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Pharmaceutical Innovation and Parallel Trade

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Abstract

Under a regime of international exhaustion of intellectual property rights, the patent holder is prevented from engaging in price discrimination due to arbitrage. The purpose of this paper is to investigate the e□ects yielded by the interaction between government policies and parallel trade, with a particular focus on the pharmaceutical sector. We provide a complete welfare analysis that accounts for investment decisions in R&D. We study the patent holder's decisions in the case a foreign government can introduce a direct price control, or use instead the threat of compulsory licensing to lower the price of patented drugs. In the case of a direct price control, parallel trade improves global welfare under an intermediate form of commitment by the foreign government. In the case of compulsory licensing, parallel trade has instead bad properties in that it reduces the pace of innovation, although compulsory licensing can allow for greater access to drugs in the foreign country.

Keywords: **IPRs, parallel trade, pharmaceutical R&D, compulsory licensing.**
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1 Introduction

Parallel imports are genuine products produced under protection of a patent, trademark, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the owner of the intellectual property right (IPR). Parallel trade exists when there are significant price differences between countries, making this trade attractive. International price differences can be sustained only if IPRs are fully protected, making the creator the exclusive owner of her innovation: it seems quite obvious for the patent holder to exert market power by charging for the same good (or similar items) a different price in different markets. This form of third-degree price discrimination yields ambiguous welfare effects. The key aspect is typically whether price discrimination causes more markets to be supplied compared to a uniform pricing regime.[1]

With the aim to curb some negative effects determined by price discrimination, policies at the international level support parallel trade when conducted among a group of relatively homogeneous countries (Malueg and Schwartz, 1994). Nevertheless, there is no unequivocal view about the implications of parallel trade, especially because of the trade-off between static and dynamic efficiency (Valletti and Szymanski, 2006). Reflecting this, the question whether parallel trade should be permitted or inhibited still triggers hot political debates in many countries. The pharmaceutical industry, which relies mostly on the patent system to protect its returns on innovation, emphasizes that parallel trade, or any reduction in the degree of protection of IPRs, could cause a fall in the pace of innovation, due to decreased private incentives to invest in R&D. For sure, the empirical relevance of parallel trade is undisputed.

This paper aims to analyze pros and cons of parallel trade, with a particular emphasis on the implications for the pharmaceutical sector. Our primary purpose is to conduct a welfare analysis that takes into account investment opportunities in R&D, as well as the set of formal and informal rules that countries face when dealing with parallel trade issues. Parallel trade is at the interesting intersection of IP, trade, and competition policy. Therefore its assessment depends critically on the details of trade regulation as well as IPRs. We study how different regimes of IPRs interact with specific features of government intervention, namely regulations such as price caps and compulsory licensing.

We develop an analysis based on the strategic interaction between a single innovative firm, based in the North, and a foreign government, located in the South. We adopt a framework where international exhaustions have real effects *only* **when combined with**

[1] See Varian (1985), and Danzon (1997) for an application to the pharmaceutical industry.

other regulatory instruments, as demand elasticities between countries do not differ in our model. This analysis underlines how the efficacy of the South government policy, measured by the impact on welfare in the South, is subject to the assumption that the policy maker has abilities to commit. We demonstrate how the commitment propensity of the South government matters dramatically when its policy maker engages in drug price control. With that regard, identifying the effects of the government's choices on the pace of innovation, we deal with the well known hold-up problem. We investigate the advantages that the government might obtain following a commitment strategy, distinguishing between different degrees of ability to commit. We draw a distinction between an R&D investment stage, and a subsequent stage where there is a further and costly delivery of drugs to the South. The extent of the efficacy of a price regulation scheme hinges crucially on its actual timing vis-à-vis these two stages. Although it is well known that the use of price cap might deter the monopolist to serve regulated markets (Danzon *et al.*, 2005), when parallel trade is permitted these effects interact with possible arbitrage between markets, affecting the monopolist's incentives (Kyle, 2007; Danzon and Epstein, 2008). Under an international exhaustion regime which allows parallel imports, the price control in the South affects the price in the North as well, which can induce the South government to increase its controlled price to ensure that its consumers are adequately served. Interestingly, we show how a regime with parallel trade and only 'partial' commitment, whereby the South government regulates the price prior to drug delivery in the South - but after investments have already occurred - yields the highest consumer surplus in the South as well as the highest welfare globally.

We also discuss the consequences stemming from compulsory licensing. Policy makers in less developed countries have typically a weak bargaining power when confronting big pharmaceutical companies (Laffont, 2005). This makes price regulation in the South not very effective. However, under specific circumstances, the Trade Related Aspect of Intellectual Property Rights (TRIPs) agreement enables the use of compulsory licensing, allowing the governments to resort to patented technology against the patent owner's will. This represents a real threat for the monopolist, if the costs related to the use of this involuntary licence are low enough. We show that, under the parallel trade regime, the government of the South can condition the monopolist's choices of investments in R&D. Indeed, we find that if policy makers are able to commit to use of this non-voluntary licence for the domestic market only, the presence of parallel trade is irrelevant for the monopolist's investments, affecting only marginally global welfare. On the contrary, if under international exhaustion the policy makers have no capability to enforce the IPRs system, the use of compulsory licensing will be detrimental for the introduction of new

innovation, yielding a rather large welfare loss.

One factor that is particularly important when discussing trade policies that a□ect less developed countries, is the role played by the health care system on the access to drugs. As mentioned above, in our model we introduce explicitly the notion of access to the health care system in the South. We believe that the system by which drugs are supplied within a country is another aspect that has an important impact on the final price of drugs, and on their accessibility (Pecoul et al., 1999; WHO, 2002). In this respect, our analysis discusses when compulsory licensing gives to the South government more flexibility in choosing accessibility to drugs, instead of having to provide financial incentives to the monopolist to supply coverage.

The remainder of the paper is as follows. In the next section we discuss international exhaustion and the derogation from IPRs. In Section 3 we present our model assumptions and describe the benchmark situation without parallel trade. Parallel trade is considered in Section 4. In Section 5 we extend the benchmark by studying the impact of price regulation. In Section 6 we consider compulsory licensing and assume that the monopolist's trade partner has the capability to manufacture autonomously patented drugs. Finally, in the last section we summarize our results and conclude.

2 International exhaustion and IPRs derogation

In this section we analyze the economic issues concerning the exhaustion of property rights under the TRIPs agreement. We focus our attention on those exceptions that restrict the rights of the patent owner and allow the use of a patent against its will.

2.1 Parallel Trade

The term "parallel" emphasizes the fact that genuine but unauthorized products are imported across country borders creating a parallel channel to the manufacturers' authorized distribution. Even though parallel trade does not refer either to illegal or informal sector activities, or to trade in pirated or counterfeit goods, it is commonly referred to as "grey market". Parallel trade represents one of the most controversial issues in the international trade-policy ground, and has raised di□cult questions, especially in the pharmaceutical industry.

The question whether or not parallel trade should be permitted requires to take into account both the peculiarities of the market in which trade is implemented, and the national demand patterns (Maskus, 2000). Both static and dynamic e□ects also need

to be considered. Allowing the IPR holder to prevent parallel trade could represent an obstacle to free trade,[2] but on the other hand incentives need to be given to secure investment incentives.

