International Compulsory Licensing

Rafael Pinho Senra de Morais

Rio de Janeiro State University

This Version: January 2013

JEL classification: O34, F13, I18

Keywords: Compulsory Licensing, Pharmaceuticals, TRIPs, Drug Price Regulation

1 FCE-UERJ. Rua São Francisco Xavier, 524 – 8º andar – sala 8.019 – Bloco B
Phone: +55 21 2334-0794 +55 21 2334-0676 Email: rpinhodemorais@gmail.com
Abstract

The focus of this paper is on compulsory licensing of drugs by a developing South and its impact on profits and innovation rates in the northern pharmaceutical sector, and world welfare, in both the presence and absence of parallel trade in medicines. We propose a model – which builds on Grossman and Lai (2008) – where the southern country, on top of regulating drug prices, is allowed to issue compulsory licenses on patented medicines in accordance with the TRIPs Agreement and the “paragraph 6 system” of the 2001 Doha Declaration on the TRIPS Agreement and Public Health. This means in particular that drugs produced under compulsory licenses are mainly for domestic usage or for exportation to countries unable to manufacture them – the least-developed countries, which through this “paragraph 6 system” had access to compulsory licensing as a policy instrument.

Grossman and Lai (2008) challenged the orthodox view that parallel trade in pharmaceuticals undermines intellectual property rights and dulls the incentives for investment in this research-intensive industry. Our results turn out to challenge both the orthodox wisdom and the generality of the results in Grossman and Lai (2008). We show that if compulsory licensing is available to southern countries, the tolerance of parallel trade by northern countries has absolutely no impact on R&D incentives and innovation.

Moreover, conditions apply for compulsory licensing to be optimally used by a developing country. In particular, it should not be used for neglected diseases, like malaria and tuberculosis. For other diseases, when used, it actually allows the South to recover most of the welfare losses caused by the authorization of (parallel) drug reimportation by the North. The best outcome, however, is shown to be market segmentation, i.e. no parallel trade in the first place.
I - Introduction

Intellectual property rights (IPRs) are effective when its enforcement implies restricting access to inventions, which is necessary for creating economic incentives for investment in Research and Development (R&D). As concerns pharmaceutical innovation, the patent system interacts with the regulation of drug prices for creating those incentives, as the price charged by a monopolist patent holder might be constrained by some imposed price cap. On top of that, in the World Trade Organization (WTO) era, those policy instruments interact with activities from the international arena, such as parallel trade and (potential and effective) compulsory licensing of drugs.

Drug prices differences across countries, as pointed out by Grossman and Lai (2008)\(^2\), emerge from retailer price discrimination, vertical price restraints or different regulations. Their paper and ours focus on the last one. The classic tradeoff about access to medicines and the incentives to invest in R&D for new and better drugs is the relevant one when a country chooses the price ceiling to impose (or not) on some medicine.

However, when parallel trade comes into play, the regulated price cap becomes a strategic variable in an international setting. Parallel trade is an arbitrage mechanism through which the drugs produced in a low-price market flow into the high-price market. If parallel trade is widespread, at equilibrium uniform prices are re-established in the presence of a large number of parallel traders and absence of frictions (transportation and transaction costs). Under these restrictive conditions, the resulting world price is the lowest among all prices set worldwide for an individual drug.

As concerns public health and compulsory licensing, the restrictions imposed by the IPRs system on access to (patented) drugs must be somehow reasonable, not creating situations where entire populations are denied access to known therapies. Therefore, the 1994 WTO TRIPs Agreement contains provisions on safeguards, exceptions and mechanisms to protect essential public health interests. The strongest of those “TRIPs flexibilities” is surely compulsory licensing: the possibility of allowing production and sales of a patented medicine without the authorization of the patent owner.\(^3\)

Although international compulsory licensing have a huge importance in the international debate – being at the centre of the debates at the Ministerial discussions in Doha (2001) and Cancun (2003)\(^4\) – and implications to national public health worldwide,

---

\(^2\) Grossman and Lai (2008) will be referred to as GL hereafter.

\(^3\) Throughout this paper, by compulsory licensing we mean any of the possibilities for non-authorized use (article 31 of the TRIPs Agreement). Any distinction between on-patent generic production and public non-commercial use (common in the literature) are irrelevant for the purposes of the paper.

\(^4\) See for example Alavi (2008).
Economics has not proposed a theoretical modelling dealing with the varied aspects involved, both from Industrial Organization and International Economics: price regulation, price setting and the decision of withdrawing a drug from a market, developed countries’ decision to allow (or not) parallel importation of drugs and developing and least-developed countries’ decision on the use (or not) of international compulsory licensing.

In this paper, we focus on the use (or not) of compulsory licensing by non-innovative countries both in the presence and absence of parallel trade (international and national exhaustion regimes of IPRs, respectively). We propose a North-South model where South can potentially issue compulsory licenses (mainly for domestic usage) and analyze the effects of the existence of such trade policy instrument on the regulated drug prices, innovation and welfare.

Our results show that compulsory license is never used in a regime of national exhaustion of IPRs (i.e. when parallel trade is not tolerated). In an international exhaustion regime (i.e. when parallel trade is allowed), it is sometimes used if its cost is non-prohibitive but, more strikingly, is not always a South’s optimal decision even when it requires no implementation cost. In some circumstances, it is used strategically: South might lower its regulated prices in order not to be served and therefore be able to issue a compulsory license. Moreover, compulsory licensing is shown to be a way for South to counterbalance its losses due to the price convergence implied by parallel trade, through ensuring access of its population to affordable drugs through market segmentation. However, the most efficient measure, our model shows, would be to move back to national exhaustion (no parallel trade).

While GL were concerned about intra-European or North-American (USA-Canada) parallel trade, in the present paper we focus on a non-cooperative sequential game involving a developed innovative North and a developing non-innovative South, able to use compulsory licenses. Our results are much in line with Danzon and Towse (2003), as their work advocates for a strengthening of drug market separation and proposes measures to implement it, compulsory licensing in particular. Their point is that welfare and profits are increased by allowing pharmaceutical firms to discriminate prices across countries, which is wiped out when parallel trade is tolerated. Contrary to this, GL show that profits, innovation and welfare in the developed world increase if parallel trade is allowed, at the expense of welfare in South.

Chien (2003) empirically challenges the common wisdom that the use of compulsory licenses undermines the incentives to R&D and consequently the rates of innovation. Although based on too small a data set, his paper suggests that “compulsory licenses need not

---

5 Danzon and Towse (2003) argue on the basis of optimal Ramsey prices deriving from different demand elasticities across regions. In contrast, in our model consumers are identical in both North and South; our results emerge from different market sizes, innovative capabilities and regulatory regimes.
result in a decline in innovation and that this policy option for increasing access to medicines deserves greater exploration.” Our paper follows such track and contributes to the debate.

The paper is organized as follows. We start by motivating the topic in Section II, arguing on the importance of the instrument and its current use. We then present the formal analysis in Section III, where we propose a four-stage game dealing at a time with IPRs exhaustion regime (i.e. parallel trade tolerance), drug prices regulation and compulsory licensing. Section IV explores the case of neglected diseases in the developing world, while Section V presents our conclusions.

II – Compulsory Licensing at Work

In the present paper, we focus explicitly on the on-patent pharmaceutical market and the compulsory licensing of northern medicines by southern governments. The innovative North invents drugs which are essential for patients in both the rich North and the poor South. During patent validity, a large pharmaceutical laboratory has some market power in the relevant market of its new drug. In order to recoup its R&D investments, it charges a high price, frequently affordable only to wealthy patients / governments.

