

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 effects 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 pharmaceutical 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

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

framework where international exhaustions have real effects *only* when combined with other regulatory instruments, as demand elasticities between countries do not differ in our model. This analysis underlines how the efficacy of the Southern 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 Southern 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.² 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 '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 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

²See, among others, Grout, 1984, and Grossman and Hart, 1986.

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 affect 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.³ In this respect, our analysis demonstrates that 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 difficult questions, especially in the pharmaceutical industry.

³Different health care systems along with improper high taxes and dispensing fees contribute to undermine the availability of several essential drugs (Pecoul et al., 1999; WHO, 2002).

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 effects also need to be considered. Allowing the IPR holder to prevent parallel trade could represent an obstacle to free trade,⁴ 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.⁵ Parallel trade represents a growing business catching the attention of the international community.⁶ 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.⁷

Some studies argue that parallel trade, where it is permitted, has not yielded the expected results in terms of convergence in price.⁸ Although several policy papers have been addressed to this scope, less attention has been paid on the economic implications of parallel trade on IPRs.⁹ 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

⁴Preventing parallel trade by means of private contracts could be considered an anticompetitive behavior that prevails under competition law (Gallini and Hollis, 1999; Fink, 2005).

⁵According to the principle of the free movement of goods, parallel imports are part of the free trade policy.

⁶Official statistics in the European pharmaceutical sector reveal that in 2002 the total share of parallel imports reached nearly 20% of the high-price markets (Kontozamanis et al., 2003; Kanavos and Costa-Font, 2005).

⁷This 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).

⁸Parallel 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).

⁹For a review of the literature see Szymanski and Valletti (2005).

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). Moreover, it is well known that policy makers are affected in their choices by the influence of the lobbying activities of interest groups (Grossman and Helpman, 1994; Gawande and Krishna, 2003) and this has been confirmed also in the health care sector (Steinbrook, 2007).

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 try to negotiate a voluntary licence with the patent owner, for which the latter will receive a corresponding royalty. If the negotiation fails, then a compulsory licence is 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 may 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”.¹⁰ 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 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 pharmaceutical companies (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.¹¹

Along the lines of the Thai experience, other countries have followed the same path, but obtaining different 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. Although the use of discount exposes the monopolist to

¹⁰The 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>).

¹¹Thai Government has engaged in a robust campaign to remove all the barriers in the health care sector, including the plan to subsidize production and distribution (NHSO, 2007).

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 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.¹²

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 suffer 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 effects, 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

¹²Under 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).

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.¹³ On the other hand, if compulsory licensing is used for giving medicines to poor people, then the primary market has to be domestic.

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 unit mass of heterogeneous consumers, 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, we specify that 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 $C''(u) > 0$. To obtain

¹³An 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.

closed-form solutions, we employ the following cost function:

$$C(u) = \frac{(u - 1)^2}{2},$$

for any $u \geq 1$, whereby, if no investment is sunk, the monopolist still supplies a “basic” good of quality $u = 1$. This normalization is immaterial for most of our results.¹⁴ All 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 fraction 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 $H''(x) > 0$. Again, to obtain closed-form solutions we employ the following function:

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

Given our normalization, x represents also the mass of consumers served in the South. In other words, we have in mind that, in the South, there is a unit mass of consumers who live distributed over a line of unit length. 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 $x = 1$ 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. 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.¹⁵

¹⁴In Section 6 below, we explicitly comment on one case (with parallel trade and compulsory licensing) where some results depend on this assumption.

¹⁵We do not study a strategic trade game between the North and the South, abstracting also from

We proceed in developing the model in several steps. We assume that there are 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 perfect 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. Notice that arbitrage is perfect and reimportation costs do not exist (e.g., re-packaging and transport costs are zero).

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

$$\tau_i = p_i/u,$$

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

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

In the last stage, the monopolist sets a price p_N in the North and a price p_S in the South

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.

to maximize its profits

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

It follows immediately that

$$p_N = p_S = \frac{u}{2},$$

and

$$\underline{\tau}_N = \underline{\tau}_S = \frac{1}{2},$$

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 $\pi_S = (\frac{u}{4} - \frac{x}{2})x$. The optimal coverage of the South is also immediately derived and equal to

$$x = u/4,$$

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

$$\Pi = \pi_N + \pi_S - C(u) = \frac{u}{4} + \frac{u^2}{32} - \frac{(u-1)^2}{2}.$$

The monopolist thus offers both in the North and in the South a good having the same optimal quality equal to

$$u = \frac{4}{3} > 1.$$

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 $p^{PT} = u/2$ everywhere and supplies $u^{PT} = 4/3$, where PT means “parallel trade”.

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

The above analysis establishes our benchmark. All the equilibrium values are summarized below in Table 1 where we also include Global Welfare, defined as the sum $\Pi + CS_N + CS_S$. 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.

u	x	CS_N	CS_S	Π	$Global\ Welfare$
4/3	1/3	1/6	1/18	1/3	5/9 \approx 0.556

Table 1: *Welfare analysis in the benchmark*

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.¹⁶ We develop our analysis by assuming that the South government has the ability to set a price cap in its own market.¹⁷ 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 three different levels of commitment the South government might have, corresponding to its intervention at different points of the time line.