The legal status of parallel trade differs worldwide. Within the European Union parallel imports are a legitimate trade, despite that all European members recognize IPRs as established at the international level.[3] Parallel trade represents a growing business catching the attention of the international community.[4] The U.S. does not allow parallel trade in pharmaceuticals, while many Asian countries do, particularly in copyrighted products (Kyle, 2009). At the international level, a first attempt to find a solution to this disputed matter has been done during the Uruguay Round negotiations. Article 6 of the TRIPs agreement states that it is possible to resort to parallel trade by the exhaustion of the IPRs, however ultimately the WTO has left each member country the possibility to fix its own regime for such exhaustion.[5]

Some studies argue that parallel trade, where it is permitted, has not yielded the expected results in terms of convergence in price.[6] Although several policy papers have been addressed to this scope, less attention has been paid on the economic implications of parallel trade on IPRs.[7] Scholars who believe that such arbitrage could erode the IPRs weakening the incentive for investment in R&D (e.g., Chard and Mellor, 1989; Barfield and Groombridge, 1998; Danzon and Towse, 2003; Maskus and Chen, 2004; Li and Maskus, 2006), prefer Ramsey-type differential pricing as the best way to improve access to low-price drugs while still preserving investment in R&D. Complementary to this perspective, cross-national drug price differentials may not be based on demand elasticity, but on differences in other relevant demand factors (Maskus, 2000; Scherer, 2003). The interference of national governments in private markets by way of regulation of drug prices is a factor causing price differences at international level (Anis and Wen, 1998; Pecorino, 2002; Jelovac and Bordoy, 2005).

[2]Preventing parallel trade by means of private contracts could be considered an anticompetitive behavior that prevails under competition law (Gallini and Hollis, 1999; Fink, 2005).

[3]Parallel imports are in fact part of the free trade policy.

[4]Official European statistics show that in 2002 the total share of parallel imports reached nearly 20% of the high-price pharmaceutical markets (Kontozamanis et al., 2003; Kanavos and Costa-Font, 2005).

[5]This aspect has been stressed with the particular aim to provide developing countries affected by endemic diseases, such as HIV/AIDS, and malaria, the necessary policy to tackle their health problems. On the other hand, the US government has recognized the possibility to prevent parallel trade from specific countries (Australia, Morocco, Singapore) by contractual means (Fink and Reichenmiller, 2005).

[6]Parallel trade does not imply necessarily price convergence if consumers do not believe that the original drug and the parallel imported drug have the same value (Jelovac and Bordoy, 2005). Empirical studies in the EU include Maskus and Chen (2002 and 2004), Ganslandt and Maskus (2004), Kanavos and Costa-Font (2005) and Kyle (2007).

[7]For a review of the literature see Szymanski and Valletti (2005).

A more recent strand of the literature reassesses the role of parallel trade and focuses on the willingness to invest in R&D. In the presence of parallel trade, welfare either increases or decreases depending on whether dynamic effects of parallel trade are examined (Rey, 2003; Valletti and Szymanski, 2006; Valletti, 2006). In particular, this issue has been addressed by Grossman and Lai (2008) who show that, in a world where international exhaustion is permitted, the pace of innovation often is faster than in one with national exhaustion. More precisely, Grossman and Lai (2008) consider that where parallel trade is permitted at the international level, a foreign government has incentives to apply a less stringent price control of pharmaceuticals, because it recognizes that its policy has a global impact and fosters investments. In a world with two countries, both the innovative country and its trading partner can achieve benefits from parallel trade in terms of increased consumer surplus and a boost in the pace of innovation.

2.2 Compulsory Licensing

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.

Strong criticism has been raised recently against the pharmaceutical lobbies because, despite significant steps being made in the treatment of important diseases, these innovations remain unaffordable for many people. It seems that the use of compulsory licensing could be beneficial in curbing high prices and increasing access to patented drugs. Indeed, although the introduction of the TRIPs agreement forces all WTO members to provide appropriate protection of the IPRs, governments which pursue health targets are allowed to employ the exceptions included in the TRIPs agreement and apply for a compulsory license on patented drugs.

Clearly, in order to have a compulsory licence, the occurrence of specific conditions are required. As described in the TRIPs agreement (art. 31), before applying for a licence, the person or company that has an interest in making use of a patented invention must first try to negotiate a voluntary licence with the patent owner. If the negotiation fails, then a compulsory licence can be delivered. The patent owner still has the right to make use of its own IPR, also in the same country where a compulsory licence has been granted. Moreover, with the aim to protect the IPRs of the innovative firm, the TRIPs agreement regulates an important exception about the international exhaustion of IPRs. Products made under compulsory licensing should be manufactured for $domestic\ use$ mainly, which therefore makes parallel trade irrelevant, despite under

certain circumstances they could be imported or exported. This question is known as the "Paragraph 6 problem".[8] Apart from a few important exceptions (i.e., Brazil, India and Thailand), most developing countries possess weak manufacturing capabilities, that makes worthless the possibility to invoke compulsory licensing. Although, the TRIPs agreement has never defined an unambiguous solution for this problem, under specific circumstances it is still possible to call for compulsory licensing, permitting parallel trade among WTO members for those goods manufactured under a non-voluntary licence (Matthews, 2004).

Compulsory licensing has been used as a bargaining device by specific countries in order to achieve discounts from big pharmas (Chien, 2003). One of the most successful cases of compulsory licensing comes from Thailand. In 2006, with the aim to provide universal health care, the Thai Ministry of Public Health issued the first of a subsequent series of compulsory licenses for three branded drugs. This licence allows the Thai Government Pharmaceutical Organization to import generic versions from countries where these drugs are not patented, or make use of the patented technology, qualifying Thailand for the production of the generic version in its own country, simultaneously to the monopolistic firm that still holds a patent on it (NHSO, 2007; Steinbrook, 2007).

Along the lines of the Thai experience, other countries have followed the same path, but obtaining di□erent results. Only a credible threat is able to achieve a price reduction in the negotiation with the monopolist. Brazil seems to have this ability. The strategy adopted by the Brazil government has been based on the mere threat of issuing a compulsory licence, by which deep discounted prices have been obtained without formally issuing a compulsory licence.[9] Although the use of discount exposes the monopolist to the risk that these lower prices may be used as external references pricing in other markets, it allows to keep up its reputation at the international level, preserving at the same time its market shares in large markets such as Brazil. When considering the adoption of compulsory licenses, governments must evaluate the costs of this exception. Indeed, the recourse to this derogation is not free of charge. The grant of a compulsory licence usually involves a long process. A government would first have to try and negotiate a licence with the patent owner; only after that failed could they get a compulsory licence. These procedures are time consuming and entail expensive legal and administrative costs

[8]The generic copy made under compulsory licences is allowed to be exported to countries that lack production capacity. In theory, all WTO member countries are eligible to import under this decision, apart from 23 developed countries. More details in Article 31(f), of the TRIPs agreement. With that regard, in 2006 the European Parliament intervened in the favor of those countries that are affected by the lack of manufacturing capabilities, allowing the use of parallel trade to address public health problems (see http://eur-lex.europa.eu/LexUriServ/ LexUriServ.do?uri=OJ:L:2006 :157:0001:0007:EN:PDF).

[9]See, for istance, http://www.cptech.org/ip/health/c/brazil/.

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 rise. These costs are related to reputational losses, sanctions and unilateral retaliation in response to the violation of the international law.[10]

Pharmaceutical companies believe that, if broadly used, compulsory licensing might undermine the incentives for innovation. The issuance of a compulsory licence might harm the patent holder by reducing the time during which the monopolist can exert its market power (Scherer and Watal, 2002). However, the fall of investments in R&D as a result of the use of compulsory licensing regimes is not a straightforward consequence as the patent holder has the ability to anticipate a compulsory licence (Rozek, 2000). In particular, the capability of countries to enforce the rules of the IPRs system plays an important role. Studies conducted on compulsory licensing regimes show that the speed of innovation did not su□er any destructive consequence from the presence of non-voluntary licenses (McFetridge, 1998). It has also been argued that in markets where a compulsory licence has been issued, not only has the licensee benefitted from some positive spillover e□ects, but under the competitive pressure the original innovator has also increased its R&D expenditures (Chien, 2003).