Compulsory licensing is the possibility of allowing production and sales or public use of a patented medicine without the authorization of the patent owner during patent validity. As already presented by Reik (1946), compulsory licensing is not only justifiable in the case of non-working (i.e. if the patent holder does not produce the good), but should take place whenever “the immediate need of the nation outweighs the absolute right of the patentee to exclude all others from in any way utilizing the patented invention throughout the lifetime of the patent”.

II.1 – Developed Countries

Compulsory licensing has been a (legal) policy instrument commonly used for decades inside developed economies, including the USA, with the purpose of spreading

---

6 In a further section we deal with southern neglected diseases, such as malaria, tuberculosis etc.
7 Compulsory licensing is only relevant during patent validity. After patent expiry, production of generic versions can be authorized, a much simpler, cheaper and less controversial procedure. For an analysis of regulation in the off-patent pharmaceutical market, check Morais (2006).
8 Another paragraph from Reik (1946) also deserves being cited here: “The existence of the public interest has generally been affirmed if the domestic demand for a patented article was not being met to an adequate extent. However, it is held that this applies only to cases in which a serious need of the public had remained unfulfilled; there is, consequently, no legitimate claim to compulsory license in cases concerned with fancy articles, such as finery, jewelry, toys and the like”. We analyze medicines.
knowledge and boosting innovation. Such instrument was already present in a British law reforming the patent system in the end of the 19th century, and appeared in the American legal texts in 1910. In Canada, patent legislation authorizes the compulsory licensing of medicines since 1923, and such instrument was intensively employed from 1923 to 1993. It was exactly the frequent use of this licensing that allowed the development of an internal market of generic drugs in Canada. In 1993, however, pressure from the United States during the NAFTA negotiations were responsible for excluding this instrument from Canadian law.

Nowadays, it is used in rich countries in an attempt to overcome the existing barriers in new high technology medical treatments based upon biotechnology and gene therapies. It has sometimes also been used by competition authorities, in particular in the USA and Italy.

In all those situations, rich countries’ governments are the target of vivid lobbies from pharmaceutical firms. The (extreme) textbook case was not even a molecule for a drug but Myriad’s monopoly over all use of breast cancer genes, including in R&D and for expensive testing, obtained in 1997. Another example could be Roche’s pressure on the German government to push a compulsory license for patents on "Blood screening HIV probe" held by Chiron, which resulted in a (voluntary) licensing agreement being obtained in May 2001 under Roche’s explicit commitment to stop attempting to obtain a compulsory license.

When it comes to public health needs and national emergency in rich economies, the most striking case involving compulsory licensing was the anthrax scare in the fall of 2001. The argument for using the instrument was that the sudden need of a large enough stockpile of ciprofloxacin (Cipro) to treat 10 million people was far greater than the patent-owner Bayer’s stock and timely production capacity, although Bayer consistently rejected such claim. In the end, the U.S. government reached a deal for buying Cipro from Bayer at half price. Only the threat of using compulsory licensing was enough – which was great for a U.S. administration that had an eye on the upcoming WTO negotiations in Doha.

Somehow contradictorily, when it comes to the international arena, most large pharmaceutical companies and their home countries oppose compulsory licensing of medicines, in particular in poor countries, in spite of public opinion’s concerns over the breadth of access to medicines. They believe poor countries will abuse the compulsory licensing system, this will lower returns from research and development (R&D) and undermine the labs’ ability to charge high prices in the more developed countries. There is plenty of evidence that much political pressure and lobby activity are involved.

II.2 – Developing Countries and Least-Developed Countries

Our focus in this paper is on this compulsory licensing which generates an international conflict of interest: one country licensing drugs whose (valid) patents belong to
foreign firms. Conditions for such licensing are stated in article 31 of the WTO TRIPS Agreement, whose goal is to ensure that the interests of patent owners and national governments are balanced. However, concepts like “national emergency or other circumstances of extreme urgency” are quite vague, and moreover are not even required “in cases of public non-commercial use” (art. 31, b). This leaves a huge margin of manoeuvre for any member State in issuing compulsory licenses, as far as “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use” (art. 31, f).

This way, compulsory licensing represents a possibility for a government in particular in a poor country to ensure that its population has access to essential drugs at affordable prices. It has not been much used, which by no means should be taken as an indication of its inefficacy: the simple availability of the instrument has in many occasions shown extremely efficient as a bargaining device for developing countries in obtaining large discounts from big labs. This happened for example in Brazil’s negotiations of anti-HIV/AIDS drugs: the threat of compulsory license gave rise to expressive discounts in March 2001 (Merck agreed to cut the Brazilian prices of Indinavir and Efavirenz by 65% and 59%), August 2001 (Roche agrees on an additional discount of 40% on Nelfinavir, sold under the brand name Viracept), September 2003 (further reductions were obtained in five ARVs: Nelfinavir, Lopinavir, Efavirenz, Tenofovir and Atazanavir) and June 2005 (Brazil and Abbott reached a compromise on the price of Kaletra, although such deal is highly criticized by specialists).

Since 2005, in some circumstances, however, the threat has not sufficed (or been credible enough) and developing and least-developed countries have issued compulsory licenses. For example, the anti-HIV/AIDS medicine Efavirenz was the object of compulsory licensing by Thailand in 2006 and Brazil in 2007, which was followed by other threats and deals. More specifically on least-developed countries, Mozambique, Cameroon and Zambia issued compulsory licenses on specific drugs to be locally produced, while Ghana, Eritrea and Zimbabwe used general statements on essential drugs with the purpose of importation.

As for the “adequate remuneration” to the patent holder required by the TRIPs Agreement (article 31, h) in case of compulsory licensing, this does not seem to be a relevant burden on the issuing country, who basically has total freedom in setting its terms. Thus, the licensing decision does not seem to be constrained in any way by this remuneration. In most cases of international compulsory licensing, stated remuneration has ranged from 0,5% to 4% of the sales value. Bearing in mind that this sales value usually ranges between 1/10 and 1/50 of the original drug price, this compensation is absolutely insignificant for a big lab holding the patent. Evidence on this is that in many cases the patent holder simply does not claim its rights for those remunerations, as in the compulsory licenses on two triple combination of AIDS drugs in Malaysia (4% not claimed on still quite high sales prices, in some cases over a
hundred dollars per patient per month) and Indonesia (0.5% on ARVs Nevirapine for 7 years and Lamivudine for 8 years not claimed).

The model presented later in this paper assumes that the non-innovative country is capable of producing drug imitations at a low cost if a compulsory license is issued. We thus at first sight seem to focus on developing countries holding drug manufacturing facilities, such as Brazil, South Africa, India or Thailand. Those are middle-income countries commonly hosting an ill population in spite of having know-how for producing the needed medicines, as people do not have access to essential (patented) drugs at affordable prices.\(^9\)

However, the analysis applies naturally to least-developed economies incapable of manufacturing the needed drugs, since the recent approval of the TRIPs “paragraph 6 system”. This refers to paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, agreed to at the 2001 WTO ministerial in Doha, Qatar. In such “system”, any country is allowed to issue compulsory licenses and produce essential medicines for exportation to countries unable to produce the medicines themselves. Also, any country with “insufficient or no manufacturing capacity in the pharmaceutical sector for the product(s) in question” can be an “eligible importing member”. If a country wishes to use the system as an importer, it has to notify the TRIPS Council— unless it is a least-developed country, in which case no such notification is even needed.

A waiver allowing the system was agreed to in 2003, and this was made a permanent amendment to the TRIPS Agreement on 6 December 2005. This means that nowadays a least-developed country can acquire patented medicines at affordable prices even if it does not have the needed facilities for producing copies. For this, it will import (at a low price) from a laboratory located abroad, possibly in a developed country.

Although by January 2010, only one WTO notification has been filed,\(^10\) we believe this instrument will increasingly be used. In any case, only its existence and the potential threat of use it engenders is enough for the purposes of this paper. Also, the non-use of the instrument can hide an evidence of price decrease as a response to the availability of the instrument, as our model will argue.

