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Pharmaceutical innovation and parallel trade☆

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ABSTRACT

This paper proposes a North–South model to study the interaction between price regulation policies and parallel trade, with a particular focus on the pharmaceutical sector. We show that, under parallel trade, R&D investment can rise only when the South government takes into full account its impact both on investment and on the firm's decision to supply the regulated country. This arises because of a complete withdrawal from price regulation. When policy choices are endogenized, indeed the South wants to achieve this level of full commitment when it is large in size. When instead it is smaller in size, the South chooses an intermediate form of commitment whereby it anticipates its effect only on local distribution and delivery, but not on global R&D investment. As a response to these credible levels of price control commitments, the North reacts by allowing parallel imports from the South.

1. Introduction

Despite broad consensus that innovation is central to the long-run performance of an economy, there is no accord on the optimal protection of intellectual property rights (IPRs). This reflects the classic trade-off between the static efficiency loss (higher prices) and dynamic gains (R&D) associated with IPR protection. Issues related to intellectual property have been particularly contentious in the context of North–South trade, because of the possible differences in the safeguard of IPRs. Imagine a company that has a patent in the North. This company will typically want to export its product also in the South, as this enlarges its market, from which R&D will benefit. But as the South may apply a different level of IPR protection, e.g., it may regulate the price, the North company will reassess both its R&D and its export policy, especially if the controlled price in the South can backfire in the North. A possible fall in the pace of innovation may ensue.

In this paper we study the role played by parallel imports in the international domain, with a particular emphasis on the long-run implications for the pharmaceutical sector. Parallel imports exist 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. However, because parallel trade exhausts international IPRs, it makes the unauthorized import of branded drugs perfectly legal. This principle has been subject to criticism for undermining innovation, and, as a consequence, the availability of new drugs.

The conventional wisdom that parallel trade is detrimental to profits and investment has recently been challenged by Grossman and Lai (2008). They show that, in a world where international exhaustion is permitted, the pace of innovation is often faster than in one with national exhaustion. More precisely, they consider that, where parallel trade is allowed, 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. Clearly, this result depends on the ability of the foreign government to intervene before R&D has taken place. If, instead, price regulation occurs when R&D costs are sunk, price control would be more stringent, and parallel trade could kill the incentives to invest in R&D. Anticipating tough price regulation, the patent holder may not want to deliver its drug abroad at all.

This paper develops a North–South model of parallel trade where policies towards the exhaustion of IPRs and price regulation are determined endogenously. In our model, R&D investments also arise endogenously. This combination makes our paper innovative, and its findings clarify contrasting results in the extant literature.

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We introduce a key distinction between "global" costs that companies have to sink (e.g., R&D investments), and "local" costs to deliver goods to the South.[1] Once this distinction is drawn, we consider the ability of the policy maker in the South to affect these two activities of the patent holder via drug price controls. Without any commitment (i.e., when the South government sets its regulated prices last, without taking into account neither the global nor the local investment decisions of the firm), parallel trade has no impact, since in any case the firm does not supply its good to the South. More interestingly, we show that parallel trade unambiguously reduces investment in a regime of 'partial' commitment, whereby the South government regulates the price to ensure drug delivery in the South — but after R&D investments have already occurred. On the other hand, investments increase under 'full' commitment, when the South government moves first, that is, before both global R&D and local delivery choices are made. When it moves first, the South government always prefers to withdraw from any price regulation. This leads to higher investment compared to when the South is insulated from the North and some price regulation would be applied. Our results thus make precise the conditions that are needed for parallel trade to have beneficial long-term effects.

When we endogenize the policy choices, we find that the South has incentives to achieve 'full' commitment only when its size is large. When it is instead smaller, a regime of 'partial' commitment yields the highest consumer surplus in the South. It follows that the South should find some credible way to achieve commitment to ensure local delivery, but not always to the extent to anticipate its full effects on global R&D: this depends on size. In both cases, as some level of commitment is credible, price controls will never be too tough in equilibrium. This lets the North respond by adopting a system of international exhaustion.