No commitment 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

¹⁶See Vickers and Yarrow (1988). For an overview of theory and practice of price regulation in the pharmaceutical sector, see Danzon (1997) and Danzon and Chao (2000).

¹⁷We challenge this assumption in Section 6.

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, $\Pi = u/4 - (u - 1)^2/2$. The monopolist still invests, but an amount lower than before, as it is now $u = 5/4 < 4/3$. Profits and consumer surplus decrease everywhere, especially in the South where there is no supply at all. See Table 2.

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 different reason.

u	x	CS_N	CS_S	Π	$Global\ Welfare$
5/4	0	5/32	0	9/32	7/16 \approx 0.438

Table 2: *Welfare analysis with no commitment*

Partial commitment 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.

Notice that 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 $p_N = u/2$ in the North, while coverage in the South is decided from maximizing $\pi_S = p_S(1 - p_S/u)x - x^2/2$, that is

$$x = p_S(1 - p_S/u). \quad (3)$$

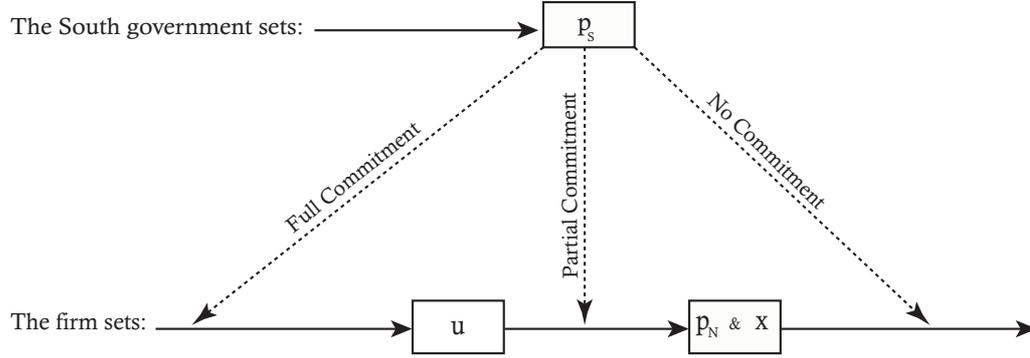


Figure 1: *Sequence of moves for different commitment levels*

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

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

which results in a price-cap of

$$\hat{p}_S = \frac{u}{4},$$

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

In the first stage, the monopolist maximizes the global profit

$$\Pi = \pi_N + \pi_S - C(u) = u/4 + (3u/16)^2/2 - (u - 1)^2/2,$$

from which we obtain a level of quality $u = 320/247 \approx 1.296$, which is higher than the previous case without commitment, but lower than the unregulated case. The cap is set at $\hat{p}_S = 80/247 \approx 0.324$.

We now turn to parallel trade. In the last stage, the monopolist anticipates that the price set in the South will determine the price globally, and thus maximizes

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

with respect to the coverage in the South, which still gives $x = p_S(1 - p_S/u)$, exactly as in the case without parallel trade.

Because of this, in the second stage the Southern government in principle should still set the same price cap as without parallel trade, that is, $\widehat{p}_S = u/4$. Investments then change in the first stage since the capped price is applied globally, and the monopolist maximizes $\Pi = 3u/16 + (3u/16)^2/2 - (u-1)^2/2$, resulting in $u = 16/13 \approx 1.231$.

However, this candidate solution immediately entails a problem: the global profits of the monopolist would amount to $\Pi = 3/13$, which are “too low”, as we now show. In fact, the monopolist can always refuse to ship the good to the South, in the anticipation that it will be capped, and remain an unregulated monopolist in the North alone, thereby earning a guaranteed profit of $\Pi = u/4 - (u-1)^2/2$. From this strategy, it would set $u = 5/4$, and earn $\Pi = 9/32 > 3/13$.

Therefore the regulated price cannot be $\widehat{p}_S = u/4$ with parallel trade. Instead, the government of the South will set a cap, subject to inducing the monopolist to supply the product there. Recall that, in stage 2, the 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 Southern government maximizes

$$\begin{aligned} \max_{p_S} CS_S &= \frac{(u - p_S)^3 p_S}{2u^2} \\ \text{s.t. } p_S(1 - \frac{p_S}{u})(1 + x) - \frac{x^2}{2} &= \frac{p_S}{2}(1 - \frac{p_S}{u})[2 + p_S(1 - \frac{p_S}{u})] \geq u/4. \end{aligned} \quad (4)$$

The solution to this problem is simply to set the lowest price that makes the firm’s participation condition binding, that is

$$\widehat{p}_S = \frac{1}{2}(u - \sqrt{4u + u^2 - 2u\sqrt{2(2+u)}}). \quad (5)$$