\(^9\) Obviously the patent is not the only reason behind the non-access in poor countries, distributional channels deficiencies and corruption being commonly cited. Our focus though is on patent barriers and we further assume that the patent documents perfectly describe the production procedure, in such a way that inverse engineering costs (and lags), once the compulsory license is issued, are neglectable.

\(^10\) Rwanda filed submission IP/N/9/RWA/1 dated 19 July 2007, concerning the importation of 260,000 packs of TriAvir – a fixed-dose combination product against Aids, whose original patent belongs to GlaxoSmithKline – to be manufactured in Canada for exportation to Rwanda by Apotex Inc., the largest Canadian drug firm.
II.3 – The interactions of compulsory licensing

Wholesalers in developing countries are keen on exporting drugs to earn profits on price differentials across countries. It is the rich economies, however, who commonly prefer not to allow their importation, even if it is the same drug, produced by the same pharmaceutical firm. This is also called reimportation (or parallel trade) as those drugs are produced abroad by the same pharmaceutical firm as domestically or by a licensee under its authorization.11

Forbidding or allowing drug reimportation in their territory is associated with the exhaustion regime of IPRs a country adopts. Under national exhaustion, a patent is valid (and monopoly rights are guaranteed) until its expiry in the country. Under international exhaustion, the IPR is considered expired when the first unit is sold anywhere under no patent protection. Thus, with international exhaustion the patent holder cannot bar reimportation, although the IPR is still valid in the domestic country.

There are obvious concerns about the safety of those (re)imported drugs pushing developed economies to bar them by choosing a national exhaustion regime. This is less true when those drugs come from developed countries, where lower prices may emerge from patents not being in force any longer, or from regulatory differences.

Drug price regulation is of particular interest to developing and least-developed economies, which are commonly keen on constraining such prices in order to avoid monopoly pricing by foreign laboratories. In these poor countries, compulsory licensing is increasingly seen as an alternative measure for obtaining access to existing drugs at affordable prices. Although a priori more costly (price regulation only requires imposing a price cap, while licensing requires prior bargaining with the IPR holder, notification to the WTO and effective production or domestic licensing)12, compulsory licensing can be preferred to price regulatory measures: the latter alone carries a risk for South of not being served, while the former solves for that. This paper analyzes on the interaction between those two instruments and their use by South in face of a reactive North, where the innovative firms are located.

11 It could also be a somehow legal imitator, as a drug producer based in a non-WTO member or a member benefiting from a transitory waiver in enforcing pharmaceutical patents. Our analysis remains valid in those cases, too.
12 One could argue that regulation requires much information-gathering and expertise. The potential use of international reference pricing weakens such argument. International reference pricing refers to establishing the price ceiling in a given country for a given medicine as a (weighted) average or the minimum of its (regulated) prices in a basket of supposedly comparable or relevant countries.
III – The model

In this section, we present our theoretical model, which builds directly on Grossman and Lai (2008). The crucial difference is that in our paper compulsory licensing of drugs is a potential policy instrument for developing countries, on top of price cap regulation. We only deal with the baseline situation where firms in North invent the relevant medicines and are allowed to price freely in their home country, while South does not innovate but regulates the domestic prices of prescription drugs. In other words, only North innovates and only South sets binding price controls and can use compulsory licensing.13

Whenever possible, we keep the notation and structure of GL. The game we propose adds an extra stage to their game, in order to incorporate the potential use of compulsory licensing by southern governments.

The driving force for the results in GL (where compulsory license was absent) was the incentives faced by South when setting its price controls, in particular when parallel trade is allowed by North. There are two such streams pushing in opposite directions: the incentives for South to free-ride on North’s innovation – already present in Lai and Qiu (2003), Grossman and Lai (2004) and Morais (2005) – and the incentives for South to ensure its consumers have access to northern drugs, i.e. its fear of not being served, which is introduced by GL.

In a regime permitting parallel trade, the first incentive is mitigated and the second appears, both pushing the regulated price in South upwards. South has less incentive to free-ride on North’s innovation, as a low regulated price in South would trigger parallel trade and undermine worldwide incentives to innovate. Also, the novelty reinforcing such effect is that South is explicitly concerned about ensuring that its consumers are served.

We argue in the present paper that this second effect disappears (even if parallel trade is allowed) when compulsory licensing is truly a policy instrument available to the southern government. It is the fear of having these drugs shipped to the high-income markets that sometimes induce innovative pharmaceutical companies not to serve poor markets in an international exhaustion regime. Such fear vanishes under a credible threat of compulsory licensing. Moreover, by anticipating that a poor country has a true possibility of obtaining a patented good at a low price (possibly as low as at marginal cost) even without the authorization of the IPR holder, the latter will have some incentive to lower her price in order to remain the provider for the poor country.

13 As our paper deals with genuine North-South trade, these assumptions are arguably more representative of real situations here, as compared to GL, where the baseline model works as a benchmark to facilitate intuition.
III.1 – Basic setup

There are two regions (North N and South S) with \( M_i \) consumers in each region \( i \) and two sectors (one producing a homogenous good and the other one a continuum of differentiated goods, which require R&D investment). The representative consumer decides how much of each differentiated good to consume along the economic life of length \( \tau \) of each differentiated good. He is also assumed to have some positive residual demand for the homogenous good. This assumption ensures that each household attains indirect utility equal to the present discounted value of lifetime spending plus the present discounted value of consumer surplus captured on purchases of differentiated products.

Research activity produces new varieties according to
\[
\phi_j(z) = \frac{1}{\beta} K_j^{1-\beta} L_R(z)^{\beta}
\]
where
\( K \) is the (fixed) stock of research capital and \( L_R \) is the (effective) labour devoted to research, while \( \phi_j(z) \) is the flow of new products developed in country \( j \) at time \( z \), which is constant at steady state. \( K_S \) is zero in our model, where South does not innovate.

Once invented, a (patented) good can be produced in North at marginal cost \( c \), where \( c \) is the number of units of labour required and wage in North is the numeraire. After patent expiry, that same good can be produced in North as well as in South by any firm at the same marginal cost \( c \).\(^{14}\) In our model, this is also true when a compulsory license is issued, any difference in productivity of southern facilities \textit{vis-à-vis} northern ones being reflected in wages. However, we need to make the (reasonable) assumption that either those facilities producing compulsorily licensed drugs are public or there is a competitive fringe of private laboratories willing to produce these imitations. This way we ensure that the market is served at \( p_S = c \) when a compulsory license is issued.\(^{15}\)

The profits that a patent holder makes per consumer when it charges the price \( p \) in some market and serves all local demand at that price is \( \pi(p) \). Consumers in both regions have identical demands, so these profits are the same (as a function of price) for sales in North and South. Similarly, \( C(p) \) is the surplus that a consumer in either country enjoys when the differentiated product \( i \) is available at price \( p \) while \( C_C = C(c) \) is the surplus per consumer when a differentiated product is available at the competitive price \( c \) and \( C_M = C(p_M) \) is the surplus per consumer when the patent holder charges the unconstrained monopoly price \( p_M \).

\(^{14}\) As in the general equilibrium model in GL, here too “any wage gap that exists between North and South reflects a difference in the productivity of labor in all of its uses”, which implies the same production cost worldwide.

\(^{15}\) As argued previously, in the era of the Paragraph 6 system, this becomes a reasonable assumption, even for least developed countries. Laboratories anywhere will compete to provide those generics.
We now proceed with the steady state analysis. The present value of a flow of profits accruing to a northern patent holder (also called “the value of innovation”) is:

\[ v = [M_N \pi(p_N) + M_S \pi(p_S)]T \]

where \( p_i \) is the price of a patented good in region \( i \), while \( T \) is the present value of a flow of 1 dollar from time 0 to time \( \tau \) (when the patent expires and the good is priced at marginal cost \( c \)), i.e. \( T \equiv (1 - e^{-\rho \tau}) / \rho \) where \( \rho \) is the discount rate.