Although our main interest lies in the pharmaceutical industry, compulsory licences are used in a wider variety of cases, in both the patent and copyright areas. For example, in the U.S., National Public Radio and PBS have a licence as non-commercial institutions to play music on public broadcasting. In the biotech industry, the U.S. government has granted a number of compulsory licences 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. Compulsory licences are therefore used in the U.S. either for public-interest reasons like clean air, or to promote more competition. The government limits patents or copyrights, and grants compulsory licenses for these purposes. Here is where compulsory licensing and parallel trade can interact. For example, if a country uses compulsory licensing as a remedy to an anti-competitive problem, it can permit companies that get such a compulsory licence to export the product into world markets.[11] On the other hand, if compulsory licensing is used for giving medicines to poor people, then the primary market has to be

[10] Under the TRIPs agreement all WTO members must provide patent protection in their own nation, ensuring an effective action against any infringement of IPRs. It follows that countries that do not meet their new obligations are subject to trade penalties (Kerr and Gaisford, 2007).

[11] An example which involves a zero royalty licence is the U.S. Federal Trade Commission's requirement for open licensing of Dell's VL bus, a technology used in personal computers. See http://www.cptech.org/ip/health/cl for more information and examples.

domestic.

3 Model assumptions

There are two countries that we denote respectively as the North (N) and the South (S). In each country, consumers are heterogeneous, with preferences à la Mussa and Rosen (1978). Specifically, a consumer of type τ that buys a product of quality product u at a price p enjoys a net utility given by:

$$U(\tau) = \tau u - p, \tag{1}$$

where τ measures the consumer's marginal valuation of quality. The taste parameter τ is distributed uniformly over the interval $\tau \in [0, 1]$. Consumers can also decide not to buy any supplied good, and in this case they obtain their reservation utility, which is independent of type and 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.

Notice that, in contrast with previous literature, preferences in each country are $identical$, so that parallel trade cannot exploit differences in willingness-to-pay per se. Similar results would arise with alternative specifications that still resulted in the same elasticity of demand in both countries. This modelling choice is made to abstract from other aspects that have already been investigated by the literature, and thus make our contribution more transparent.

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 good, with the cost of quality, denoted as $C(u)$, increasing at an increasing rate, $C'(u) > 0$ and $C''(u) > 0$. These costs are incurred only at the investment stage, while all other costs at the manufacturing stage are set equal to zero.

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, this does not hold for the South. In particular, we assume that, when a mass x of consumers is supplied in the South, there are some associated entry 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 x of consumers served varies in equilibrium with k. Hence the role of k is also to take into account differences in the market size in the North relative to the South.

In other words, we have in mind that, in the South, there is a certain mass of potential consumers who live distributed over a line, with unit density. At each location, consumers have the same preferences as those defined by (1). The line represents how easy or difficult it is to supply and administer drugs at that location, as this involves infrastructure and skills (e.g., hospitals, trained doctors). Consumers at $x = 0$ are those in the biggest city, where it is very easy to supply them (e.g., because infrastructure is already in place), while those at the end of the line represent the least accessible patients, for whom great expenditures are needed to give them access to drugs. Notice that, at each location, there is heterogeneity of taste (i.e., rich and poor people live both in cities and in rural areas). A multi-dimensional screening problem, whereby τ and x were somehow correlated, is beyond the scope of this paper.

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 system of IPR that grants a patent to the monopolist for reasons that we do not model but just take as given. In contrast, we consider different approaches of the South government in relation to drug price control and compulsory licensing that we will further specify below. Hence the strategic players in our model are the monopolist firm and the South government.[12]

We proceed in developing the model in several steps. We study two different regulatory regimes on the exhaustion of IPRs. If parallel trade is banned, the firm can set a different price in each market, because market segmentation is possible. However, if parallel trade is permitted, the firm is forced to set an identical price both in the North and in the South market, as it would otherwise attract arbitrageurs. Arbitrage is perfect and reimportation costs do not exist (e.g., re-packaging and transport costs are zero).

[12] We do not study a strategic trade game between the North and the South, abstracting also from tariffs and subsidies (see, e.g., Acharyya and Garcia-Alonso, 2010; Roy and Saggi, 2011). While the North government is quite passive in our model, we are agnostic on who sets the preferred regime of parallel trade. We do evaluate the impact on welfare in the North, and therefore our results have implications in terms of what regime would be promoted by the North in international negotiations.

In the following Section, we first examine the simplest model where the South government is also passive and does not regulate drug prices, which are therefore freely set by the patent holder.

4 A benchmark: the irrelevance of parallel trade

Without parallel trade, perfect market segmentation is possible. Both in the domestic and in the foreign market, the patent holder behaves as a monopolist. We solve a two-stage game where the monopolist first decides on R&D, and then it sets the price in each market, as well as the coverage in the South.

In each market, there is 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 also convenient to define consumer surplus in both countries, which is respectively

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

In the last stage, the monopolist sets a price p_N in the North and a price p_S in the South to maximize its profits

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

It follows immediately that

$$p_N = p_S = p^* = \frac{u}{2},$$

with different profits in each country 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 $\pi_S = \frac{u}{4}x - k\frac{x^2}{2}$. The optimal coverage of the South is also immediately derived and equal to

$$x = \frac{u}{4k},$$

which is increasing in quality, as gross profits at each location in the South also increase

in quality.

In the first stage, the patent holder maximizes its global profits

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

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

$$\frac{1}{4} + \frac{u}{16k} = C'(u). \tag{3}$$

Since the monopolist already sets the same price everywhere, it is immediate to obtain our first result: parallel trade, despite forcing the monopolist to set a uniform price in every market, has no impact. Thus the monopolist still charges $\widetilde{p} = p^* = u/2$ everywhere, where we use the tilda sign for any regime with parallel trade.

Proposition 1 *In the benchmark, parallel trade does not affect the investment decision, and consumer surplus and welfare also are invariant to the exhaustion regime.*

The above analysis establishes our benchmark. Notice that we framed our approach in terms of a realistic two-stage game where investment choices are prior to the price setting. This timing is inconsequential though, since all decisions are taken by a single decision maker, and parallel trade does not affect optimal pricing. In the next section we show how parallel trade and the precise timing of moves have instead real effects when the government in the South engages in drug price control.

5 Price cap and commitment

In this section we analyze the effects produced by the introduction of price regulation in the South. Quite often governments regulate prices with the final aim to benefit consumers while still providing incentives to innovate.[13] We develop our analysis by assuming that the South government has the ability to set a price cap in its own market.[14] The price cap is chosen by a benevolent government with the aim to maximize the welfare of consumers in its own country alone. What will turn out to be critical for the analysis is the order of moves, which reflects also the South government's commitment ability. The complete sequence of the moves are shown in Figure 1, where we already anticipate the

[13] For an overview of theory and practice of price regulation in the pharmaceutical sector, see Danzon (1997) and Danzon and Chao (2000).

[14] We challenge this assumption in Section 6.

three different levels of commitment the South government might have, corresponding to its intervention at different points of the time line.

No commitment (NC) We start with the starkest example, where the South government has no commitment at all, and sets its regulated price in the last stage of the game. Thus, as it is shown in right branch of Figure 1, we consider the following timing of the game: first the firm invests in R&D, and successively decides the coverage of the South country, as well as the price in the North. Then, in the last stage, the South government sets the price in its own country.

It is immediate to show that the South government, once the good has been invented and delivered to the South, will always have an incentive to set its price as low as possible, that is, $p_S = 0$, as we normalized to zero all manufacturing costs. Therefore the monopolist anticipates that no profits will be made in the South, so it decides not to cover any part of it. Global profits are made only from the North, $\Pi = u/4 - C(u)$. The monopolist still invests, but an amount lower than before, as it is now $1/4 = C'(u^{NC})$ and thus, compared to (3), it is immediate that $u^{NC} < u^*$. Profits and consumer surplus decrease everywhere, especially in the South where there is no supply at all.