Under the parallel trade regime, $p_N = p_S = \widehat{p}_S$ ensures a global profit $\Pi = u/4 - (u-1)^2/2$, which allows the monopolist to set $u^{PT} = 5/4$, earning $\Pi = 9/32$ that is, by construction, identical to the profit that the monopolist gains from serving the unregulated market only. Parallel trade reduces investments, however it also brings a more lenient price cap in the South to ensure delivery ($\widehat{p}_S \approx 0.408$), which increases coverage in the South. In terms of global welfare, when the foreign government has partial commitment capabilities, the parallel trade regime leads to a higher global welfare compared to no parallel trade. In fact, although consumers in the South enjoy a lower surplus than when parallel imports are banned, consumers in the North benefit from the cheaper price set in the South. Despite the reduction in quality, this price effect prevails

and global welfare increases overall. Results are shown in Table 3.

	u	x	CS_N	CS_S	Π	$Global\ Welfare$
No Parallel Trade	1.296	0.243	0.162	0.089	0.310	0.560
Parallel Trade	1.250	0.275	0.284	0.078	0.281	0.643

Table 3: *Welfare analysis with partial commitment*

Full commitment 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).

Hence the game now has a different 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 $x = p_S(1 - p_S/u)$.

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

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

from which ensues

$$\frac{\partial \Pi(p_S, u(p_S))}{\partial u} = \frac{5}{4} + \frac{p_S^3}{u^2} \left(1 - \frac{p_S}{u}\right) - u = 0, \quad (6)$$

which characterizes implicitly the optimal investment $u(p_S)$ as function of p_S . In the Appendix we show how the solution entails in the first stage an optimal price cap of $\hat{p}_S \approx 0.334$ and a resulting quality level of $u \approx 1.267$, that is less than the case with partial commitment.

Now we imagine that parallel trade is permitted. The effect of the policy chosen by the South government affects the profits of the innovative firms 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:

$$\begin{aligned} \max_u \Pi &= (1+x)p_S(1 - \frac{p_S}{u}) - \frac{x^2}{2} - \frac{(u-1)^2}{2} \\ \text{s.t. } x &= p_S(1 - p_S/u). \end{aligned} \quad (7)$$

This leads to the following first-order condition

$$\frac{\partial \Pi(p_S, u(p_S))}{\partial u} = 1 + \frac{p_S^2}{u^2} + \frac{p_S^3}{u^2}(1 - \frac{p_S}{u}) - u = 0, \quad (8)$$

which characterizes the optimal $u(p_S)$ as function of price set by the government of the South. From (8) we are able to define the following relation

$$\frac{du}{dp_S} = \frac{up_S(2u + 3up_S - 4p_S^2)}{u^4 + 2p_S^3u - 3p_S^4 + 2p_S^2u}. \quad (9)$$

In the first stage, the Southern government defines the price-cap, anticipating the monopolist's investment decision in R&D while still ensuring delivery into the South. Thus, the problem of the government of the South comes to

$$\begin{aligned} \max_{p_S} CS_S &= \frac{(u - p_S)^3 p_S}{2u^2} \\ \text{s.t. } \Pi &\geq 9/32 \\ \frac{du}{dp_S} &= \frac{up_S(2u + 3up_S - 4p_S^2)}{u^4 + 2p_S^3u - 3p_S^4 + 2p_S^2u}. \end{aligned} \quad (10)$$

The participation constraint under which the government of the South maximizes its consumer surplus is binding.¹⁸ Under the parallel trade regime the monopolist has the incentive to serve the South, if by supplying both markets its global profit is at least equal to the profit it would make from serving the unregulated market only. Hence, we have that, when parallel trade is permitted, the government of the South establishes a price cap of $\hat{p}_S \approx 0.394$, exerting an influence on the monopolist decisions of investment and coverage, which serves both markets with a good of quality level of $u^{PT} \approx 1.148$. Results are summarized in Table 4.

¹⁸See the Appendix for details.

	u	x	CS_N	CS_S	Π	<i>Global Welfare</i>
No Parallel Trade	1.267	0.246	0.158	0.084	0.311	0.554
Parallel Trade	1.148	0.259	0.248	0.064	0.281	0.593

Table 4: *Welfare analysis with full commitment*

Comparisons Having completed the case analysis, we are now in a position to conduct several comparisons using the summaries in Tables 2-4. First, consider the timing, i.e., the commitment ability of the South government. When the government of the South acts as the Stackelberg leader, its decision results in a greater coverage of its market than with partial commitment, but only without parallel trade, while the reverse is found under parallel trade. Essentially, this depends on the effects of price regulation. Investments, however, are always higher with partial rather than with full commitment. Because of this, we obtain that, when the government of the South is endowed with full commitment abilities, the policy chosen does *not* allow to improve the welfare in its own country compared to the partial commitment case (while, clearly, any type of commitment is far better than no commitment at all which would generate zero surplus in the South).

