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Compulsory licensing, price controls, and access to patented foreign products☆

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ABSTRACT

We analyze how a price control and the threat of compulsory licensing (CL) affect consumer access in a developing country (South) to a patented foreign product. In the model, the Southern government sets the level of the price control on a Northern patent-holder who chooses between entry and voluntary licensing (VL). While entry incurs a higher fixed cost, licensed production is of lower quality. If the patent-holder does not work its patent locally, the South is free to use CL. The threat of CL: ensures that consumers have access to (a lower quality version of) the patented good when the patent-holder chooses not to work its patent locally; improves the terms at which VL occurs; can cause the patent-holder to switch from VL to entry; and can delay consumer access when CL replaces VL or entry. We also show that a price control and CL are mutually reinforcing instruments.

1. Introduction

The use of price controls in the market for pharmaceuticals has a long history in developing countries. Consider, for example, the case of India. Price controls over drugs were first introduced by India in 1962 and have been essentially in effect ever since. Over the years, a series of price control orders have been issued by the central government of India, with the most recent one coming in 2013.[2] This price control order significantly expanded the list of drugs whose prices are subject to government control in India.[3] Based on the report of a specially appointed committee with the self-explanatory title of *The Committee on Price Negotiation for Patented Drugs*, the Indian government also circulated a draft proposal that discussed various options for regulating the local prices of patented medicines.[4] In its report, this committee noted that market prices for patented drugs were beyond the reach of the general masses of India and recommended several methodologies for lowering and/or directly controlling them. Of course, this concern is hardly unique to India and is, in fact, much more acute for countries whose local pharmaceutical industries are nowhere near as well developed as that of India.

As one might expect, regulation of prices in the pharmaceutical industry has important consequences for consumers. For example, in her structural study of 155 pharmaceutical products sold in India, of which 14 were under price control, Dutta (2011) finds that, if implemented, price deregulation would cause significant welfare losses for consumers.[5] According to her estimates, for some drugs, the negative effects of such deregulation could exceed even those of patent enforcement required by the WTO's Agreement on Trade Related Aspects of Intellectual Property (TRIPS).

Tempting as it is, a strategy of using price controls to improve consumer access can become counter-productive if foreign pharmaceutical companies refuse to sell their patented medicines in markets where such controls are too stringent. The existing empirical evidence on

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[2] Further details are available at http://pharmaceuticals.gov.in/.

[3] This policy announcement received wide press coverage both domestically and internationally. See, for example, "India Widens Price Control over Medicines" in *Wall Street Journal*, May 17, 2013 and "Government Notifies New Drug Price Control Order" in the *Indian Express*, May 17, 2013.

[4] This report is available online at http://spicyipindia.blogspot.com/2013/03/patents-vs-patients-department-of.html.

[5] Similarly, Chatterjee et al. (2013) find that the removal of price controls in the oral anti-diabetic segment of the Indian pharmaceutical market would have significant negative repercurssions for Indian consumers.

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drug launches indicates that the presence of price controls and related regulations indeed deters entry in pharmaceutical markets. For example, in her large sample study of 68 countries over the time period 1982–2002, Lanjouw (2005) found that price regulations delayed the introduction of new drugs. Similarly, in her study of the 28 largest pharmaceutical markets in the world, Kyle (2007) found that the presence of price controls and other such regulations delayed or reduced the probability of drug launch in countries that imposed them.

What options, if any, does a country have when a foreign patent-holder refuses to sell either due to the presence of price regulations or because it finds local sales unprofitable for other reasons? As per TRIPS rules, when faced with no or limited access to a patented foreign product, a country may choose to engage in compulsory licensing (CL), i.e., an authorization granted by a government to someone other than the patent-holder to produce the product without the patent-holder's consent.[6] Article 31 of TRIPS (which pertains to "use without authorization of the right holder") lays down the conditions that govern the use of CL of patented products. This Article requires that the entity (company or government) seeking a compulsory license should have been unable to obtain a voluntary license from the right holder on "reasonable" commercial terms and that "adequate remuneration" must be paid to the patent-holder in the event of CL.[7]

Motivated by common features of some recent cases of CL (discussed below) and WTO ground rules that govern the use of CL, this paper develops a North–South model to analyze the dual roles played by a price control and the threat of CL in determining consumer access in the South to a patented product sold by a Northern patent-holder. In the model, the Southern government sets the level of the price control while the patent-holder chooses between serving the Southern market by entering directly or by (voluntarily) licensing its technology to a local firm.[8] From the patent-holder's viewpoint, the trade-off between voluntary licensing (VL) and entry is that while the fixed costs incurred under licensing are relatively lower, so is the quality of production. To assess the value of CL to the South, we examine two scenarios: one where the Southern government can issue a CL to the local firm if the patent-holder fails to work the patent in the South and another where it cannot. The local firm's quality of production under CL is the same as that under VL (i.e. it is inferior to that under entry).

Our analysis addresses several inter-related questions: What factors determine the patent-holder's decision regarding its optimal entry mode? How does each instrument – i.e. a price control and CL – affect the patent-holder's decision? What is the relationship between the two instruments? What are their respective effects on Southern consumers, the patent-holder, and welfare? Does a price control obviate the need for CL?