Labour is used in R&D by northern firms up to the point where its marginal value product equals wage (normalized to 1):

\[ \frac{v(L_N / L_{RN})}{\frac{\nu}{1-\beta}} = 1 \]

The steady-state flow of new innovations here is

\[ \phi_N = \frac{1}{\beta} K_N^{1-\beta} L_{RN}^\beta \]

In North, spending \( E_N \) is the difference between national income \( Y_N \) and national savings (or investment). National income comprises labour income, the return to research capital, and the flow of monopoly profits paid as dividends.

\[ Y_N = L_N + rK_N + n_m[M_N \pi(p_N) + M_S \pi(p_S)] \]

where \( L_N \) is the aggregate labour supply in North, \( r \) is the return to research capital and \( n_m = \phi_N \cdot \sigma \) is the number of viable products under patent protection at any time at steady state. Investment is devoted entirely to R&D, the cost of which is \( L_{RN} + rK_N \).

Then

\[ E_N = L_N - L_{RN} + n_m[M_N \pi(p_N) + M_S \pi(p_S)]. \]

As for South, all income comes from wages and is spent:

\[ E_S = L_S. \]

As in Lai and Qiu (2003), Morais (2004) and Grossman and Lai (2004), the two regions differ in their interests as they have different innovative capacity and market size. Moreover, North decides if imported drugs can enter its market or not, which was the focus of Grossman and Lai (2008). In this paper, on top of that, South does not only regulate drug prices, but also decides whether to use compulsory licenses or not, which is our focus.

### III.2 – The four-stage game

Our game includes 4 stages as follows:

1. **1st stage**: North chooses whether or not to allow for parallel importation of drugs (and this is a long-term commitment)\(^{16}\)

2. **2nd stage**: South sets a potentially binding price cap on drugs \( \bar{p}_S \)

(\( \text{North sets a price cap } \bar{p}_N = \infty \text{ in the model analyzed here.} \))

\(^{16}\)The commitment is necessary to ensure R&D investment will be recouped and not expropriated by the government by imposing \( p = c \) after discovery. A proper reputation mechanism can ensure it.
3rd stage: The innovative firms (located only in North) set prices $p_S$ and $p_N$, which have to be lower than the price ceilings established in the 2nd stage in case they want to sell their products in a given market.

4th stage: If not served, South decides whether to issue a compulsory license and serve domestic consumers at the exact same production cost $c$, incurring however some positive fixed cost of compulsory licensing.

Compulsory licensing refers to covering the domestic market only or to exporting to countries unable to manufacture the drugs themselves (under the “paragraph 6 system”), which is in accordance with the TRIPs Agreement. This means that those drugs licensed compulsorily are constrained by South’s boundaries and thus cannot be the object of parallel trade to North, even if the northern region had decided for an international exhaustion regime and charges a higher price. As such, compulsory licensing represents a way to ensure southern consumers are served and incentives to northern firms are dulled only to the extent of the market size in South, as compulsory licensing represents an exception to the rule of uniform pricing in a regime allowing parallel trade.

There is nonetheless some fixed cost associated with the issuing of compulsory licenses. This is due to administrative procedures, but also (potentially) some reputational loss and retaliation.\(^\text{17}\) The underlying idea is that it is cheaper for South to regulate the prices of northern drugs than to engage in a complicated WTO procedure for the license. Also, it would actually be cheaper to produce the existing drug in North than to have it licensed by South, as marginal cost is the same in both regions, but there is no fixed cost (of compulsory licensing) in North.

As such, compulsory licensing is not efficiency-enhancing per se.\(^\text{18}\) Instead, it is a loophole for South to elude high prices charged by firms located in North.

We now consider the welfare functions. The southern government chooses a price ceiling to maximize the discounted value of the sum of spending and consumer surplus minus some eventual fixed cost of issuing compulsory licensing $FC$:

$$W_s = \frac{L_S}{\rho} + \frac{M_S \phi_S}{\rho} \left[ TC(p_s) + (\bar{T} - T) C_c \right] - I_{CL}.FC$$

(4)

where $\bar{T}$ is defined analogously to $T$: $\bar{T} \equiv (1 - e^{-\rho \bar{T}}) / \rho$ and $I_{CL}$ is an indicative function taking the value 1 if South issues a compulsory license and 0 otherwise.

\(^{17}\) As argued previously, royalty fees in cases of compulsory licenses are quite insignificant and not even claimed by the patent owners in many cases. As they do not seem to affect the quantity produced or demanded nor the decision to issue a compulsory license, they will be ignored.

\(^{18}\) Compulsory licensing has some transaction cost that is not present in setting price caps. Regulation, thus, is a cheaper way (more efficient “technology”) to achieve the same goal, as argued previously.
Such southern welfare will depend on the exhaustion regime of IPRs, on South fearing being served or not and on the use of compulsory licenses.

As for North, it chooses the IPRs exhaustion regime in order also to maximize the sum of its spending and consumer surplus. Its spending, however, includes the profit incomes, but is diminished by savings to finance the investment in R&D.

\[ W_N = \frac{L_N - L_{max}}{\rho} + \frac{\phi_N}{\rho} \left[ \pi M_N C(p_N) + (1 - T) M_N C_c + T \Pi_N \right] \] (5)

where \( \Pi_N = [M_N \pi(p_N) + M_{\delta} \pi(p_{\delta})] \) is the global profit flow of a northern firm on an individual product it has a patent on.

We solve the game by backwards induction. As South can potentially license patented drugs without the authorization of the patent holder – differently from GL – this region is therefore not thrilled by the perspective of not being served if setting too low a regulated price. However, if issued, a compulsory license requires incurring some fixed cost FC.

North compares its welfare in each exhaustion regime of IPRs, anticipating the subsequent choices of South. South maximizes its welfare \( W^j_S \) where \( j \in \{ne, ie\} \) by choosing its price cap, for a given exhaustion regime of IPRs chosen by North (\( ne \) means national exhaustion or no parallel trade while \( ie \) stands for international exhaustion), and anticipating it can issue compulsory licenses if it is not served.

III.3 – Solving for the price controls

South has no interest in leaving rents to northern firms. Since through price controls (2\textsuperscript{nd} stage) South can impose its preferred price level (constrained by parallel trade or not) upon northern firms, its price ceiling is always binding.\(^{19}\)

In North, as prices are not controlled, under national exhaustion we have \( p_N = p_M \) (the monopoly price firms freely choose). Under international exhaustion, if a firm charges different prices in the two markets, parallel traders will cover the high-priced market with products from the low-priced market. As a consequence, firms charge in North the same binding price caps imposed in South and thus \( p_N = p_S \), i.e. there is importation of price controls in a regime permitting parallel trade.

III.3.1 – National Exhaustion

\(^{19}\) In this paper, we do assume there is no asymmetric information issue, such that all information is common knowledge.
If North had decided in the 1st stage for no parallel trade, northern firms will be willing to serve the southern market at any price above marginal cost. However, the optimal choice in South will be \( p_S = c \) only if \( M_S \) is small enough, as its price gives incentives to northern R&D to the extent of the size of the southern market.

An interior solution where the price in South in a national exhaustion regime is larger than \( c \) is the price solving the following first-order condition from maximizing equation (4) in the absence of compulsory licensing:

\[
\frac{d\phi_N}{dv} \frac{dv}{dp_S} \left[ TC(p_S) + (\bar{T} - T)C_c \right] + \phi_N TC'(p_S) = 0
\]

By incorporating (1), (2) and (3) we obtain:

\[
\frac{\beta}{1 - \beta} \left[ C(p_S) + \left( \frac{\bar{T} - T}{T} \right) C_c \right] \left[ \frac{\pi'(p_S)}{-C'(p_S)} \right] = \pi(p_S) + m \pi(p_M)
\]

where \( m = \frac{M_N}{M_S} \) is the relative (northern) market size.\(^{20}\) For \( m \) larger than some threshold \( m_1 \), the right-hand side of (6) exceeds the left-hand side for all \( p_S > c \). We thus have that \( p_S^* = c \) for \( m > m_1 \). For \( m < m_1 \) the chosen price \( p_S^* \) is the solution of (6).