Notice that, once again, there is an irrelevance result arising from parallel trade. In fact, under parallel trade, if the firm supplied the South, the price regulated at zero would apply to the North as well, cannibalizing profits everywhere. Thus, under parallel trade, the firm will decide not to supply the South market, hence achieving the same outcome as without parallel trade, though for a slightly different reason.

Partial commitment (PC) The previous case points to the fact the South government has to give incentives to the firm to be present in its own market, both with and without parallel trade. These incentives arise from restraining its ability to regulate prices and avoid hold-up problems. Therefore we now alter slightly the timing of the game, which is again in three stages. First, the firm chooses R&D. Then the government of the South sets its regulated price. Finally, the firm decides the coverage of the South market, as well as the price in the North. This timing endows the foreign government with some commitment capabilities, as in the second stage it acts anticipating the monopolist's coverage decision. The complete timing of the events corresponds to the middle branch of Figure 1.

We start first with the case without parallel trade. In the last stage, the firm sets the monopoly price $p_N = u/2$ in the North, while coverage in the South is decided from

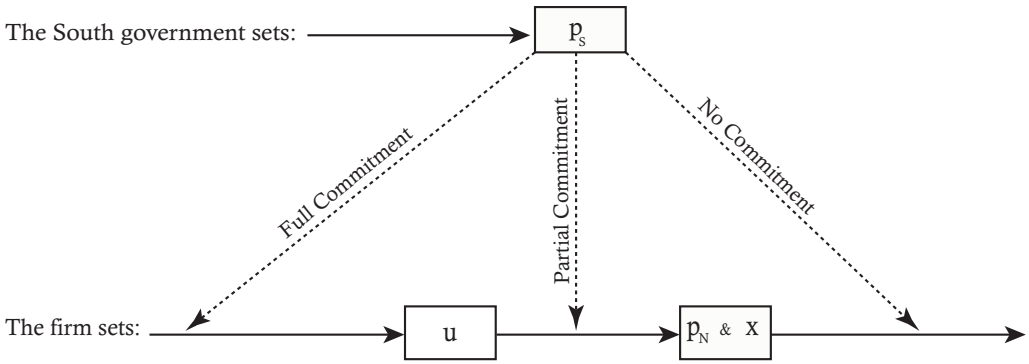

Figure 1: *Sequence of moves for different commitment levels*

maximizing $\pi_S = p_S(1 - p_S/u)x - kx^2/2$**, that is**

$$x = p_S \frac{u - p_S}{ku}. \tag{4}$$

In the second stage, the South government sets the price cap $p_S = p_C$ **that maximizes its consumer surplus, given by (2), anticipating the firm's coverage reaction:**

$$CS_S = x\frac{(u - p_C)^2}{2u} = \frac{(u - p_C)^3 p_C}{2ku^2},$$

which results in a price-cap of

$$p_C = \frac{u}{4},$$

that is obviously greater than zero (as otherwise coverage would also be zero), but also lower than the unrestricted monopoly price. From (4), coverage is then $x = 3u/16k$.

In the first stage, the monopolist maximizes the global profit

$$\Pi = \pi_N + \pi_S - C(u) = \frac{u}{4} + \frac{9u^2}{512k} - C(u), \tag{5}$$

from which we obtain a level of quality u^{PC} **that satisfies** $u^{NC} < u^{PC} < u^*$**,**[15] **i.e., investment is higher compared to the previous case without commitment, but lower than in the unregulated case. It also follows that the cap is set at** $p_C = u^{PC}/4 < p^*$.

We now turn to parallel trade. In the last stage, the monopolist anticipates that the

[15]The second inequality derives from comparing $\partial\Pi/\partial u$ with (3), and noting that $18u/512k < u/16k$.

price set in the South will determine the price globally, and thus maximizes

$$\pi_N + \pi_S = p_S(1 - p_S/u)(1 + x) - kx^2/2$$

with respect to the coverage in the South, which still gives (4), exactly as in the case without parallel trade.

Because of this, in the second stage the South government in principle should still set the same price cap as without parallel trade, that is, $p_S = p_C = u/4$. However, as the cap applies everywhere, the government of the South must ensure that the monopolist is willing to supply the product there. Recall that, in stage 2, quality has already been chosen and investment is sunk. Should the monopolist block sales to the South, it will then sell only in the North at a price $p_N = u/2$ with associated gross profits of $u/4$. Therefore the South government maximizes

$$\begin{aligned} \max_{p_C} CS_S &= \frac{(u - p_C)^3 p_C}{2ku^2} \qquad (6) \\ \text{s.t. } p_C(1 - \frac{p_C}{u})(1 + x) - \frac{kx^2}{2} &= \frac{p_C}{2}(1 - \frac{p_C}{u})[2 + \frac{p_C}{k}(1 - \frac{p_C}{u})] \geq u/4. \end{aligned}$$

We can now state the following result.

Proposition 2 *Imagine the South government can partially commit. (i) When the cost of supplying the South is low ($k \leq \frac{9u^{NC}}{32}$), investment is higher than without commitment but lower than in the benchmark. Parallel trade reduces both investment and the price cap: $u^{NC} < \widetilde{u}^{PC} < u^{PC} < u^*$ and $\widetilde{u}^{PC}/4 = \widetilde{p}_C < p_C = u^{PC}/4 < p^*$. (ii) When the cost of supplying the South is high ($k > \frac{9u^{NC}}{32}$), then parallel trade further reduces investment despite a more lenient cap: $u^{NC} = \widetilde{u}^{PC} < u^{PC} < u^*$ and $\widetilde{u}^{PC}/4 < \widetilde{p}_C$, $p_C = u^{PC}/4$, with $\widetilde{p}_C > p_C$ for very high values of k.*

Proof. The solution to (6) is simply the unconstrained solution $\widetilde{p}_C = u/4$ (which is the same expression as without parallel trade, though the qualities might di□er) if the constraint is not binding, which can be rewritten as $\frac{3u}{16} + \frac{9u^2}{512k} \geq \frac{u}{4}$. This does not bind if k is low enough. Otherwise it amounts to setting the lowest price that makes the firm's participation condition just binding. The solution then is

$$\widetilde{p}_C = \begin{cases} \frac{u}{4} \text{ i□ } k \leq \frac{9u}{32} \\ \frac{1}{2}(u - \sqrt{4ku + u^2 - 2u\sqrt{2k(2k + u)}}) > \frac{u}{4} \text{ i□ } k > \frac{9u}{32} \end{cases}. \qquad (7)$$

Under the parallel trade regime, $p_N = p_S = \widetilde{p}_C$ implies a global profit

$$\Pi = \pi_N + \pi_S - C(u) = \begin{cases} \frac{3u}{16} + \frac{9u^2}{512k} - C(u) & \text{if } k \leq \frac{9u}{32} \\ \frac{u}{4} - C(u) & \text{if } k > \frac{9u}{32} \end{cases}.$$

Compared to (5), the solution therefore is $u^{NC} < \widetilde{u}^{PC} < u^{PC}$, and thus $\widetilde{p}_C = \widetilde{u}^{PC}/4 < p_C = u^{PC}/4$, when $k \leq 9u^{NC}/32$. When $k > 9u^{NC}/32$, it is $\widetilde{u}^{PC} \equiv u^{NC}$. When k is close to the threshold value, then from (7) $\widetilde{p}_C$ is above but still close to $u/4$ and the prevailing effect is the reduction in quality: $\widetilde{p}_C < p_C$. When instead k is very high the inequality is reversed. To show this, take the limiting case $k \to \infty$: from (5) without parallel trade it is $u^{PC} \to u^{NC}$, with $p_C = u^{PC}/4$. Under parallel trade, from (7), it is $\widetilde{p}_C \to \widetilde{u}^{PC}/2$, with $\widetilde{u}^{PC} = u^{NC}$. Hence $\widetilde{p}_C > p_C$ for high enough values of k. QED

[Insert figure]

Proposition 2 shows that there are now real effects from parallel trade, which are further investigated with the help of Figure 2. The four panels plot the differences of several key variables (respectively global investment, price cap, consumer surplus in the South, and global welfare) with and without parallel trade, as a function of k, under a quadratic investment function, $C(u) = u^2/2$. When supplying the South is not very costly ($k \leq 0.087$), participation is not at stake, but the unconstrained price cap set in the South applies globally under parallel trade, which depresses investment. Price regulation in the South benefits consumers in the (unregulated) North under parallel trade, which is underlined by a higher global welfare. On the other hand, when incentives must be given to induce the firm to supply the South, as it is quite costly to do so, parallel trade further reduces investment down to the lowest level as without any commitment at all; however, as it brings a more lenient price cap in the South to ensure delivery, it can also increase coverage in the South.

