend on the relative size of the countries. While we do not want to claim absolute generality, the next result shows that the example of Figure 2 is not special, in that it extends to all values of $k/(a^4\sigma^2)$.

Proposition 2 *Imagine* $C(u) = \frac{u^2}{2}$. *When compulsory licensing is exercised (region (iii)) it always improves global welfare compared to a regime that did not allow it.*

[Insert Figure 2 around here]

5 Robustness check: International exhaustion of IPRs

We now consider how compulsory licensing might interact with other aspects of international trade regulations. We study the consequences of the spillover effect that the drug price in the South might have in the North. The channel (and policy tool) that we examine is an international exhaustion regime making parallel trade legal, although our results can also be interpreted as any weakening of IPRs such that the price in the South will have an impact on the price set in the North. We stress again that the TRIPs agreement does not make the issue of compulsory licensing and parallel trade very clear. Although the use of compulsory licensing represents one of the flexibilities recognized by TRIPs, the same rules establish that all goods yielded under compulsory licensing should be confined to the country that has called for a compulsory license. However, exceptions are permitted, which makes the emergence of "grey markets" a real possibility.

With this regard, extending our analysis to the parallel trade case, we assume that, when the government of the South does not accept the monopolist's offer and recurs instead to compulsory licensing, two scenarios are possible. In the first case of "restricted parallel trade", the government of the South making use of the compulsory licensing aims at serving the domestic market only, hence, $p_N \neq p_S$. In the second case of "unrestricted parallel trade", exceptions are in force and the goods manufactured under compulsory licensing are allowed to be parallel traded.

If parallel trade is permitted, arbitrage is perfect and reimportation costs do not exist (e.g., re-packaging and transport costs are zero). The firm is therefore forced to set a uniform price both in the North and in the South market, $p_N = p_S$, as it would otherwise attract arbitrageurs.[15]

[15] This is a standard assumption in the literature on parallel trade. It is easy to accommodate imperfect

In order to make the analysis sharper, we now set the highest willingness to pay $a = 1$ also in the South. Under this assumption, without CL, prices would be $p_N = p_S = p^* = \frac{u}{2}$ both in the North and in South. Hence there would be no arbitrage possibilities. Parallel trade can thus have a role *only* under CL. In other words, this simplification is conceptually useful as it eliminates other confounding factors that have already been examined in the literature, and do not need to be repeated here. To further simplify calculations, we now also set $\sigma = 1$, but this is immaterial for the results that follow.

Under these assumptions, we can extend our previous analysis. As before, if $Fk < \frac{u^2}{8} - \frac{(u-p_S)^3 p_S}{2u^2}$ the offer is rejected and compulsory licensing is preferred. If $Fk > \frac{u^2}{8} - \frac{(u-p_S)^3 p_S}{2u^2}$, the government of the South accepts the monopolist's offer. Thus the optimal price schedule still takes the same form as (7).

In the first stage, the monopolist chooses the level of R&D to maximize (8), where now the expressions of both π_S and π_N depend on the value taken by the fixed cost and by the particular regime of parallel trade.

Proposition 3 *(i) When $Fk \geq 3(u^*)^2/32$, parallel trade is irrelevant. (ii) When $\widetilde{L} < Fk < 3(u^*)^2/32$, with $L < \widetilde{L}$, the South is still supplied by the monopolist and parallel trade reduces investment, despite increasing the price in the South: $\widetilde{u}^{CL} < u^{CL} < u^*$, $u/4 < p^{CL} < \widetilde{p}^{CL} < p^*$. (iii) When $Fk \leq \widetilde{L}$, parallel trade is irrelevant if it is restricted, otherwise it further reduces investment.*

Figure 2 is again helpful to discuss the results, where the dotted curves, when relevant, refer to parallel trade. For intermediate values of F (region (ii)), the outside option binds but the monopolist still supplies the good to the South. Because there is no recourse to compulsory licensing, there is no difference between a situation of "unrestricted" or "restricted" parallel trade, since in both cases there is a uniform price everywhere as the good is supplied by the monopolist. Parallel trade, by reducing the monopolist's global profits, reduces investment in u compared to the absence of parallel trade. The effect of parallel trade on coverage x in this intermediate region is generally ambiguous: while parallel trade reduces quality, which should also reduce coverage in equilibrium, there is a countervailing force from the price effect: parallel trade results in higher prices in the South, which tends to increase coverage. In Figure 2, the former prevails in the "right" part of region (ii), but not in the "left" part.