To better understand this somehow surprising result, take the case of parallel trade, and contrast what happens with partial commitment (as given by the program (4)) with what happens with full commitment (program (10)). Under partial commitment, the price cap ensures that the monopolist earns exactly the *ex post* profit of $u/4$, which gives an incentive to the monopolist to choose $u = 5/4$, obtaining $\Pi = 9/32$ overall. With full commitment, instead, the price cap has to make sure that $\Pi = 9/32$ is earned *ex ante*, taking also into account the investment best reply given by (8). Hence the South government faces an *additional* constraint which results in lower surplus for the South. Put it differently, if the South government still wanted to give the firm the same incentives to achieve $u = 5/4$ as under partial commitment, this is now more costly as investment costs are not yet sunk. Thus the government would have to ensure a much higher price cap, while instead it prefers to set a lower price despite this goes against quality provision. This is summarized in our next Proposition.

Proposition 2 *When the government of the South has the chance to act as a first mover, the price-cap set by the policy maker leads to a lower consumer surplus in its own country than under partial commitment. Investment decreases as well as global welfare. This holds both with and without parallel trade.*

From the above analysis we can also conclude that, when the government of the South has varying abilities to commit, results differ considerably. In fact, we showed how the precise timing matters to the effectiveness of the policy decided by the South government. In order to make further judgements, one has to look at the relevant policy objectives. The first that comes to mind is obviously global welfare. According to this criterion, the worst-case scenario is the case with no commitment at all, while the best is the case of partial commitment. Global welfare is highest with parallel trade, and in particular it is higher than in the benchmark with no regulation at all. Alternatively, since commitment possibly results from effort of the South government, e.g., to establish credibility in the regulatory arena, it is the South government that should determine its own incentives by looking at CS_S in the various regimes of exhaustion. Also from this perspective, a regime of partial commitment is the preferred one, and, in particular, without parallel trade. As far as the North is concerned, although we did not consider it as a strategic player since the price in the North is always left unregulated, we note that there is a trade-off: the monopolist always loses compared to the unregulated benchmark, while consumers in the North always gain from parallel trade, as they can benefit from the lower price cap established in the South. We recapitulate these findings in a Proposition.

Proposition 3 *Different levels of commitment of the South affect the incentives of the monopolist to deliver its product internationally. The lack of commitment of the South government deters completely the monopolist from introducing its good in the foreign market. A full commitment by the foreign government entails a slackening of the pace of innovation compared to partial commitment. Global welfare is maximized in a regime of partial commitment and with international exhaustion.*

An effect of parallel trade is also to increase the coverage x of the South, for a given level of commitment. This is because, under parallel trade and some form of commitment, the price cap is less severe, which induces the monopolist to cover more areas in the South. Yet, if the policy objective was accessibility to drugs in the South, then the best case would still be the benchmark as, with no regulations at all and separate markets, the monopolist earns the highest profits and thus covers more rural areas than in any other situation. An alternative to price regulation, with the specific aim of achieving greater access, is compulsory licensing that we study next.

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").¹⁹

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 offers 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 offers 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 efforts. In the second stage, the firm proposes a price p_S to the South government (this is equivalent to a royalty). If the offer 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 offer 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., 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

¹⁹See supra at footnote 10 and Matthews (2004).

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*.

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.

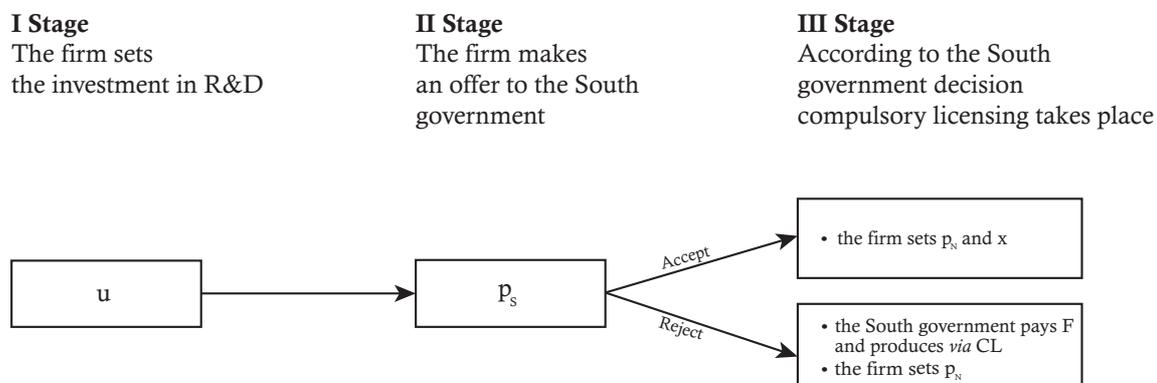


Figure 2: *Sequence of moves under the compulsory licensing regime when parallel trade is banned*

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

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

which is essentially 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

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

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

$$W_S^{CL} = \frac{u^2}{8} - F. \quad (11)$$

Alternatively, in case the government accepts the offer of the monopolist, then essentially the game unravels as in the previous sections, where the monopolist covers $x = p_S(1 - p_S/u)$ which ensures a welfare in the South which coincides with its consumer surplus of

$$CS_S = x \int_{\underline{\tau}_S}^1 (\tau u - p_S) d\tau = \frac{(u - p_S)^3 p_S}{2u^2}. \quad (12)$$

Comparing (11) and (12), if $F < \frac{u^2}{8} - \frac{(u - p_S)^3 p_S}{2u^2}$ 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, 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 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 $\pi_S = p_S^2(u - p_S)^2/2u^2$ in the South.