Full commitment (FC) We now consider the possibility that the foreign government behaves differently. With the purpose of increasing its reputation, the government of the South is committed to set a price regulation that anticipates its full effects not only on the market coverage, but also on the investment in R&D. Such precommitment is the timing specifically considered in Grossman and Lai (2008), although our models differ in several other respects. Hence the game now has the following timing. The government of the South gets to move first and sets the price-cap in its own market. Then the monopolist observes the price-cap and chooses the amount of R&D investments. Finally, the monopolist sets the price applied in the unregulated market (in the absence

of parallel trade), as well as the market coverage in the South. The left branch of Figure 1 displays the complete timing of the game.

Without parallel trade, solving by backward induction, in the last stage the firm sets $p_N = u/2$ in the North achieving a profit $\pi_N = u/4$, while the South market coverage is the same as in the case with partial commitment, that is (4).

In the second stage, the monopolist chooses the optimal level of R&D by maximizing its global profits

$$\Pi = \frac{u}{4} + \frac{[p_S(1 - p_S/u)]^2}{2ku^2} - C(u),$$

from which ensues

$$\frac{\partial \Pi(p_S, u(p_S))}{\partial u} = \frac{1}{4} + \frac{p_S^3}{ku^2}\left(1 - \frac{p_S}{u}\right) - C'(u) = 0, \tag{8}$$

which characterizes implicitly the optimal investment $u(p_S)$ as function of p_S. We now establish an intermediary result.

Lemma 3 *Imagine the South government can fully commit. If the South government can force a price above the monopoly price, it can induce the monopolist to choose a quality which is above the level set in the unregulated benchmark. This is not possible if instead it can set only a price ceiling.*

Proof. From (3) and (8) we need to compare only $\frac{u}{16k}$ with $\frac{p_S^3}{ku^2}\left(1 - \frac{p_S}{u}\right)$. This last expression is first increasing in u and then decreasing, and reaches a maximum when $p_S = 2u/3 > p^* = u/2$. The value taken at this maximum is $\frac{8u}{81k} > \frac{u}{16k}$, and therefore the case with full commitment can generate a higher investment than u^* in case the marginal revenue intersects C' in this range. If instead a forced price is impossible, then at most the price can be p^*, in which case marginal revenue with full commitment can at most coincide with the benchmark case. QED

It is somewhat surprising that investment can be made higher than in the unregulated benchmark: however, for this to happen, the South government must be able to "force" very high prices of the drug (which may not be in its own interest in the first stage of the game). This comes from the fact that the quantity sold at each location takes the expression $1 - p_S/u$. Hence an increase in u implies a clockwise rotation around the horizontal intercept at 1 when $p_S = 0$. For very low prices the impact of u is negligible, while it becomes more and more relevant the higher is the price. However, the Lemma also finds that, if the government can only set a cap (and the firm is free to set prices below the cap), then an investment higher than in the benchmark cannot be obtained.

At the first stage, the maximization problem of the South government amounts to setting a price cap $p_S = p_C$ to maximize

$$\max_{p_C} CS_S = \frac{[u(p_C) - p_C]^3 p_C}{2ku(p_C)^2},$$

from which we derive our next result.

Proposition 4 *Imagine the South government can fully commit and there is no parallel trade. It is always more costly (i.e., a less stringent cap is needed) to elicit the same investment than under partial commitment. When $k > 3/16C''$, it is always $u/4 < p_C < p^*$; it is also $u^{NC} < u^{FC} < u^{PC} < u^*$ if k is high enough. When $k \leq 3/16C''$, it is always $u^{NC} < u^{PC} < u^* \leq u^{FC}$ and $p_C \geq p^*$.*

Proof. The first-order condition for the South is

$$\begin{aligned} \frac{dCS_S}{dp_C} &= \frac{\partial CS_S}{\partial p_C} + \frac{\partial CS_S}{\partial u}\frac{du}{dp_C} \\ &= \frac{(u - p_C)^2(u - 4p_C)}{2ku^2} + \frac{(u - p_C)^2 p_C(u + 2p_C)}{2ku^3}\frac{du}{dp_C} = 0. \end{aligned} \tag{9}$$

Suppose first that the South government wants to get a certain level u of quality. From

l03(u)-6(t)3.0011(h)-336.3980Td[(()2.99886(36)4.1874]TJR2010.9091Tf7.079691.67969Td[())30011(o)-346.986(m)-2.99886(a)

k. If instead k is close to $3/[16C''(u^{PC})]$, then p_C is close to p^* and investment will approach $u^* > u^{PC}$.

If $k \leq 3/16[C''(u^{FC})]$, then (9) is always positive at $p = p^*$. If the South government could ensure a price higher than the unregulated price, it would do so and achieve $u^{FC} > u^*$, making use of the previous Lemma. If the South cannot force a price above the monopoly level, it will set $p_C = p^*$ and achieve $u^{FC} = u^* > u^{PC}$. QED

Essentially, when k is small, investment is very responsive to price regulation. In fact, we established that when k is low enough the South government would even want to force prices above the unregulated monopoly level. When this cannot be enforced, the best the South government can do is not to regulate at all, in which case we fall back into the unregulated benchmark. Hence, despite having a full commitment ability, the South uses it by withdrawing regulation entirely. If instead investment is not too responsive to price regulation (which happens when the cost of supplying the South is very large), then the South government will want to set a binding price cap. In the limit, when k is made arbitrarily large, it would set the same price cap as under partial commitment: however this will achieve a strictly $lower$ investment because, under full commitment, R&D costs are not yet sunk and it is now more difficult to elicit investment.

Now we imagine that parallel trade is permitted. The effect of the price cap policy chosen by the South government affects the profits of the innovative firm also in the market of the North. The game takes the same timing as in the no parallel trade regime.

As above, at the third stage the monopolist defines the South market coverage with the aim to maximize its global profit. In the second stage, the firm determines its R&D investment according to the following maximization problem:

$$\begin{aligned} \max_u \Pi &= (1+x)p_C(1-\frac{p_C}{u}) - k\frac{x^2}{2} - C(u) \\ \text{s.t. } x &= p_C\frac{u-p_C}{ku}. \end{aligned}$$

This leads to the following first-order condition

$$\frac{\partial \Pi(p_C, u(p_C))}{\partial u} = \frac{p_C^2}{u^2} + \frac{p_C^3}{ku^2}(1-\frac{p_C}{u}) - C'(u) = 0, \qquad (10)$$

which characterizes the optimal investment $u(p_C)$ as function of price set by the government of the South.