The difference between "unrestricted" and "restricted" parallel trade arises and is stark when $Fk < \widetilde{L}$. The "unrestricted" regime extends the validity of region (ii) where

arbitrage in the model, e.g., by having unit tranportation costs t for parallel traders. In this case, if t is not large, $p_N = p_S + t$.

the monopolist still supplies the South to very low values of F: the firm prefers to always sell to the South in order to avoid the risk of triggering a compulsory license, which would then imply reimportation at a zero price. The "restricted" regime instead protects IPRs more, and region (iii) emerges, as in the case without parallel trade. Actually, region (iii) is now larger, i.e., it occurs for a wider range of values of Fk.[16]

When there is a prohibition of re-importation ("restricted" regime), parallel trade has no effect on either u or x for low F in region (iii), as the South is completely insulated from the North, apart from changing the range of validity of region (iii) itself. Conversely, when the government of the South is not able to confine the circulation of the unbranded good within its borders, e.g., due to an ineffective enforcement of IPRs, "unrestricted" parallel trade implies that there is a rapidly declining investment in R&D, and everybody loses. In the extreme when F tends to zero, both investment and coverage (as well as consumer surplus and profits) go to zero with "unrestricted" parallel trade.

We conclude by commenting briefly on the welfare analysis, when focused on the impact of parallel trade. In region (ii), parallel trade further reduces investment compared to its absence. Hence welfare goes down under parallel trade for intermediate costs of compulsory licensing. In region (iii), the welfare properties of parallel trade depend crucially on the enforcement of "Paragraph 6". If the drug produced under compulsory licensing is indeed confined to the South boundaries, parallel trade has no welfare impact (apart from letting compulsory licensing arise for a wider range of values of F). If instead there is no such enforcement, and the good produced in the South can be traded freely, parallel trade has extremely negative characteristics, and it shuts down innovation completely in the limit when F is very low.

6 Summary and conclusions

Post TRIPs, governments across the developing world have tried to improve consumer access to medicines sold by engaging in compulsory licensing. We have presented a formal model of compulsory licensing, which is seen as a bargaining tool in the hands of developing countries to improve access to essential drugs for those who need them. We have shown that access depends largely on the South country's capability to manufacture a generic version in a relatively cheap way and on its ability to distribute it to the wider

[16] Precisely because in region (iii), under a "restricted" regime, the good produced under CL in the South would not be reimported in the North, while in region (ii) the good produced by the monopolist (and not under CL) would be lawfully subject to parallel trade, the monopolist has a stronger incentive to let region (iii) emerge under parallel trade than without. This explains why $\widetilde{L} > L$.

population. 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.

Our results are as follows. If the cost associated to a compulsory license is too high, compulsory licensing is not a credible threat, and the monopolist supplies the drug to the South in an unconstrained manner. As the cost goes down, compulsory licensing becomes a credible threat and forces the manufacturer to reduce the prices, while still voluntarily supplying the South. This could be the case of Brazil that managed to get better prices for a number of branded drugs after threatening the manufacturing companies with compulsory licensing. However, a lower price does not guarantee that the drug will reach all those in need. The manufacturing company, being a profit maximizer, would in fact cover less population as a response to the cheaper price of the drug.

When instead the cost of manufacturing for the South becomes very low, then compulsory licensing emerges as an equilibrium feature of our model. Access to drugs reaches its highest levels, as the South government aims to cover a wider population. Chaudhuri *et al.* (2006), taking India as an example, suggest that drugs produced locally are easier to reach Indian patients than those produced outside the country. This is what they call the "ease of access" effect, which seems to support the findings of our model.

While a compulsory license improves access to essential drugs, pharmaceutical companies believe that, if broadly used, compulsory licensing might undermine their incentives for innovation. Indeed, this is what we find. Nonetheless, the welfare effects do not necessarily go in the same direction. In fact, we have shown how welfare increases globally in many circumstances, which should cast a much more positive light on compulsory licensing. This result is the more interesting as, in our setting, we assumed that compulsory licensing brings inefficiencies, such as duplications of costs. Also, we conducted a long-run analysis that fully includes the impact on R&D investments, as well as the inability to write contracts ex ante, i.e., before R&D costs are sunk. Even when the South is relatively large, and thus has the largest negative impact on reducing on global R&D, it is still better to supply a relatively lower quality drug to many more people in the South under compulsory licensing, improving global welfare.