### III.3.2 – International Exhaustion

In case of international exhaustion of IPRs, parallel trade eliminates firms’ power to discriminate prices across markets. Therefore, no matter how tiny the southern market is, it is the regulated price in South that determines worldwide incentives to R&D and innovation, and South knows it. As a consequence, the (unconstrained) price cap \( p^* \) South will prefer to enforce is the one that would solve equation (6) when \( m \to 0 \) (as if the whole world were South):

\[
\frac{\beta}{1 - \beta} \left[ C(p^*) + \left( \frac{\bar{T} - T}{T} \right) C_c \right] \left[ \frac{\pi'(p^*)}{-C'(p^*)} \right] = \pi(p^*)
\]

Northern firms could possibly forego sales in South. This would happen in an international exhaustion regime when profits of selling in both North and South at the southern price cap were smaller than the profit of only selling in North at monopoly price.

---

\(^{20}\) As explained by GL, this equation “expresses the tradeoff between the benefit to South of the extra product diversity that results from greater innovation and the loss in surplus that Southern consumers suffer as a result of higher prices there. The term \( \beta/(1 - \beta) \) represents the elasticity of innovation \( \phi_N \) with respect to the value of a patent \( v \), and thus can be interpreted as the supply elasticity of R&D. The government of South sets a more lenient price control (price ceiling) when innovation is more responsive to profits, when product life is long relative to the duration of patents, and when South’s market is relatively large.”
Therefore, in the absence of compulsory licenses, under "ie" South anticipated the 3rd stage and incorporated an extra constraint to its maximization problem for ensuring its consumers were served: 
\[ p_s^* = \max(\bar{p}, p^*) \]
where \( \bar{p} \) is defined implicitly as the price yielding the same profit for the monopolist if he sells in both North and South at a uniform price (below the monopoly price, equal to the price ceiling in South), or if he foregoes sales in South and sells only in North at monopoly price (as there is no price control in North in the model):
\[ (M_N + M_s)\pi(\bar{p}) = M_N\pi(p^M) \]

In our framework, if South is not served, it can unilaterally issue compulsory licenses and have access to the medicines at marginal cost, but incurs some fixed cost. 21

III.4 – South’s strategic behaviour with and without parallel trade

South is called to play twice in our game. In the 2nd stage, knowing the IPR regime chosen by North, it sets the ceiling on the drug prices the northern firms can charge. In the 4th (and new) stage, it decides whether or not to issue compulsory licenses, in case northern firms have preferred not to sell in South.

III.4.1 – South’s optimal choices with National Exhaustion

If North rules out parallel trade, any patented drug reimportation is illegal per se. In such case, there is no need to emphasize that compulsory licensing refers to serving the domestic market only – which will be essential in our analysis of international exhaustion.

In the 4th stage of the game, South will issue compulsory licenses if it is not served. (If the non-served South does not issue compulsory licenses, it gets zero welfare.). This means South incurs some fixed cost FC but is able to serve its consumers at the marginal cost \( c \), provided FC is not prohibitive:
\[ W_{s}^{CL} = \frac{L_s}{\rho} + \frac{M_s\phi_{N}}{\rho}TC_{c} - FC \]
(8)

where \( \phi_{N}^{c} \) is the innovation rate when southern consumers are served at marginal cost. This \( \phi_{N}^{c} \) is strictly smaller than \( \phi_{N} \) whenever the price chosen for the maximization of (4) is strictly larger than \( c \) (which holds always for international exhaustion, and for national exhaustion when \( m < m_1 \)).

21 In some circumstances, South can use price controls strategically: South might prefer choosing too low a price cap in order not to be served, allowing it to use compulsory licenses in a further stage. This case will be explored later on.
However, in the 3rd stage, northern firms are willing to serve South at any price above marginal cost $c$, and South knows it when it chooses the price control in the 2nd stage. As such, South has to compare $W_S^{CL}$ and $W_S^{ne}(p_S)$, where the former is the welfare when compulsory license is used and the latter is the welfare obtained under national exhaustion by setting a price cap $p_S$ (as in Figure 1):

If the welfare in South were higher under compulsory licensing, then South would (strategically) set a very low price ceiling in order not to be served ($p_{S}^{ne} < c$), which is a requisite for compulsory licensing, and then issue a license. However, our first result shows that this is never the case.

**Proposition 1:** Suppose that South does not innovate and North imposes no price controls. In a national exhaustion regime, South’s optimal choice of price control is not influenced by the potential use of compulsory licenses.

A corollary is that Figure 1 below remains valid in its lower part (ne).

*Proof:*

- For $m \geq m_1$, South is small enough for not being concerned about generating incentives to R&D in North. As no parallel trade is allowed here, South knows northern firms will be willing to serve the southern market at any price above marginal production cost. South can already induce $p_S = c$ at the 2nd stage of the game by setting $p_{S}^{ne} = c$ and South will be served. Using compulsory licenses would simply mean obtaining the drugs at a higher cost, as southern facilities produce at the same marginal cost $c$ but there is some fixed cost of using compulsory licenses. Consequently, $W_S^{CL} < W_S^{ne}(c)$.

- For $m < m_1$, South could induce $p_S = c$ at the 2nd stage but achieves higher welfare by setting $p_{S}^{ne} > c$ (as shown in Figure 1). Its market is large enough for South to benefit more from the dynamic gains of (more) innovation than it suffers from the static losses of a price higher than marginal cost. We thus know that $W_S^{ne}(p_S) > W_S^{ne}(c)$, where $p_S$ is the one obtained from equation (6). Moreover, as argued in the previous paragraph: $W_S^{ne}(c) > W_S^{CL}$. It is then straightforward that South’s welfare for $m < m_1$ is larger under the price caps in figure 1 than if South uses compulsory license.
We plot below a slightly modified\textsuperscript{22} version of GL’s Figure 1, representing the optimal choice for the binding price ceiling in the absence of compulsory licensing. The graph shows $p_s$ as a function of the relative market sizes $m$ in both IPRs regimes.

![Figure 1: Price Ceilings under Alternative Parallel Trade Regimes and no Compulsory Licensing](image)

For the lower part of Figure 1, $p_s^{ne}$ shows that in the absence of parallel trade, South sets a price equal to marginal cost if its market size is small enough (for $m > m_1$), as northern firms are willing to serve South at any price higher or equal to cost. For $m < m_1$, South is large enough to be concerned about the impact of its price ceiling on overall profits of northern firms and their incentives to innovate, as these determine the number of goods invented at steady state, which benefit (also) southern consumers. For $m < m_1$, the larger the market in South, the higher is the price cap chosen by the Regulator in South. In the limit, if South is huge, being the only region responsible for providing incentives to innovation (i.e. if the size of the northern market is insignificant), the price cap chosen in South will be the same as its preferred one under international exhaustion (as shown by the intersection of both bold curves at $p^*$). This is the first crucial insight.