In the first stage, the South government defines the price-cap, anticipating the monopolist's investment decision in R&D while still ensuring delivery into the South. If

the firm refuses to supply the South, the firm can ensure a payo equal to the case without commitment, whereby only the North is supplied at the monopoly price. Thus, the problem of the government of the South becomes

$$\begin{aligned} \max_{p_C} CS_S &= \frac{[u(p_C) - p_C]^3 p_C}{2ku(p_C)^2} \\ s.t.\ \Pi &\geq \frac{u^{NC}}{4} - C(u^{NC}). \end{aligned} \tag{11}$$

Proposition 5 *Imagine the South government can fully commit and there is parallel trade, hence no price can be forced above p^* even if it were feasible in the South. When $C(u)$ is not too convex, it is always $\widetilde{p}_C = p^*$ and $\widetilde{u}^{FC} = u^*$. Parallel trade strictly increases investment compared to its absence when k is high enough.*

Proof. The (unconstrained) first-order condition still takes the form as in (9) where $\frac{du}{dp_C}$ is now derived from (10), leading to

$$\frac{du}{dp_C} = \frac{up_C(2ku + 3up_C - 4p_C^2)}{ku^4C'' + 2p_C^3u - 3p_C^4 + 2p_C^2ku}. \tag{12}$$

We obtain that, at the unregulated price, it is

$$\left.\frac{dCS_S}{dp_C}\right|_{p_C=p^*} = \frac{u(8k + 3u - 16kuC'')}{8k(8k + u + 16kuC'')}.$$

At $p_C = p^*$ we can also simplify the monopolist's FOC (10) that becomes the same as (3) which we re-write as

$$k = \frac{u}{4[4C'(u) - 1]},$$

where it must hold that $C' > 1/4$. We substitute this expression and finally get

$$\left.\frac{dCS_S}{dp_C}\right|_{p_C=p^*} = \frac{(4C' - 1)(12C' - 1 - 4uC'')}{8C' + 2 + 8uC''}.$$

The first bracket at the numerator is always positive. The second bracket can be written as $4C' - 1 + 4(2C' - uC'')$, which is always positive as long as C'' is not too convex.[16] At this price the participation constraint does not bind, since the monopolist earns profits as in the unregulated benchmark, strictly more than in the case with no commitment. If the South tried to force a price above p^* (but in the South alone), then parallel trade

[16] For instance, if one uses a power function $C(u) = u^\alpha/\alpha$, the expression is non-negative iff $\alpha \leq 3$.

would make this policy ine□ective as the price p^* set in the North would apply in the South too. Hence the South government can just withdraw regulation and achieve the benchmark.

Contrasting these results with the previous proposition, we also immediately derive that, when $k > 3/16C''$, parallel trade increases investment: $\widetilde{u}^{FC} > u^{FC}$. When instead when $k \leq 3/16C''$, parallel trade achieves either the same level of investment if the South can only set a cap, or a lower level if the South can force prices above p^* without parallel trade. QED

[Insert figure]

Our main result is that the e□ects of parallel trade change dramatically under partial and full commitment. Parallel trade can have the paradoxical e□ect of causing more rather than less investment *only* under full commitment, and when k is high enough. Indeed, when k is low, the impact of the South on global investment is so large that it is better for its government of the South to withdraw any regulation, both with and without parallel trade. Parallel trade therefore has no impact as preferences are identical at every location in our model. It is only when k is high enough that parallel imports achieve more investment: when the South is insulated, its government would want to regulate the local price, reducing investment, compared to the case with parallel trade when it is optimal to leave the monopolist unregulated. For the same reason, parallel trade always increases the price when k is high enough: only without parallel imports price cap regulation would in fact be binding.

In Figure 3 we plot again some key variables as a function of k, now for the full commitment case. When the cost of supplying the South market is large ($k > 0.187$), the government regulates its price only without parallel trade and elicits less investment. In this range, the North, which carries a big weight compared to a relatively small South, is always left unregulated.

Another interesting set of findings relate to the value that the South can get from commitment. While no commitment is clearly the worst case, we have shown that partial commitment is better than full commitment. This is particularly evident under parallel trade: under full commitment the best the South can do is to withdraw regulation, as otherwise too little investment would occur. Instead, under partial commitment, there is always a region of parameters such that the government prefers to set a binding cap, after investment has occurred. Since the unregulated price is always available also under partial commitment, a simple revealed preference argument implies that the South must be better o□ under partial commitment. Although we have not discussed the additional

costs that the South government might have to incur in order to achieve commitment, it follows from our analysis that the South government should not spend additional resources to achieve full commitment and move first.

6 Compulsory Licensing regime

Our focus in this section is on the compulsory licensing regime. We develop a model in which we consider that the non-innovative country is now capable to bypass the monopolist's good, if a compulsory licence is granted and used. Recall from Section 2.2 that compulsory licensing represents one of the exceptions issued by the TRIPs agreement. It is a non-voluntary licence that allows to produce lower cost equivalents of branded good with the aim to cover a specific market, or to export the good to countries unable to manufacture the drugs by themselves (under the "Paragraph 6 problem").[17]

We now illustrate how the model is extended and amended to account for compulsory licensing. In Section 5 we endowed the South government with a strong bargaining power, as it was indeed the South government who made take-it-or-leave-it o□ers to the monopolist, at the stage of price regulation. While this modelling feature has been used pervasively in the literature, it is arguably not very convincing when considering relatively small developing countries, confronted with powerful multinational pharmaceutical companies. If one instead assumed there that it was the monopolist to make take-it-or-leave-it o□ers to the Southern government, clearly we would always obtain the benchmark results, as the firm would behave as an unconstrained monopolist. We now employ this alternative assumption, but we also allow the government of the South to have an outside option, given by the threat to recur to compulsory licensing.

More precisely, we consider the following timing (see Figure 2). First, the monopolist decides on its R&D e□orts. In the second stage, the firm proposes a price p_S to the South government (this is equivalent to a royalty). If the o□er is accepted, in the last stage the firm decides on the coverage of the market in the South, and simultaneously sets the price in the North. If the o□er is not accepted, the government of the South can resort to compulsory licensing, and the firm still sets the price of the branded good in the North. The use of compulsory licensing implies that the government of the South serves domestic consumers (i.e., 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. These costs are due to administrative and legal procedures (e.g.,

[17] See supra at footnote 8 and Matthews (2004).

legal costs connected to the violation of international law), but also (potentially) to some reputational loss and retaliation as the monopolist might have a whole portfolio of drugs. The idea is that it would be cheaper for the South to regulate the price the drug than to engage in a complicated WTO procedure for the licence. 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 e□ciency-enhancing *per se*.

Initially we develop our analysis assuming a regime in which parallel trade is banned. Afterwards, we introduce parallel imports. Those drugs compulsorily licensed are in principle constrained by the South boundaries and thus cannot be the object of parallel trade to the North, even if the northern region had decided for an international exhaustion regime and charges a higher price. Compulsory licensing represents an exception to the rule of uniform pricing in a regime allowing parallel trade. However, this interpretation is itself subject to criticism, and therefore we will also consider the case where parallel trade is applicable to drugs manufactured under compulsory licensing as well.