We have also shown that the capability of countries to enforce the rules of the IPR system plays an important role both in access and innovation. We have found that if policy makers are able to commit to the use of this non-voluntary license for the domestic market only, the presence of parallel trade is irrelevant for the monopolist's investments. On the contrary, if under international exhaustion the policy makers have no capability

to enforce the IPR system, the use of compulsory licensing will completely backfire and reduce access and, what is more, it will be detrimental for the introduction of innovation, yielding a rather large welfare loss.

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APPENDIX

Proof of Proposition 1. In region (i), if F is high, the outside option is ineffective, thus we obtain the same result as in the unregulated benchmark case, that is, $u^{CL} = u^*$, which therefore is valid as long as $Fk/(a^4\sigma^2) > 3(u^*)^2/32$. The other limiting case is in region (iii) when F is very low, so that the firm never sells in the South, then $\pi_S = 0$ and quality is $u = u^N < u^*$. This candidate solution is valid as long as $Fk/(a^4\sigma^2) < 37(u^N)^2/512$. The analysis is more involved in region (ii), valid for intermediate values of F, the constraint identified by the threat of the government to use the outside option binds, which is re-written as

$$CS_S = \frac{u^2 a^4 \sigma^2}{8k} - F \Rightarrow 4(au - p_S)^3 p_S \sigma^2 - u^2(a^4\sigma^2 u^2 - 8Fk) = 0. \tag{11}$$

In the first stage, the firm solves

$$\frac{d\Pi}{du} = \frac{\partial \Pi}{\partial u} + \frac{\partial \Pi}{\partial p_S}\frac{\partial p_S}{\partial u} = 0. \tag{12}$$

By means of implicit differentiation of (11), it is

$$\frac{\partial p_S}{\partial u} = \frac{\frac{\partial \frac{u^2 a^4 \sigma^2}{8k}}{\partial u} - \frac{\partial CS_S}{\partial u}}{\frac{\partial CS_S}{\partial p_S}} = \frac{(au)^4 - 2(au - p_S)^2 p_S(au + 2p_S)}{2u(au - p_S)^2(au - 4p_S)}. \tag{13}$$

The numerator of (13) is always positive, as the expression $2(au - p_S)^2 p_S(au + 2p_S)$ is single peaked in p_S for $p_S < au$, and even at the maximum can never exceed in absolute value $(au)^4$. The denominator is always negative as we are in a range of prices between the unregulated benchmark and the preferred price for the South: $au/4 < p_S < au/2$. Thus $\frac{\partial p_S}{\partial u} < 0$, as an increase in u increases relatively more the value of the outside option, and hence the price must be *decreased* in order to make the South accept the offer. Since in (12) it is also $\frac{\partial \Pi}{\partial p_S} = 0$ for $p_S = p_S^*$, and $\frac{\partial \Pi}{\partial p_S} > 0$ for all $p_S < p_S^*$, we can then conclude that quality starts at u^* when $Fk/(a^4\sigma^2) = 3(u^*)^2/32$, and then decreases monotonically as F becomes smaller and $p_S < p_S^*$. The solution is found by looking, in the $\{p_S, u\}$ space and within the admissible cone $au/4 < p_S < p_S^*$, at the highest isoprofit curve of the monopolist satisfying the constraint (11). It is easy to prove that there is always an interior solution strictly inside the cone. Although we omit the expressions for space limitation, this result is obtained because the isoprofit curves are vertical at $p_S = p_S^*$ and then convex for lower prices, while instead the constraint is vertical at $p_S = au/4$ and then concave for higher prices; thus there is always a tangency point.

We can also prove that the monopolist chooses this solution as long as it makes at least the same amount as $\frac{u^N}{4} - C(u^N)$. In fact, as $\frac{\partial \Pi}{\partial u}\big|_{u=u^N} < 0$ for low enough p_S, we can show that it is optimal for the monopolist: a) to push the interior solution for values of $Fk/(a^4\sigma^2)$ up to a limit value L strictly lower than $37(u^N)^2/512$, where L is defined by the isoprofit curve $\Pi = \frac{u^N}{4} - C(u^N)$ subject to (11), and b) it necessarily offers a quality below u^N for values of $Fk/(a^4\sigma^2)$ approaching L from above.