We can easily establish some limiting cases. First, if the monopolist was unconstrained, the profits in the South would be maximized for $p_S = u/2$, from which it follows a consumer surplus of $CS_S = u^2/32$ 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 instead of its profits, it would offer a price $p_S = u/4$. At this price, the corresponding consumer surplus is $CS_S = 27^2 u/512$, 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.

Consequently, the optimal solution takes the following form

$$p_S(u) = \begin{cases} u/2 & \text{if } F > u^2/8 - u^2/32 = 3u^2/32, \\ \frac{(u-p_S)^3 p_S}{2u^2} = \frac{u^2}{8} - F & \text{if } 37u^2/512 \leq F \leq 3u^2/32, \\ \text{offer rejected} & \text{if } F < u^2/8 - 27u^2/512 = 37u^2/512. \end{cases} \quad (13)$$

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

$$\max_u \Pi(u, p_S(u)) = \pi_N + \pi_S - C(u) = \frac{u}{4} + \pi_S - \frac{(u-1)^2}{2},$$

where the value of π_S depends on the value taken by the fixed cost. If F is high, we know that the outside option is ineffective, thus we obtain the same result as in the unregulated benchmark case, that is, $u = 4/3$, which therefore is valid as long as $F > 3(4/3)^2/32 = 1/6 \approx 0.167$. The other limiting case is when F is very low, so that the firm never sells in the South, then $\pi_S = 0$ and the quality is $u = 5/4$. This is valid as long as $F < 37(5/4)^2/512 \approx 0.113$. Finally, 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

$$4(u - p_S)^3 p_S - u^2(u^2 - 8F) = 0. \quad (14)$$

While this cannot be solved explicitly, by means of implicit differentiation we are able to define the following relation

$$\frac{dp_S}{du} = \frac{u^4 - 2p_S u^3 + 6p_S^3 u - 4p_S^4}{2u(u - p_S)^2(u - 4p_S)}. \quad (15)$$

This is used in the first-stage maximization problem,²⁰ together with (14), to obtain the solutions reported in Table 5, where we also summarize the other variables.

From the above analysis we can draw several conclusions and results. 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 benchmark, as in Table 1. The more interesting cases arise for intermediate and low fixed costs, which make compulsory licensing a credible threat.

For intermediate values of F , despite the low bargaining power of the foreign gov-

²⁰That is, in the first stage we calculate $\frac{d\Pi}{du} = \frac{\partial \Pi}{\partial u} + \frac{\partial \Pi}{\partial p_S} \frac{\partial p_S}{\partial u} = 0$. We omit reporting the rather long resulting algebraic expression.

ernment, 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. In this intermediate range, notice from Table 5 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. Overall, welfare instead decreases compared to the benchmark.

F	p_S	u	x	W_S	CS_N	Π	<i>Global Welfare</i>
≤ 0.113	0	1.250	0.625	$0.195 - F$	0.156	0.281	$0.632 - F$
0.12	0.475	1.220	0.290	0.066	0.152	0.323	0.541
0.13	0.518	1.248	0.303	0.065	0.156	0.326	0.548
0.14	0.560	1.273	0.314	0.063	0.159	0.330	0.552
0.15	0.601	1.296	0.322	0.060	0.162	0.332	0.554
≥ 0.167	0.667	1.333	0.333	0.056	0.167	0.333	0.556

Table 5: *Welfare analysis under compulsory licensing when parallel trade is not permitted*

For very low values of F , the monopolist, when choosing its R&D investment, does not make any profits in the South, since the South always recurs to compulsory licensing. Indeed, under the outside option, 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. As a matter of the fact, there is an upward “jump” in x , and the market coverage of the South is the largest possible. Whether or not global welfare is lower than the benchmark depends on the specific value taken by F .

The following proposition summarize our results on compulsory licensing, when compared against the unregulated benchmark, in the absence of parallel trade.

Proposition 4 *When the use of compulsory licensing is credible, the South government always benefits from it compared to the unregulated benchmark, despite a reduction in investments. Market coverage in the South decreases when the South is still supplied by the monopolist, while it increases when the South government produces the good itself under compulsory licensing. Global welfare decreases under compulsory licensing, unless the fixed costs of compulsory licensing are very low ($F < 0.072$).*

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.²¹ 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 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 offer and recurs instead to compulsory licensing, two scenarios are possible. In the first case, 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, exceptions are in force and the goods manufactured under compulsory licensing are allowed to be parallel traded.