In recent years, several countries have moved to issue compulsory licenses for patented drugs needed locally.[9] In a case that drew significant attention in the press, on January 2007 the government of Thailand issued a compulsory license for Kaletra, an AIDS drug, to the Government Pharmaceutical Organization (GPO) — a government owned Thai producer of medicines.[10] Regardless of one's views about the merits of CL, one aspect of the Thai experience that is worrisome for all concerned is that the quality of GPO's production was below world standards — an aspect of production under CL that is central to the model that we develop below. Indeed, the Global Fund to Fight HIV/AIDS had granted the GPO $133 million in 2003 so that it could upgrade its plant to meet international quality standards. Following in Thailand's footsteps, in May 2007 Brazil decided to issue a compulsory license for Efavirenz, another patented AIDS drug, after price negotiations with the patent-holder (Merck) had broken down. Brazil had previously used the threat of CL to pressure companies to lower prices of patented medicines, but Efavirenz was the first patented HIV medicine for which it actually issued a compulsory license.[11] It turned out that Farmanguinhos – the leading government owned pharmaceutical manufacturer in Brazil – struggled to manufacture Efavirenz since it lacked the technological know-how to do so (Daemmrich and Musacchio, 2011). It eventually took Farmanguinhos two years to be able to supply Efavirenz to the local market. In the meantime, Brazil had to resort to importing a generic version of the drug from India.

There are three common (and crucial) aspects of the experiences of Thailand and Brazil with CL. First, price considerations were a major factor in prompting the use of CL. Indeed, national governments seemed to have used their power to lower prices as well as the threat of CL for improving consumer access to patented foreign medicines. Second, in both Thailand and Brazil, there was essentially a single local producer that had the competence to produce the relevant drug. Third, in both instances, the local producer's technological capability was inferior to that of the original patent-holder. We believe that these features capture important ground realities confronting the potential use of CL in developing countries and the model that we develop puts them at center stage.

To isolate the roles of price controls and CL, we first analyze a scenario where the Southern government does not have the option to issue a CL. Due to the presence of mode-specific fixed costs, both entry and VL can be unprofitable for the patent-holder even in the absence of a price control. In such a situation, the product is simply not sold in the South and the price control policy of the government is irrelevant. When only one of the modes is profitable, it is optimal for the government to set the price control at a level that allows the patent-holder to break even (i.e. cover its fixed costs) under the profitable mode. However, when both modes are profitable and the break-even price under entry is relatively higher (i.e $\overline{p}_E \geq \overline{p}_L$), to be able to induce entry the government has to set a relatively lax price control that allows the patent-holder to earn some rents under entry. When $\overline{p}_E \geq \overline{p}_L$ setting the price control $\overline{p} = \overline{p}_E$ is not optimal since doing so induces the patent-holder to choose VL (under which it earns positive profits) which could be induced at $\overline{p}_L$. From the patent-holder's viewpoint, the scenario where $\overline{p}_E > \overline{p}_L$ is necessarily better but the government also prefers it if the quality of production under VL is quite low.

Our analysis shows that the option to use CL has the potential to increase Southern welfare due to three separate reasons. One, it lowers the licensing fee paid to the patent-holder under VL. Two, it can cause a switch from VL to entry thereby improving the quality of the product available to Southern consumers. Third, and perhaps most importantly, it can ensure that at least a lower quality version of the patented product is available locally if the patent-holder decides not to work its patent. However, these benefits of CL for the South are somewhat tempered by the fact that the possibility of CL can make it less likely that the

[6] Indeed, some observers have interpreted compulsory licensing as the "breaking of a patent" (Cahoy, 2011); what is broken is the right of a patent holder to exclude others.

[7] Article 5 of the Paris Convention for the Protection of Industrial Property (commonly known as the Paris Convention), originally adopted in 1883, allowed signatories to adopt legislative measures "for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, *failure to work*" (Pozen, 2008). Thus, even as early as 1883, the non-working of a patent (equivalent to not supplying a patented medicine to a particular country in our context) was seen as justifiable grounds for compulsory licensing.

[8] This aspect of our model is related to the literature that explores how the optimal entry strategy used by a firm to penetrate a foreign market depends upon the degree of IPR protection available in that market. See, for example, Ethier and Markusen (1996), Markusen (2001), and McCalman (2004).

[9] Of course, one of our key arguments is that for the option to invoke CL to matter, CL need not actually be observed: the threat to issue a compulsory license can affect the behavior of patent-holders to the advantage of developing countries thereby making its use unnecessary.

[10] The decision to issue a compulsory license was explained by Dr. Mongkol, the Thai Health Minister, as follows: "We ask for the understanding of pharmaceutical companies. Much of our affected population cannot afford your drugs and we want people to have access to the medicines that they need." He also noted that there would be no need for CL if pharmaceutical companies "would voluntarily reduce prices." (Baron, 2008).

[11] For example, prior to the negotiations with Merck, Brazil had threatened to issue a compulsory license for Kaletra but did not actually do so since Abbott Laboratories agreed to lower the price of Kaletra to $1380 per year through 2011.