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. Section 4 describes the benchmark unregulated situation where parallel trade is immaterial. Section 5 is the central part of the paper, where we extend the benchmark by studying the impact of price regulation. In Section 6 we consider the policy game where the exhaustion of IPRs, as well as price regulation commitments, is chosen. Finally, in the last Section we summarize our results and conclude.

2. International exhaustion and parallel trade

In this section we analyze the economic issues concerning the exhaustion of property rights under the trade-related aspects of intellectual property rights (TRIPs) agreement. The term "parallel" emphasizes the fact that genuine 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 "gray market". Parallel trade represents one of the most controversial issues in the international trade-policy ground, and has raised difficult questions, especially in the global pharmaceutical industry, which was in fact a major proponent of the TRIPs agreement.

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.[2] 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 IPRs, however ultimately the WTO has left each member country the possibility to fix its own regime for such exhaustion.[3]

Some studies argue that parallel trade, where it is permitted, has not yielded the expected results in terms of convergence in price.[4] Although policy papers have been written, starting with Malueg and Schwartz (1994), less attention has been paid on the long-run economic implications of parallel trade on IPRs. Scholars who believe that such arbitrage could erode IPRs, weakening the incentive for investment (e.g., Chard and Mellor, 1989; Danzon and Towse, 2003; 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). The interference of national governments in private markets by way of regulation of drug prices is, in particular, a factor causing price differences at the international level (Jelovac and Bordoy, 2005; Pecorino, 2002; Saggi, 2013).

A more recent strand of the literature, to which our paper belongs, reassesses the role of parallel trade and focuses on the willingness to invest in R&D. This is particularly relevant, since normative results regarding parallel imports should ideally come from models in which innovation is accounted for. Welfare can either increase or decrease depending on whether dynamic effects of parallel trade are examined (Chen and Schwartz, 2013; Grossman and Lai, 2008; Valletti, 2006; Valletti and Szymanski, 2006).

An important aspect emerging from the literature is that the patent holder's decision to export is endogenous. Pricing regulations have a significant influence on the entry of firms into foreign markets, especially into less developed countries (Goldberg, 2010). These entry decisions depend on entry costs, as well as on the impact that local regulations might have globally. In our model we introduce explicitly the notion of local delivery costs in the South. The system by which drugs are supplied within a country is an aspect that has a key impact on the final price of drugs, and on their accessibility (WHO, 2002).[5] Chaudhuri et al. (2006) stress the importance of weak distribution networks in India. They show that, even when multinational patent holders enter developing countries, the distribution and marketing networks of multinationals are limited and costly, so that their products may not be reaching remote rural areas. They also argue that access to drugs and distribution coverage should be a crucial part of any welfare analysis. We follow their spirit and in the next Section we model (costly) access to drugs in the South.

3. Model assumptions

As patents create monopoly power in the pharmaceutical industry (indeed, that is their very purpose), a monopoly model with a partial

[1] Goldberg (2010) shows how the coverage of distribution networks and associated ease of access to drugs in India are decisive to make any welfare assessment about the strength of IPRs.

[2] Parallel imports are in fact part of the "free trade" policy. Official European statistics show that in 2002 the total share of parallel imports reached 20% of the high-price pharmaceutical markets (Kanavos and Costa-Font, 2005).

[3] 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 U.S. government has recognized the possibility to prevent parallel trade from specific countries (Australia, Morocco, Singapore) by contractual means (Fink and Reichenmiller, 2005). This is also controversial, as preventing parallel trade by means of private contracts could be considered an anticompetitive behavior that prevails under competition law (Gallini and Hollis, 1999).

[4] 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 Ganslandt and Maskus (2004), Kanavos and Costa-Font (2005) and Kyle (2007).

[5] Lack of public health infrastructures and services constitute an important barrier to the access to drugs for many developing countries (for more details see http://www.unmillenniumproject.org/documents/TF5-medicines-Complete.pdf).