Let us start with the first case, which we call "restricted parallel trade", where there is a prohibition of importation into the North of products manufactured under compulsory licensing in the South. As before, if $F < \frac{u^2}{8} - \frac{(u-p_S)^3 p_S}{2u^2}$ the offer is rejected and compulsory licensing is preferred. Consequently, the monopolist withdraws from

²¹Instead of (11), the value of the outside option would now be $W_S^{CL} = \frac{(u^2 - p^2)^2}{8u^2} - F$, where p is the solution to the break-even condition in the South $\frac{(u-p)^2(3p-u)(p+u)}{8u^2} - F = 0$.

the market of the South and sets $p_N = u/2$ in the North, since goods manufactured in the South cannot be traded legally in any other country. If $F > \frac{u^2}{8} - \frac{(u-p_S)^3 p_S}{2u^2}$, the government of the South accepts the monopolist's offer, and the monopolist fixes the price $p_N = p_S$, because now, under the international exhaustion regime, goods produced and shipped by the monopolist are allowed to be traded legally.

In the second stage, if F is high enough, then parallel trade is applied. But it turns to be ineffective since the unconstrained monopolist sets the same price in all markets, $p_S = p_N = u/2$. If F is low, the offer is rejected and the South government makes use of the compulsory licensing for domestic needs. Finally, for intermediate values of F , the price p_S comes from the binding outside option for the South government. Thus the optimal price schedule still takes the same form as (13).

In the first stage, the monopolist chooses the level of R&D to maximize

$$\max_u \Pi(u, p_S(u)) = \pi_N + \pi_S - C(u) = \pi_N + \pi_S - \frac{(u-1)^2}{2}, \quad (16)$$

where now the expressions of both π_S and π_N depend on the value taken by the fixed cost. If F is high, the outside option is ineffective, thus we obtain the same result as in the unregulated benchmark case, that is, $u = 4/3$. If F is very low, the firm never sells in the South, so that $\pi_S = 0$ and the quality is $u = 5/4$. If F is intermediate, then $\pi_N = p_S(1 - p_S/u)$ and $\pi_S = p_S^2(u - p_S)^2/2u^2$. Given these, the monopolist maximizes (16) subject to (14). The results for these intermediate values of F that derive from the binding constraint, along with the complete welfare analysis, are shown in the bottom half of Table 6.

We now turn our analysis to the second case, that we name "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). The last stage is identical, except from the fact that now, no matter what the South government decides, the same price $p_S = p_N$ would be applied in all markets.

In the second stage, the monopolist's profits are always $\pi_N = p_S(1 - p_S/u)$ in the North. In the South profits are $\pi_S = p_S^2(u - p_S)^2/2u^2$ if the offer is accepted, and $\pi_S = 0$ otherwise. If F is high enough, the monopolist knows that compulsory licensing is not a credible threat and it sets a price $p_N = p_S = u/2$ everywhere. If F is low enough, any offer would be rejected and the government of the South always prefers the use of compulsory licensing. Therefore, the South price of zero would apply internationally. For intermediate values of F , the price p_S comes from the binding outside option for the South government. The optimal solution is again the same as (13).

In the first stage, the monopolist maximizes

$$\max_u \Pi(u, p_S(u)) = \pi_N + \pi_S - C(u) = p_S(1 - p_S/u) + \pi_S - \frac{(u-1)^2}{2}, \quad (17)$$

where π_S takes different values according to whether the South government accepts or rejects the monopolist's offer. If F is high, the outside option will never take place, thus the monopolist sets $u = 4/3$. If F is very low, due to international exhaustion, the South price of zero applies in all markets. This deters the monopolist from undertaking any investment, and the quality thus stays at the initial level of $u = 1$. This is valid as long as $F < 37/512 \approx 0.072$. If F is intermediate, then $\pi_S = p_S^2(u - p_S)^2/2u^2$, and the monopolist maximizes (17) subject to (14). The complete welfare analysis along with the results for these intermediate values of F are shown in the upper part of Table 6.

As without parallel trade, when F is very high, then monopolist is de facto unconstrained and we fall back to the initial benchmark case and parallel trade is ineffective. We thus confine our comments to the more interesting cases arising for intermediate and low values of F .

	F	p_S	u	x	W_S	CS_N	Π	<i>Global Welfare</i>
Unrestricted	≤ 0.072	0	1	0.50	$0.125 - F$	0.50	0	$0.625 - F$
Parallel Trade	0.084	0.417	1	0.243	0.041	0.170	0.273	0.484
	0.090	0.438	1.031	0.252	0.043	0.170	0.283	0.496
	0.10	0.471	1.078	0.265	0.045	0.171	0.297	0.513
	0.11	0.502	1.122	0.278	0.047	0.171	0.308	0.526
	0.12	0.533	1.164	0.289	0.049	0.171	0.317	0.537
	\vdots	\vdots	\vdots	\vdots	\vdots	\vdots	\vdots	\vdots
	≥ 0.167	0.667	1.333	0.333	0.056	0.167	0.333	0.556
Restricted	≤ 0.113	0	1.250	0.625	$0.195 - F$	0.156	0.281	$0.632 - F$
Parallel Trade	0.12	0.533	1.164	0.289	0.049	0.171	0.317	0.537
	0.13	0.563	1.203	0.299	0.051	0.170	0.323	0.544
	0.14	0.592	1.241	0.309	0.052	0.170	0.328	0.550
	0.15	0.621	1.276	0.318	0.053	0.168	0.331	0.552
	≥ 0.167	0.667	1.333	0.333	0.056	0.167	0.333	0.556