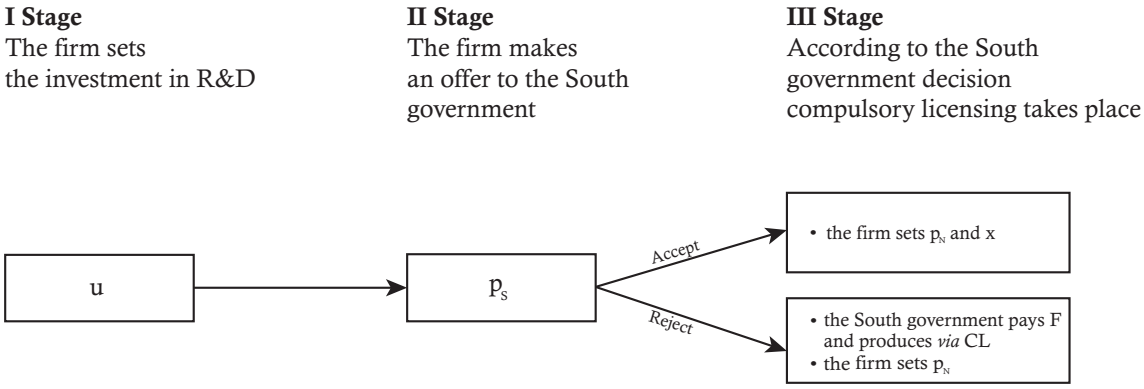

Figure 2: *Sequence of moves under the compulsory licensing regime when parallel trade is banned*

Compulsory licensing Compulsory licensing endows a country with manufacturing capabilities to yield the generic version of the branded drug without the authorization of the patent holder. Indeed, when a non-voluntary licence has been accorded, the foreign government is allowed to use the monopolist's technology to manufacture and sell drug domestically (or, equivalently, import it from a third country). Under the compulsory licensing regime, in the last stage of the game the Southern government optimally sets the price of the drug to zero (the marginal production cost) and also sets the market

coverage to maximize the following welfare function

$$W_S = x\int_{\underline{\tau}_S}^{1}(\tau u)d\tau - k\frac{x^2}{2} - F,$$

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

$$x = \frac{u}{2k},$$

which identifies the welfare of the South achievable under compulsory licensing (CL) as

$$W_S^{CL} = \frac{u^2}{8k} - F. \tag{13}$$

Alternatively, in case the government accepts the o□er of the monopolist, then the game unravels as in the previous sections, where the monopolist's coverage is (4) which ensures a welfare in the South which coincides with its consumer surplus of

$$CS_S = x\int_{\underline{\tau}_S}^{1}(\tau u - p_S)d\tau = \frac{(u-p_S)^3 p_S}{2ku^2}, \tag{14}$$

since F is now not spent. Comparing (13) and (14), if $F < \frac{1}{k}[\frac{u^2}{8} - \frac{(u-p_S)^3 p_S}{2u^2}]$ the o□er is rejected and compulsory licensing is preferred, otherwise the government of the South accepts the o□er made by the monopolist. To conclude the characterization of the third stage, since we are in the regime where parallel trade is not permitted, the price in the North is always set at $p_N = u/2$.

In the second stage, the monopolist makes its take-or-leave-it o□er, subject to the foreign government's ability to recur to compulsory licensing. If the o□er 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 $\pi_S = \frac{[p_S(1-p_S/u)]^2}{2k}$ in the South, precisely as in the case of full commitment.

We can easily establish some limiting cases. First, if the monopolist was unconstrained, the profits in the South would be maximized for $p_S = p^* = u/2$, from which it follows a consumer surplus of $CS_S = u^2/32k$ 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 o□er 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 instead of its profits, we know from the previous section that it would o□er a price $p_s = u/4$.

At this price, the corresponding consumer surplus is $CS_S = 27u^2/512k$, 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

$$p_S(u) = \begin{cases} \frac{u}{2} \quad \text{if } Fk > \frac{u^2}{8} - \frac{u^2}{32} = \frac{3u^2}{32}, \\ \frac{(u-p_S)^3 p_S}{2ku^2} = \frac{u^2}{8k} - F \quad \text{if } \frac{37u^2}{512} \leq Fk \leq \frac{3u^2}{32}, \\ \text{offer rejected} \quad \text{if } Fk < \frac{u^2}{8} - \frac{27u^2}{512} = \frac{37u^2}{512}. \end{cases} \tag{15}$$

Moving back to the first stage, having as a target the maximum global profit, 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

$$\max_u \Pi(u, p_S(u)) = \pi_N + \pi_S - C(u), \tag{16}$$

where $\pi_N = u/4$ and the value of π_S depends on the value taken by the fixed cost.

We are now in a position to prove our next result.

Proposition 6 *(i) When $Fk \geq 3(u^*)^2/32$, compulsory licensing (CL) is not a credible threat and the equilibrium is the same as in the benchmark: $u^{CL} = u^*$, $p^{CL} = p^*$, $x^{CL} = x^*$. (ii) When $L < Fk < 3(u^*)^2/32$, with $L < 37(u^{NC})^2/512$, CL is a credible threat but the South is still supplied by the monopolist: $u^{CL} < u^*$, $u/4 < p^{CL} < p^*$, $x^{CL} < x^*$, where $u^{CL} < u^{NC}$ when Fk approaches L. (iii) When $Fk \leq L$, CL is exercised along the equilibrium path: $u^{CL} = u^{NC}$, $p^{CL} = 0$, $x^{CL} > x^{NC}$.*

Proof. 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 $Fk > 3(u^*)^2/32$. 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 $u = u^{NC} < u^*$. This candidate solution is valid as long as $F < 37(u^{NC})^2/512$. Finally, 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

$$CS_S = \frac{u^2}{8k} - F \Rightarrow 4(u - p_S)^3 p_S - u^2(u^2 - 8Fk) = 0. \tag{17}$$

In the first stage, the firm solves

$$\frac{d\Pi}{du} = \frac{\partial \Pi}{\partial u} + \frac{\partial \Pi}{\partial p_S}\frac{\partial p_S}{\partial u} = 0, \tag{18}$$

which coincides with (10) under full commitment only in case $\frac{\partial p_S}{\partial u} = 0$. However now, by means of implicit differentiation of (17), it is

$$\frac{\partial p_S}{\partial u} = \frac{\frac{\partial \frac{u^2}{8k}}{\partial u} - \frac{\partial CS_S}{\partial u}}{\frac{\partial CS_S}{\partial p_S}} = \frac{\frac{u}{4} - \frac{(u-p_S)^2 p_S (u+2p_S)}{2u^3}}{\frac{(u-p_S)^2(u-4p_S)}{2u^2}} \tag{19}$$

The numerator of (19) is always positive, as the expression $\frac{(u-p_S)^2 p_S (u+2p_S)}{2u^3}$ is single peaked in p_S for $p_S < u$, and even at the maximum can never exceed in absolute value $u/4$. The denominator is always negative as we are in a range of prices between the unregulated benchmark and the preferred price for the South: $u/4 < p_S < u/2$. 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 (18) it is also $\frac{\partial \Pi}{\partial p_S} = 0$ for $p_S = p^*$, and $\frac{\partial \Pi}{\partial p_S}$ for all $p_S < p^*$, we can then conclude that quality starts at u^* when $Fk = 3(u^*)^2/32$, and then decreases monotonically as F becomes smaller and $p_S < p^*$. The solution is found by looking, in the $\{p_S, u\}$ space and within the admissible cone $u/4 < p_S < p^*$, at the highest isoprofit curve of the monopolist satisfying the constraint (17). 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 $p_S = p^*$ and then convex for lower prices, while instead the constraint is vertical at $p_S = u/4$ 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 $\frac{u^{NC}}{4} - C(u^{NC})$. In fact, as $\frac{\partial \Pi}{\partial u}\big|_{u=u^{NC}} < 0$ 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 up to a limit value L strictly lower than $37(u^{NC})^2/512$, where L is defined by the isoprofit curve $\Pi = \frac{u^{NC}}{4} - C(u^{NC})$ subject to (17), and b) it necessarily offers a quality below u^{NC} for values of Fk approaching L from above.

Results on coverage follow easily by noting that in region (iii) it is $x^{CL} = u^{NC}/2k$. When instead we are in the intermediate region (ii), then from (4) it is $x^{CL} < u/4k$. As we have just established that, when Fx approaches L, $u < u^{NC}$, for sure coverage jumps up when Fx is further reduced and CL is exercised in region (iii). In fact, it may even be that coverage in region (iii) is higher than in region (i) where it is $x^{CL} = u^*/4k$,

depending on the convexity of the cost function $C(u)$ and on the value of x. QED

Obviously, when the recourse to a compulsory licence is useless due to its high costs, the monopolist still asks for the unconstrained monopoly price, and we fall back to the initial 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 to a decreases both in u (reaching levels even below the case with no commitment) and x. As F is further decreased, they both increase when the South government starts manufacturing via the compulsory licence.