As for the upper part of Figure 1, when parallel trade is allowed by North, the price cap imposed by South is the uniform price worldwide (if South is served). A parallel trader will profit from any arbitrage possibility and such threat will force innovative firms to charge the same price in both regions, in case they wish to serve both markets. The incentives for South, though, when setting its price cap $p_s$ will incorporate such externality on northern prices and overall R&D incentives. The southern government thus has no incentive to set any

\textsuperscript{22} The only modification introduced in comparison to GL’s Figure 1 was striping some area of interest.
price cap below $p^*$ irrespective of how tiny it is, as South knows its price control will determine incentives to worldwide R&D. As a result, $p^*$ is independent of $m$ under $ie$. \footnote{An underlying assumption is that South is not subject to any capacity constraint, i.e. facilities in South can potentially produce drugs in quantities sufficient to cover both regions.}

On the other hand, in case of international exhaustion, South is also concerned about being served. This is expressed by $\tilde{p}$, the regulated price in South making northern firms indifferent between selling in both regions at that price or only in North at monopoly price. Clearly, $\tilde{p}$ is increasing in the northern relative market size: as the market in North becomes insignificant ($m \to 0$), firms in North are willing to serve South at any price above marginal production cost; as the market in South becomes insignificant ($m \to \infty$), firms would only accept to serve South at monopoly price.

In the absence of compulsory licenses, if under international exhaustion South charges a price below $\tilde{p}$, South is sure of not being served. This pushes South in the presence of parallel trade to be constrained to setting its price cap at $p^{ie}_S = \max \{ p^*, \tilde{p} \}$. This is exactly what is crucially different in our model, i.e. when South is allowed to issue compulsory licenses for drugs it is not being provided. \textit{A priori}, we expected our results to be constrained to the striped zone in Figure 1 above. However, as the possibility of using compulsory licensing is anticipated – not only by northern firms and government but also by the regulating government in South, results are more striking than \textit{a priori} naïvely expected.

### III.4.2 – South’s optimal choices with International Exhaustion

In this regime, the possible use of compulsory licenses changes South’s incentives in its regulatory activity, in case the fixed cost associated with compulsory licensing is small enough. South is not so concerned about being served when choosing price controls in the second stage of the game, i.e. about setting a price at least as high as $\tilde{p}$ in Figure 1 (if FC is not prohibitive). However, South cares about worldwide innovation (no matter South’s market size) as it knows parallel trade implies uniform price, i.e. the importation by North of the southern price controls.

Let $m_0$ be the value of $m$ making South indifferent between issuing a compulsory license or not in an international exhaustion regime: $m_0$ is such that $W^{CL}_S = W^{ie}_S(p_S)$. Using equation (4) we obtain that $m_0$ is determined implicitly as the value of the ratio of market sizes $m$ yielding the equality between the fixed cost of issuing a compulsory license and the positive impact on consumer surplus, which is equal to the increase from having consumers
acquiring the good at marginal cost minus the loss due to having less innovation:

\[
FC = \frac{M_S \phi_C}{\rho} \bar{T}C_c - \frac{M_S \phi_N}{\rho} \left[TC(p_S) + (\bar{T} - T)C_c\right]
\]  

(9)

If the actual ratio of market sizes \(m\) is larger than this threshold \(m_0\) then South gains from using compulsory licenses. If on the other hand \(m < m_0\) then the optimal choice of South is not affected by the availability of compulsory licensing as a policy instrument.

We divide the analysis into three separate cases, according to the size of the fixed cost FC. We start by dealing with the more interesting case of a small FC, which we analyse more thoroughly. We then present the cases for medium and large fixed costs.

1st case: Small fixed cost of compulsory licensing

Here we consider a fixed cost FC inducing a value of \(m_0\) smaller than \(m_1\).

- For \(m > m_2\) the now unconstrained South would prefer setting \(p_S = p^*\) in the presence of parallel trade. However, if it does so, it will not be served as northern firms make a higher profit by only serving North at monopoly price (as in Figure 1). However, if South is not served, its optimal choice in the last stage of the game is to issue compulsory licenses. Knowing this, South’s choice is between setting a high price control, being served and not issuing compulsory licenses, obtaining \(W^C_L(S, \bar{p})\), or setting a low price control, not being served and issuing compulsory licenses, achieving \(W^C_L\). The crucial point is that \(W^C_L(p^*)\) is not achievable and both regions know that.

For any ratio of market sizes, southern welfare is always higher under national exhaustion, as \(p^e_S\) could be chosen under national exhaustion, but some different \(p^e_S\) (strictly lower) was preferred; thus \(p^e_S\) necessarily generates a higher welfare. This holds for low values of \(m\) – where \(p^e_S\) and \(p^e_S\) are close – and with more reason for high \(m\), when the small South has lower incentives to boost northern R&D in the absence of parallel trade and is pushed to provide such protection by uniform pricing. We thus know that \(W^e_S(c) >> W^C_L(S, \bar{p})\) for \(m > m_2\), which implies for a small FC of compulsory licenses, as \(m_0\) lies to the left of \(m_1\), that \(W^C_L > W^e_S(\bar{p})\), since \(W^C_L = W^e_S(c) - FC\).

As a consequence, South sets any price control \(\bar{p_S} < \bar{p}\) as it anticipates it can issue compulsory licenses in the last stage of the game if it is not served. The northern firm will set \(p_N = p_M\) and any \(p_S > \bar{p}_S\) and only serve North at monopoly price. Compulsory licensing ensures southern consumers are served at \(p_S = c\) and South bears a small FC.
Lemma: Suppose that South does not innovate and North imposes no price controls. In an international exhaustion regime, if the market size in South is small enough such that at its unconstrained preferred price cap it would not be served \((m > m_2)\), then northern firms are better off if compulsory licenses are issued than if South was not afraid of not being served.

Proof:

Somehow strikingly, in this range of \(m\) \((m > m_2\) in Figure 1) northern firms prefer compulsory licenses to being obliged to serve both regions at the preferred southern price under parallel trade \(p^*\) (due to parallel trade and uniform pricing). From the definition of \(\tilde{p}\) and the fact that in this range of \(m\) we have that \(\tilde{p} > p^*\), we then know that \((M_N + M_S)\pi(p^*) < M_S\pi(p^W)\), where the right-hand side is the profit firms get if compulsory license is issued in South. Remember \(p^*\) is the price cap South would impose if it were not afraid of not being served, even for \(m > m_2\). The whole point is that when compulsory license takes places, it curtails parallel trade in spite of international exhaustion of IPRs. This way price segmentation can be restored and monopoly profits can be recouped by innovative firms in North.

- For \(m_1 < m < m_2\) being served or not is not an issue as the preferred choice of South under international exhaustion \(p^*\) is larger than the minimum required price ceiling for being served \(\tilde{p}\). In this case, the incentives for South to issue compulsory licenses do not come from any fear of not being served. Instead, it comes strictly from the desire not to take on the burden of incentivizing worldwide innovation (which comes from the uniform pricing imposed by parallel trade). South’s choice is between \(W^e_S(p^*)\) or \(W^{CL}_S\). Again, due to the small size of the fixed cost associated with compulsory licensing (\(W^{CL}_S = W^{ne}_S(c) - FC\)) and the fact that welfare in South is always smaller under \(ie\) than \(ne\) in the absence of compulsory licensing (Proposition 3 in GL), we have that \(W^{CL}_S > W^{ne}_S(p^*)\) as \(m_0 < m_1\).

- For \(m < m_1\) things are trickier. Compulsory licensing implies \(p = c\) but this was not the preferred choice of South under national exhaustion of IPRs as South is itself concerned about the incentives to northern innovation, due to its high relative market size.

The value of \(m_0\) defined implicitly in equation (9) determines the threshold. If the ratio \(m\) turns to be such that \(0 < m < m_0\), \(W^{CL}_S < W^{ne}_S(p^*)\) and compulsory licenses are not issued. If \(m_0 < m < m_1\) then \(W^{CL}_S > W^{ne}_S(p^*)\) and the regulated price cap will be set below \(\tilde{p}\)
in the 2\textsuperscript{nd} stage for South not to be served. When it gets to the 4\textsuperscript{th} stage, South issues compulsory licenses.