Results on coverage follow easily by noting that in region (iii) it is $x^{CL} = u^N a^2\sigma/2k$. When instead we are in the intermediate region (ii), then from (4) it is $x^{CL} < x^* = u^* a^2\sigma/4k$. As we have just established that, when $Fx/(a^4\sigma^2)$ approaches L from above, $u < u^N$, for sure coverage jumps up when $Fx/(a^4\sigma^2)$ is further reduced and CL is exercised in region (iii) (with autarky it would be $x^N = 0$). In fact, it may even be that coverage in region (iii) is higher than in region (i) where it is $x^{CL} = u^* a^2\sigma/4k$. This arises when $u^N a^2\sigma/2k > u^* a^2\sigma/4k$, or $u^* < 2u^N$, which depends on the convexity of the cost function $C(u)$ and on the value of k. The inequality is always satisfied when k is large enough, as in the limit $u^N \to u^*$. **QED**

Proof of Proposition 2. When $C(u) = \frac{u^2}{2}$, it is $u^* = \frac{4k}{16k - a^4\sigma^2}$,[17] as well as $p^N = \frac{u^*}{2}, p^S = \frac{au^*}{2}$ and $x^* = \frac{u^* a^2\sigma}{4k}$. These can be substituted in (9) to obtain

$$W^* = \frac{k(32k - 3a^4\sigma^2)}{2(16k - a^4\sigma^2)^2}.$$

In region (iii), it is $u^N = \frac{1}{4}$, and $p^N = \frac{u^N}{2}, p^S = 0,\ x^{CL} = \frac{u^N a^2\sigma}{2k}$. From (10) we compute

$$W^{CL} = \frac{8k + a^4\sigma^2}{128k} - F.$$

When $F \to 0$ it is always $W^{CL} > W^*$ for all admissible values of $k/(a^4\sigma^2) > 1/16$. The result is in fact stronger and extends to the entire region (iii). This is because, from Proposition 1, in region (iii) it must be $Fx/(a^4\sigma^2) < L < 37(u^N)^2/512$, and therefore F is bounded above by $37(u^N)^2 a^4\sigma^2/(512k)$. Even at this higher threshold, it is immediate to show that $W^{CL} > W^*$ for all admissible values of $k/(a^4\sigma^2)$. **QED**

Proof of Proposition 3. Let us start with the restricted case, where goods produced in the South under CL cannot be reimported, whereas those supplied by the monopolist can. If F is high, the outside option is ineffective, $p = p^*$ is set everywhere, thus we obtain the same result as without parallel trade (identical to the unregulated

[17] Recall that in order for the SOC to be satisfied, it must be $k/(a^4\sigma^2) > 1/16$, hence $u^* > 0$.

benchmark case). If F is very low, the firm never sells in the South (which recurs to CL) but can set $p_N = p^*$, so that $\pi_S = 0$ and $\pi_N = u/4$ and quality is again as in the case without parallel trade. If F is intermediate, then $\pi_N = p_S(1 - p_S/u)$ and $\pi_S = p_S^2(u - p_S)^2/2ku^2$. Like in the proof of the previous proposition, the solution is found by looking at the highest isoprofit curve (8) satisfying the constraint (11). The constraint is the same, with and without parallel trade, and it is still characterized by $\partial p_S/\partial u < 0$. Since it is easy to prove that parallel trade reduces the marginal revenue,[18] we thus obtain that the effect of parallel trade is to reduce investment and increase the price cap. Another difference with the case without parallel trade is that, while the monopolist still pushes this interior solution for values of Fk lower than $37(u^{NC})^2/512$, now profits when both countries are supplied are strictly lower than without parallel trade (they coincide only when $p_S = p^*$), thus the monopolist stops supplying the South for values below $\widetilde{L}$, which is strictly higher than L, and again defined by the isoprofit curve $\Pi = u^N/4 - C(u^N)$ subject to (11).

We now turn our analysis to the case of "unrestricted parallel trade". The good manufactured in the South will be exported and traded everywhere, also under the compulsory licensing regime (i.e., by means of the grey market). Cases (i) and (ii) are unchanged and do not need to be analyzed again. The difference is that now the monopolist will never withdraw from the South, hence CL will never be used along the equilibrium path. If it did so, then the price in the South would be zero but would apply everywhere, and the monopolist will not invest at all. Therefore the validity of region (ii) is now extended also for all values below $\widetilde{L}$. Investment approaches zero, as well as prices and coverage, only as $F \to 0$. **QED**

[18] The difference between marginal profits without and with parallel trade is $\frac{(u-2p_S)(2p_S^3-3p_S^2+u^3)}{4u(u-p_S)^2(u-4p_S)}$ which is positive for all $u/4 < p_S < p^*$.