Table 6: *Welfare analysis under parallel trade and compulsory licensing*

First of all, for intermediate values of F , the outside option binds but the monopolist still supplies the good to the South. Also notice that, for values of $F > 0.113$, 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 $F < 0.113$ (but still not too low). Then the “unrestricted” regime extends the validity of the region where the monopolist still supplies the South. This apparent paradoxical result is due to the fact that, from the analysis of the second stage, 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. The reverse is true for the “unrestricted” regime. In any case, parallel trade, by reducing the monopolist’s profits, reduces investments compared to the absence of parallel trade (confront the corresponding values of Table 5 and Table 6). The South government loses from parallel trade. Welfare also decreases.²²

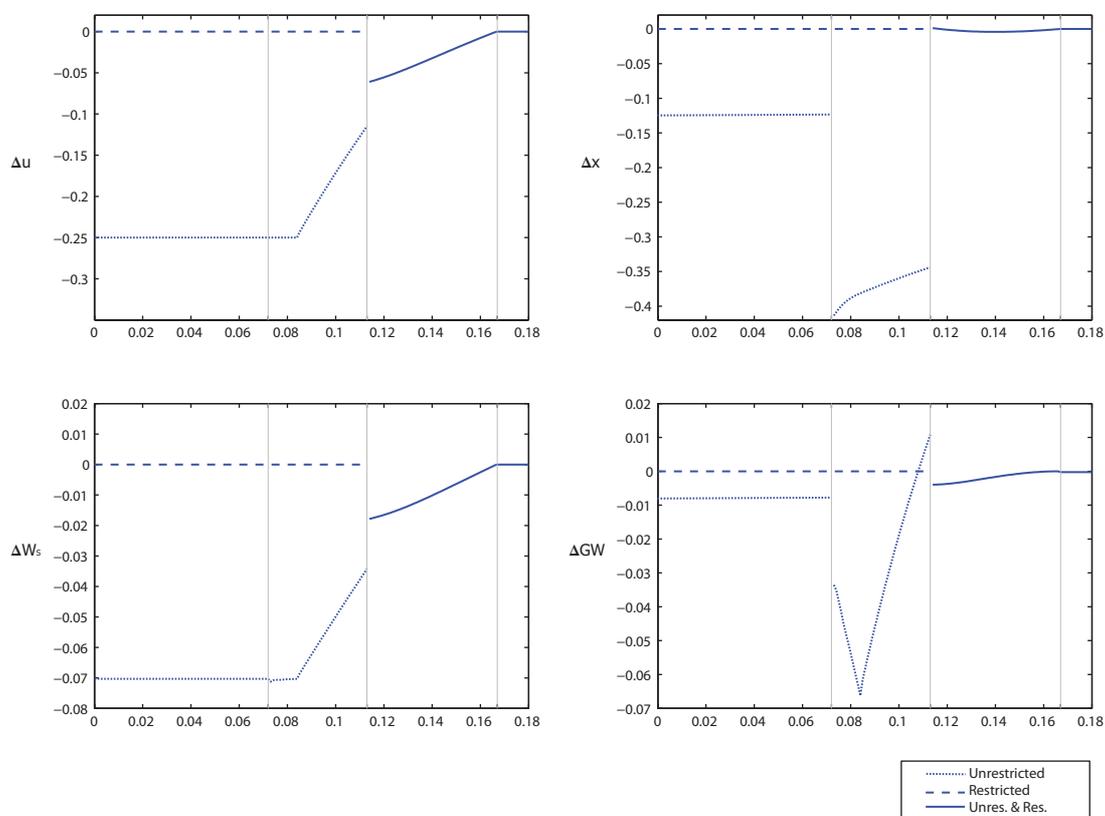


Figure 3: *Parallel Trade vs No Parallel Trade under compulsory licensing*

²²There is only a small exception for values of F just below 0.113 (more precisely, $0.109 < F < 0.113$) such that global welfare increases under “unrestricted” parallel trade. This is where the “unrestricted” regime extends the region where CL is not played in equilibrium, and therefore the fixed cost F is saved under PT, while without PT there would be recourse to CL, with its associated fixed cost.

For very low values of F , there is always compulsory licensing and 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 zero additional investment in R&D, and everybody loses. Since we chose a model specification where, in the absence of investments, the initial good with $u = 1$ is still supplied, then even in this case there is surplus both in the South and in the North. If we had instead chosen an alternative model where, without investment, there is no trade at all, then clearly the result would be even more extreme in that both consumer surplus and total welfare would be zero everywhere with “unrestricted” parallel trade.

In Figure 3 we further investigate the effects of parallel trade. The four panels plot the differences of several key variables (respectively, global investment, South coverage, welfare in the South, and global welfare) with and without parallel trade, as a function of the magnitude of F , which gives rise to different economic mechanisms in various regions. In each panel, we plot two curves when there is a material difference between “restricted” and “unrestricted” parallel trade. This holds when F is low enough, while for higher values of F the distinction is immaterial.