**Proposition 2:** Suppose that South does not innovate and North imposes no price controls. In an international exhaustion regime, South’s optimal choice is not always to use compulsory licensing, even in the absence of any costs associated with such practice. Compulsory license never happens when the relevant market in South is large enough.

*Proof:*

When there is parallel trade, for a large enough market size in South (i.e. for $m < m_0$), South prefers a regulated price even higher than the minimum price $\tilde{p}$ that would induce northern firms to serve the southern market, which is higher than marginal cost $c$, from the definition of $m_0$. It remains to show that $m_0$ is always strictly positive (i.e. never equal to 0).

For $m = 0$: welfare is the same in both regimes since North is insignificant and South charges the same price in both regimes\textsuperscript{24}: $W^\text{ne}_S(p^*) = W^\text{ne}_S(p^*)$. We also know that $W^\text{ne}_S(p^*) > W^\text{ne}_S(c)$ as $p_S = c$ could have been chosen under $ne$ but South preferred a higher price ceiling, yielding a necessarily higher welfare. Moreover, $W^\text{CL}_S = W^\text{ne}_S(c) - FC$ by definition. We then obtain that $W^\text{ne}_S(p^*) > W^\text{CL}_S$ for $m = 0$ (even when $FC = 0$), which implies that $m_0$, as defined from equation (9), is necessarily strictly larger than 0.

In other words, there always exists a range of relative market sizes ($0 < m < m_0$) for which South prefers to provide itself incentives to northern R\&D, instead of issuing compulsory licenses.

From Proposition 1, there is no interest to issue compulsory license when parallel trade is not allowed. When there is parallel trade (Proposition 2), South issues compulsory licenses only if its market is not large enough. Figure 2 plots these ideas, where we take the fixed cost of issuing compulsory licenses to be small.

\textsuperscript{24} When $m = 0$ South is virtually the whole world and the distinction $ne$ and $ie$ loses its sense.
In other words, through compulsory licensing, the small South is able to reverse back to its welfare under national exhaustion (minus some small fixed cost associated with the use of compulsory licenses) in spite of North having chosen international exhaustion (and thus parallel trade and uniform pricing). The key feature of compulsory licensing is that the targeted drugs have to be used domestically.

2nd case: Middle-size fixed cost of compulsory licensing

In this case we deal with a middle-size fixed cost, implying that $m_0$ falls between $m_1$ and $m_2$. Once again, if $m$ falls to the left of $m_0$ then compulsory license is not used, the opposite happening if $m > m_0$. The reasons are identical to the ones in the 1st case.

Proposition 3: Suppose that South does not innovate and North imposes no price controls. For a small enough fixed cost of issuing compulsory licenses, for some medium range of relative market sizes, although South is always served, South strategically sets too low a price control and issues compulsory licensing.

In other words, for $m_0 < m < m_2$ the availability of compulsory licensing changes the regulatory behaviour of South. This happens in both the 1st case analysed above (where $m_0 <
m_1) and in this 2
d case (m_1 < m_0 < m_2) for some intermediate values of the ratio between market sizes m (i.e. for m_0 < m < m_2).

In spite of always being served, South changes its regulatory practice strategically, in order not to be served and afterwards be able to use compulsory licenses. This is what happens in figure 2 for the values of m between m_0 and m_2. South charges \( p_s^e < p^* \) at equilibrium and, after not being served, South issues a compulsory license, as in such case this is a cheaper way of having access to the drug.

3
d case: Large fixed cost of compulsory licensing

In this case we consider a fixed cost of issuing compulsory licensing large enough for m_0 to be larger than m_2. If it is the case, the cost of issuing compulsory licenses is high enough for South to prefer in some cases (i.e. for m_2 < m < m_0) to allow for a higher regulated price than it would prefer if it were not worried about not being served. In other words, for some sort of middle range market in South (m_2 < m < m_0), South is constrained to allow \( \tilde{p} > p^* \) as ensuring its consumers are served is a cheaper alternative as compared to compulsory license. However, if the southern market is tiny (m > m_0), its impact on innovation will be so small that even for a large fixed cost of compulsory license such issuing will worth it. Thus, in case issuing a compulsory license implies incurring some huge fixed cost, compulsory licenses are only issued by a southern market insignificant in size.

Proposition 4: Suppose that South does not innovate and North imposes no price controls. If the fixed cost of issuing compulsory licenses are huge (or large enough), then compulsory licenses are never issued.

In other words, the results of Grossman and Lai (2008) are a special case of our model: they hold when FC is large enough.

A corollary of this result is that in such case the whole of Figure 1 remains valid.

Proof:

In the limit case where the fixed cost of issuing compulsory licenses tends to infinite, compulsory licenses are obviously never issued: from equation (8) we see that \( W_s^{CL} \) would be negative. This means that if FC \( \rightarrow \infty \), then m_0 \( \rightarrow \infty \), which means that no m is to right of m_0 and therefore compulsory license is never used. As a matter of fact, we do not need FC \( \rightarrow \infty \) for the proposition to hold (i.e. for m_0 \( \rightarrow \infty \)), as it is sufficient to have FC sufficiently large to ensure that the left-hand side of equation (9) is always larger than its right-hand side, and therefore \( W_s^{CL} < W_s^e(p_s) \) always.
Proposition 5: Suppose that South does not innovate and North imposes no price controls. Overall welfare is higher in a national exhaustion regime (no parallel trade) than in an international exhaustion regime, if compulsory licence is allowed and effectively used.

Proof:

Remember compulsory license is used if the actual ratio between the market size in North and the one in South \((m)\) lies to the right of the threshold \(m_0\).

If \(m_0 > m_1\) the result follows straightforward. In this case, for \(m > m_0\) we have necessarily that \(m > m_1\). Consequently, while in national exhaustion we had \(p_S = c\) and some welfare in North and South, under compulsory licensing we will have precisely the same welfare in North and a strictly lower welfare in South:

\[
W_{SC} = W_{SCL}^{ne}(c) - FC.
\]

It remains to show that this is also the case for \(m \in (m_0, m_1)\) when \(0 < m_0 < m_1\), as in Figure 2. This is also true as at this range, \(p_S = c\) was a possibility under national exhaustion but some higher price was preferred by South. Thus, \(W_{SCL}^{ne}(p_S) > W_{SCL}^{ne}(c)\). As by definition, we have \(W_{SC}^{CL} = W_{SCL}^{ne}(c) - FC\), it is straightforward that \(W_{SCL}^{ne}(p_S) > W_{SC}^{CL}\). Concerning North, its welfare is higher under national exhaustion, as in this range of \(m\) the price allowed in South under \(ne\) is higher than when there is \(ie\) and compulsory licenses are used. Therefore northern profits and innovation (and thus northern welfare) are higher under \(ne\). The result follows: overall welfare is higher under \(ne\) than under \(ie\) and compulsory licensing.

This result goes in favour of international price segmentation, the same one advocated in Danzon and Towse (2003) and Scherer and Watal (2002). The later proposes, on top of ruling out parallel trade from poor nations, to forbid international reference pricing where prices in poor nations are used as reference. Any such measures disconnecting the prices in North and in South seem to be in line with our results.

IV – Neglected Diseases

As clearly stated by Danzon and Towse (2003) in their Introduction, developing countries face basically two problems in what concerns public health: first, guaranteeing access to drugs in diseases affecting both developed and developing countries; second, provide the necessary incentives for R&D on diseases affecting mainly or exclusively the poor countries.