For intermediate values of F, 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 o□er. Compulsory licensing is a credible threat but it is not played along the equilibrium path. In this intermediate range, it is clear that the South government always benefits from compulsory licensing compared to the benchmark, since it gets a cheaper price, despite the reduction both in quality and in coverage.

For low 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 where the outside option just binds: it does so by actually o□ering fairly low levels of u which can be matched by a small increase in the price p_S. We have shown that the monopolist goes even below the level it would choose under non commitment (when it makes profits only in the North market, and zero in the South). This is not a paradoxical result but comes from the fact that an increase in quality improves the outside option relatively more than CS_S. The monopolist thus "stretches" the validity of the intermediate region (ii) until it finds it optimal to give up the South market, i.e., when F is very low. Indeed, under the outside option which is now taken in region (iii), 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, and the market coverage of the South can even be larger than in the benchmark.

Before turning the analysis to the case with parallel trade, 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.[18] Second, a key role is played by our assumption that the monopolist can make a take-it-or-leave-it o□er only based on price, but not on coverage. When the o□er 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 o□er and act on its own. If instead one postulated that the monopolist could make contractible o□ers based $both$ on price 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.

Parallel trade In this subsection we assume that countries have opted for an international exhaustion regime making parallel trade legal. 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 the TRIPs agreement, the same rules establish that all goods yielded under compulsory licensing should be confined to the country that has called for a compulsory licence. However, exceptions are permitted.

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 o□er and recurs instead to compulsory licensing, two scenarios are possible. In the first case, that we shall call "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.

As far as the South is concerned, this distinction is immaterial after investment has occurred. As before, if $Fk < \frac{u^2}{8} - \frac{(u-p_S)^3 p_S}{2u^2}$ the o□er 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 o□er. Thus the optimal price schedule still takes the same form as (15).

In the first stage, the monopolist chooses the level of R&D to maximize (16), where

[18] Instead of (13), the value of the outside option would now be $W_S^{CL} = \frac{(u^2-p^2)^2}{8ku^2} - F$, where p is the solution to the break-even condition in the South $\frac{(u-p)^2(3p-u)(p+u)}{8ku^2} - F = 0$.

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 7 *(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.*

Proof. 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 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 $\pi_N = 0$ and quality is again as in the case without parallel trade (identical to the case with no commitment). 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 (16) satisfying the constraint (17). 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,[19] 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 $\Pi = \frac{u^{NC}}{4} - C(u^{NC})$ subject to (17).

We now turn our analysis to the case of "unrestricted parallel trade". Due to exceptions, 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

[19] 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 $u/4 < p_S < p^*$.

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

For intermediate values of F, 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. The difference arises when $F < \widetilde{L}$. Then the "unrestricted" regime extends the validity of the region where the monopolist still supplies the South. Recall that compulsory licensing is effectively implemented when $F < 37u^2/512$. The "restricted" regime protects IPRs more, thus giving higher incentives to invest in R&D and making compulsory licensing more appealing for the South. Conversely, in the "unrestricted" regime the monopolist prefers to always sell to the South in order to avoid the risk of reimportation (at a zero price). In any case, parallel trade, by reducing the monopolist's profits, reduces investments compared to the absence of parallel trade.

For very low values of F, the difference between "unrestricted" and "restricted" parallel trade is starkest. When there is a prohibition of importation, parallel trade has no effect for low F. 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, 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 consumer surplus and profits would be zero everywhere with "unrestricted" parallel trade.

7 Summary and conclusions

The exhaustion of intellectual property rights introduced by the TRIPs agreement represents one of the most controversial issues in the debate over the protection of IPRs, especially in the pharmaceutical sector. Although the presence of parallel trade does not imply any infringement of intellectual property rights, the circulation of the patented goods occurs without the authorization of the patent owner. It follows that patented products become available in the same market where the patent holder supplies its goods, thus limiting the possibility for the monopolist to exert its market power. The pharmaceutical industry claims that the use of these exhaustions are detrimental for the pace of innovation, because incentives to invest in R&D shrink.

This paper provides insights into the role of these international exhaustions. We studied a stylized dynamic game between a monopolist, based in the North, and a for-

eign government, based in the South, and we considered the interdependence between parallel trade and the regulation policies available to the South government. Our model is deliberately simplified, assuming identical preferences in each country, invalidating the effect of parallel trade in the absence of government regulation. Thus parallel trade in our framework can have real effects *only* when combined with other regulatory instruments, as demand elasticities between countries do not differ. We focused on the interaction between international exhaustion and two policy instruments: price regulation and compulsory licensing. We accounted for the investment opportunity in R&D, and we obtained a complete welfare analysis that is able to pin down the efficacy of government policies when parallel trade is or is not allowed.

Another innovative aspect introduced by our analysis concerns the role played by the health care system whereby drugs are provided to the population. Because of weak infrastructure and skills, access to drugs for people living in the rural areas of developing countries is limited by high costs that discourage the monopolist over and above the effect arising from low income. We investigated the problem of access to drugs as measured by the market coverage in the South, considering different policies under the international exhaustion regime.

The model that we used is simple and tractable, yet quite rich in the results that it achieves. We first discussed the consequences of public intervention under the assumption that the foreign government can credibly commit to its announced regulated prices. Indeed, the standard hold-up problem can be overcome if the government of the South has commitment abilities. Specifically, when the foreign government introduces price regulation to reduce the price of patented goods, we have found that parallel trade can produce contrasting effects on investment. In particular, under the partial commitment case, when supplying the market of the South is quite costly, parallel trade unambiguously reduces investment. Since parallel trade exports the regulated price also into the North, from which consumers in the North benefit, the net assessment of parallel trade can still be positive. When, for reputational reasons, the South government defines the price policy before the investments in R&D are set, we have found that parallel trade plays no role if the cost to supply the South market is low: the South government always prefer to renounce any regulation in any case. If instead supplying the South market is costly, the government of the South still withdraws regulation when its price applies globally, while it would set a more stringed regulation if its market was insulated: this explains when parallel trade can actually create higher incentives to conduct R&D.

We also studied the effects of compulsory licensing when the government of the South has manufacturing capabilities. Allowing the government of the South to be autonomous

in the production and distribution of the patented drugs, the recourse to this outside option represents a credible threat for the monopolist if the costs connected to this exception are sufficiently low. We have found that, despite its low bargaining power in setting the price of the drug supplied by the monopolist, the government of the South is able to exert its influence on the monopolist's decisions. For intermediate values of these exceptions-related costs, the firm is induced to allow for a specific level of the welfare in the South when making an offer. An analysis of the impact of parallel trade crucially depends on the precise implementation of the protection of IPRs to products that are compulsory licensed, in particular with respect to the circulation of the compulsory licensed goods. Our results have shown that parallel trade affects negatively investments and welfare, especially when the South government is not able to ensure an effective enforcement of the IPRs.

We conclude by emphasizing once more that the welfare implications of parallel trade cannot be fully understood if one omits from the analysis its interaction with the governments' commitment capabilities. In our model, the government in the South faces different incentives for regulating prices or resorting to compulsory licensing when parallel imports are allowed by its trade partner in the North from when they are not. Parallel trade makes government policies interdependent and forces every government to consider the consequences of its actions on global incentives to invest. Therefore, a balanced approach towards the evaluation of the costs and benefits of allowing parallel imports should fully incorporate these additional strategic effects of the exhaustion regime on the level of both price and quality of drugs.

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