The following proposition summarizes our results on parallel trade under compulsory licensing, when the use of compulsory licensing is credible.

Proposition 5 *Parallel trade decreases investments and welfare when the South is still supplied by the monopolist under the threat of compulsory licensing. When the South government produces the good itself under compulsory licensing, parallel trade plays no role under an effective prohibition of importations, while it instead further reduces investments and welfare when such prohibition is ineffective. Compulsory licensing is less likely to be issued in equilibrium (i.e., for a smaller range of values of F) when parallel trade is unrestricted.*

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 foreign 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 surprisingly found that the South government benefits the most when it has only some partial form of commitment, rather than a full one. Namely, it achieves a higher consumer surplus when it regulates prices before coverage choices are made by the monopolist, but after R&D investments are undertaken. This is because a partial commitment turns out to guarantee the same profits *ex post* to the firm, without having to compensate for the R&D costs. It is cheaper to elicit investments, which allows then to regulate the price more strictly. Related to this, we have also obtained the interesting result that, when parallel trade is

not banned, in a regime of partial commitment the global welfare is higher than in the unregulated case. On the other hand, focusing on the monopolist's investment decisions in R&D, our results show that the pace of innovation could increase if the government of the South has some ability to commit, but yet investments would be highest with no regulations at all.

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. Furthermore, 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 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 drug prices.

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Appendix

Recall from (6) that, under no parallel trade, the monopolist at the second stage sets

$$\frac{\partial \Pi(p_S, u(p_S))}{\partial u} = \Pi' = \frac{5}{4} + \frac{p_S^3}{u^2} \left(1 - \frac{p_S}{u}\right) - u = 0, \quad (\text{A1})$$

that identifies $u = u(p_S)$. By implicit differentiation of (A1) we obtain

$$\frac{du}{dp_S} = - \frac{\partial \Pi' / \partial p_S}{\partial \Pi' / \partial u} = \frac{up_S^2(3u - 4p_S)}{u^4 + 2p_S^3u - 3p_S^4}. \quad (\text{A2})$$

At the first stage, the maximization problem of the South government amounts to

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

from which we derive

$$\frac{dCS_S}{dp_S} = \frac{\partial CS_S}{\partial p_S} + \frac{\partial CS_S}{\partial u} \frac{du}{dp_S} = 0, \quad (\text{A3})$$

where substituting (A2) into (A3) we obtain for the first-order condition

$$\frac{dCS_S(p_S(u))}{dp_S} = \frac{(u - p_S)(4p_S^5 - 9p_S^4u + 5p_S^3u^2 - 4p_Su^4 + u^5)}{2u^2(3p_S^3 + p_S^2u + p_Su^2 + u^3)} = 0. \quad (\text{A4})$$

From the system of equations (A1) and (A4) we obtain the unique equilibrium, which is characterized by the values $u \approx 1.267$ and $p_S \approx 0.334$.

Under the international exhaustion regime, as shown in the text, the maximization problem of the South government in the first stage is given by (10). From this problem we define the Lagrangian as

$$\begin{aligned} L(p_S, u(p_S)) = & \frac{[u(p_S) - p_S]^3 p_S}{2u(p_S)^2} + \lambda_1 \left\{ \frac{9}{32} - \left[p_S \left(1 + p_S \left(1 - \frac{p_S}{u(p_S)} \right) \right) \left(1 - \frac{p_S}{u(p_S)} \right) \right. \right. \\ & \left. \left. - \frac{1}{2} p_S^2 \left(1 - \frac{p_S}{u(p_S)} \right)^2 - \frac{(u(p_S) - 1)^2}{2} \right] \right\}, \end{aligned}$$

and the first-order conditions are defined as follows

$$\begin{aligned} \frac{\partial L(p_S, u(p_S))}{\partial p_S} &= 0 \text{ where } \frac{du}{dp_S} = \frac{up_S(2u + 3up_S - 4p_S^2)}{u^4 + 2p_S^3u - 3p_S^4 + 2p_S^2u} \text{ and } p_S > 0, \\ \frac{\partial L}{\partial \lambda_1} &\geq 0 \text{ where } \lambda_1 \frac{\partial L}{\partial \lambda_1} = 0 \text{ and } \lambda_1 \geq 0. \end{aligned}$$

From the above first-order conditions it comes that $\lambda_1 > 0$, thus the firm's participation constraint under which the government of the South maximizes its consumer surplus is just binding and the cap is

$$\widehat{p}_S = \frac{1}{2}(u - \sqrt{4u + u^2 - u\sqrt{41 - 32u + 16u^2}}). \quad (18)$$

First notice that, since $\sqrt{41 - 32u + 16u^2} \geq 2\sqrt{2(2 + u)}$ for any value of u (the equality sign holds iff $u = 5/4$), comparing (18) to (5) we establish that, to elicit the same value of u , the cap with full commitment must be higher than the cap under partial commitment.

To close the solution, this cap (18) can be used in (8), and we finally obtain that the monopolist invests in the quality $u \approx 1.148$ and the foreign government sets a price-cap $\widehat{p}_S \approx 0.394$.