In the first group, we can include all drugs usually available in North but for which southern consumers commonly lack access, such as antibiotics and most HIV-AIDS drugs. In
the second group, there are all neglected diseases that harm particularly South and for which
existent treatment is not very efficient (whenever there is one), the most striking examples
being dengue, malaria, tuberculosis, sleeping sickness and leishmaniasis.25

International NGOs sometimes advocate in favour of compulsory licensing on the
existent (although not very efficient) treatment for some neglected diseases. For example, the
Third World Network (James Love, on Compulsory Licensing, published in 2004) advocates:
“By declaring a public health emergency for HIV/AIDS, tuberculosis, malaria or other
illnesses, a government could give general authorization for the competitive sector to supply
particular types of drugs, …”. As for the Médecins Sans Frontières (MSF), their website
mentions: “To address the issue of abandoned drugs, MSF is calling on companies and
governments to find solutions to bring unprofitable but medically necessary drugs back into
production. MSF is also supporting developing countries in codifying into law the
‘safeguards’ that are allowed under international trade rules in order to protect access to
medicines.” Although not explicitly, such text leaves the doubt about if compulsory licensing
should be an instrument for dealing with those “abandoned drugs” (for neglected diseases).

Contrasting such idea, our model proposes the following:

**Proposition 6**: Drugs on neglected diseases should not be the object of compulsory
license (including for government non-commercial use).26

*Proof:* This is a corollary of the previous discussion (check Figure 2).

This would be so in the best interest of the developing world. In terms of our model, a
drug whose market in North is irrelevant or arbitrarily small (i.e. a neglected disease) means
that the value of m, the ratio between market sizes, is arbitrarily close to zero (m \(\rightarrow\) 0). In
particular, as Proposition 2 proved that \(m_0\) is strictly positive even when there is no fixed
cost associated with compulsory licensing, we are sure there exist values of m such that \(m < m_0\)
in Figure 2. This Proposition 6 applies (at least) to those diseases for which the true m lies below
\(m_0\) as defined by equation (9).

In other words, for neglected diseases, the relevant market is the one in South, and
therefore South is highly concerned about generating incentives to R&D for those diseases as
free-riding on North is nonsensical. In a national exhaustion regime, South would be better
off by setting a high price control, in particular much higher than marginal cost c. In an

---

26 Exception should be made for unexpected emergencies, disregarded if it is for a neglected disease or
not (without further in-depth analysis). By this we mean the cases in which any country (developed or
not) could reasonably issue a compulsory license, such as the USA during the 2001 Anthrax crisis.
Exceptions should be punctual, motivated and short in both time and geographic extent, in a way not to
undermine incentives to innovation.
international exhaustion regime, South prefers not to issue compulsory licenses, and stick to a high price control ($p^*$), too.

Therefore, North should not fear compulsory licensing for neglected diseases as South’s optimal choice is not to use it. If ever there is any concern on this (credibility, reputational issues), South would benefit from credibly committing not to issue compulsory licenses on drugs for neglected diseases.²⁷

However, the free-riding behaviour among southern countries, when there are many countries in South, might break down such perspective. There is always an incentive for a southern country to deviate from a commitment not to issue compulsory licensing, if no credible retaliation is enforced. If all countries but one in South commit not to issue compulsory licenses, the best decision of this one country is to issue the licenses, free-riding on the incentives to R&D on neglected diseases the other southern countries provided. Consequently, there is no symmetric Nash equilibrium where no southern country issues a compulsory license. Thus, northern firms will not have much incentive to invest in research on those neglected diseases, except if all southern countries credibly commit to use no compulsory licenses on those.

V – Conclusion

In this paper, we have analyzed countries’ decision on the implementation of binding price controls and compulsory licensing for medicines (and their interaction), which are of particular interest for the less innovative developing world, as such policies might dull incentives to innovate but provide broader consumer access to drugs.

We use a strategic North-South model, the best-suited setup for analyzing the a priori domestic regulatory policy in the post-TRIPs arena. The analysis of an increasingly globalized pharmaceutical market requires incorporating its international aspects: parallel trade and compulsory licensing.

Grossman and Lai (2008) performed a similar exercise, without however considering the possibility of compulsory licensing, as they explicitly focused on the relation between USA and Canada, or Northern Europe and Southern Europe. We extend their model by allowing South to issue compulsory licenses (on top of price controls), focusing thus on the interaction between a developed innovative North and a developing South.

²⁷ Possibly, other mechanisms than the patent system could be even better in terms of generating private incentives for R&D on neglected diseases, such as patent buy-outs or prizes (tournaments), or else the public funding of this R&D, but all these are beyond the scope of this paper, which focuses on the patent system, the most used mechanism for generating those R&D incentives in our time.
The key driving force in their paper was South’s fear of not being served if imposing too low a price cap on northern drugs in the presence of parallel trade (international IPR exhaustion). In the present paper, the possibility for South of using compulsory licenses turns out to counterbalance the power of such threat by northern firms.

They had shown that parallel trade (and the attached threat) increased R&D and thus innovation and welfare in North, at the expense of welfare in South, as compared to the situation where there is no need for interactive decision (national IPR exhaustion, no parallel trade). In our paper, compulsory licensing ends up being a way for South to reverse back to a situation close to the one with no parallel trade, restoring most of its welfare. At the same time as our results complement the main results in Grossman and Lai (2008), our paper challenges their generality.

Their conclusion advocated that the pharmaceutical lobby (and more broadly, North) should move towards allowing parallel trade in a way to increase profits of innovative firms and innovation at the same time and thus welfare in North. South would be hurt by such decision in their setting. Its only (and legal!) remedy is the one neglected in their paper and analyzed in ours: compulsory licensing.

Welfare in North (and profits and innovation) is not decreased by compulsory licensing. Actually, the outcome of compulsory licensing is that North achieves the same welfare (and profits and innovation) as when there is no parallel trade or compulsory licensing, and South is strictly worse off (due to bearing the (fixed) cost of issuing licenses). However, South through compulsory licensing recovers partially what it would have lost in the presence of parallel trade (and absence of compulsory licensing) and the threat of not being served.

The most straight policy recommendation from the present paper is that governments in the developing world (the South) should first of all be conscious of their possibility of using compulsory licensing and use it as a credible threat in imposing or negotiating regulated price controls. However, one should bear in mind that this is only true for drugs for diseases affecting both North and South. For the so-called neglected diseases, where the only relevant market is the one in South, South has to provide alone incentives to R&D and therefore should have no interest in using compulsory licenses. Actually, South should (if possible) credibly commit to never issue a compulsory license on neglected diseases.

The indirect recommendation would be to lower the (fixed) costs associated with using compulsory licensing. As allowing parallel trade is a northern decision (and benefits North at the expense of South), issuing compulsory licensing should be a sovereign southern decision, as proclaimed by the WTO TRIPs Agreement and the Doha Declaration. Therefore, compulsory licence should be facilitated, and never retaliated. We have shown that even if compulsory licensing implies no cost disbursement, it is not always optimal for South to use
it. Its adoption will depend on the relative market sizes; in particular, it should never be used for neglected diseases.

Facilitation should include for example the generalization of the existing pre-qualification of generic producers by the World Health Organization (WHO). Any retaliation to the legitimate use of compulsory licensing should be punished through the WTO legal procedures. In this we should include the USA efforts in imposing restrictions on the use of compulsory licenses in bilateral trade agreements. These include, on top of explicit restrictions on compulsory licensing, data exclusivity measures and the imposition of a patent enforcement role for drug registration agencies, as argued in MSF (2004), where broad evidence on this is compiled.

Furthermore, as the model shows, the most efficient situation is a national exhaustion regime. If North and South could cooperatively search for the best outcome, this would be to bar compulsory license and parallel trade at a time. Actually, banishing parallel trade is enough, as our Proposition 1 ensures that compulsory licensing is never used under national exhaustion. Innovation and northern welfare would be the same as in a regime with both parallel trade and compulsory licensing, and southern welfare would be increased (by an amount equal to the fixed cost wasted in issuing compulsory licenses). International drugs price discrimination is shown to be a Pareto superior outcome.

References


