E C O N O M I C S B U L L E T I N

A model of parallel imports of pharmaceuticals with endogenous price controls

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Abstract

A model is developed to explore the behavior of an original manufacturer with a patent in response to a policy that permits parallel import competition from a country with price controls on the patented good. The model suggests that a manufacturer will limit its supply to the PI-exporting market. The home price is lower only under certain conditions. The relative size of the home market to the potential volume of PIs is a key determinant of the manufacturer's decision to accommodate competition or deter it. Whether the firm accommodates or deters competition, profits fall.

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1. Introduction

Importing an authentic product meant for sale in one country into another country without the authorization from the intellectual property right (IPR) holder is termed *parallel importation.*[1] Parallel trade results when IPRs are subject to international exhaustion and when there are price differentials to exploit.[2] In the case of pharmaceuticals, international price differences stem from market differences and also government policies. All OECD governments with the exception of the United States use some form of price controls on pharmaceuticals.[3] Policies include direct price controls, profit controls, reference pricing, restrictions on prescribing and dispensing, and annual price cuts. Some US policymakers have proposed allowing imports of pharmaceuticals from Canada where the prices are regulated and lower.[4] Currently this practice is illegal in the United States, but it is an alternative that is attracting attention.[5]

I develop a framework which analyzes the impact of parallel trade on the foreign price, the home price, and the original manufacturer firm's choice of foreign supply. The degree of bargaining power that the firm has (based on the uniqueness of its product) when negotiating the foreign price with the foreign government emerges as a determinant of manufacturer's response to a policy permitting parallel trade. Findings suggest that a manufacturer would limit supply to the foreign market and in certain instances, restrict supply to such a degree that parallel trade is completely deterred. The home price will be reduced only under certain conditions. Also it is possible for the foreign price to be lower or higher as a result of parallel trade. For situations similar to the US-Canada scenario, the model suggests that a manufacturer would deter competition through a strict supply limit. The US price would not be reduced and pharmaceutical firms' profits would fall.

2. Theoretical Model

The economic literature has advanced four theories to explain why parallel imports occur: price discrimination (Malueg and Schwartz 1994), national price regulation (Danzon 1997), vertical price control (Maskus and Chen 2004), and free riding on authorized distributor services (Chard and Mellor 1989).[6] In each, parallel trade distorts the market

[1] Parallel imports are legitimate goods, not knock-offs or counterfeits.

[2] The exhaustion doctrine stipulates the stage at which a firm's right to control distribution of a product is terminated. International exhaustion asserts that rights end upon first sale of the product anywhere. The United States follows a doctrine of national exhaustion; an IPR holder's distribution rights end upon first sale within the country, but the rights to exclude parallel imports are retained.

[3] See Danzon (1997) for a description of pharmaceutical price regulation across countries.

[4] See http://www.pmprb-cepmb.gc.ca/ for information on the Patented Medicines Prices Review Board which is responsible for setting the maximum price pharmaceutical companies may charge in Canada.

[5] According to the National Conference of State Legislatures (http://www.ncsl.org/), in 2007 seven state legislatures were considering legislation on pharmaceutical imports and in 2006, 14 were considering such legislation. Nationally, the "Medicine Equity and Drug Safety Act of 2000" (PL106-387) and the "Medicare Prescription Drug, Improvement and Modernization Act of 2003" (PL108-173) have been passed, allowing prescription drug imports from Canada. However, each piece stipulates that the Secretary of Health and Human Services must give safety approval; to date it has not been given. Pending importation legislation includes HR-380, S-242, and S-380 (www.congress.org).

[6] Maskus (2000) provides a general overview of the literature, policy questions, and empirical evidence related to parallel trade.

in some way.[7] Two studies specifically address parallel imports of pharmaceuticals. Ganslandt and Maskus (2004) present a theoretical model of the price-integrating impact of parallel imports and test it with data on pharmaceutical prices in the European Union. They model the actions of a manufacturer and parallel trader firms in a multi-stage game. Pecorino (2002) models a home monopoly firm engaged in Nash bargaining with a foreign government over pharmaceutical prices in situations restricting and permitting parallel trade.

In this note, both the Ganslandt-Maskus and Pecorino frameworks are utilized to further explore the effects of parallel imports of pharmaceuticals. The actions of three economic actors (a home manufacturer, a foreign government, and a group of parallel traders) in two markets (a price-controlled market and a free market) are explored. Interaction between the agents takes place in a multi-stage game where the outcome is found by solving backwards for a sub-game perfect Nash Equilibrium. Outcomes from situations permitting and prohibiting parallel trade are then compared. As in Pecorino, the foreign price is endogenously determined by Nash bargaining. As in Ganslandt-Maskus, a multi-stage game is developed with positive trade costs and parallel imports arising endogenously. Additions to the models include the manufacturer's choice over the foreign supply volume, uncertainty in foreign demand, and the endogenous determination of the foreign price control. A supply limit option is included because several major drug companies have already undertaken efforts to limit their supply to Canada and several European nations in response to the practice of Canadian pharmacies selling to US consumers at a discount.[8] Also, in the EU manufacturers are permitted to limit supply to wholesalers.[9] Finally, the foreign price is negotiated by the foreign government and the patent holder.

In the first stage, the manufacturer *M* and foreign government *G* negotiate the foreign price $\bar{p}$ in a Nash bargaining game. *M*'s objective is to maximize expected profits while *G*'s goal is to maximize foreign consumer surplus. Then *M* chooses the volume Q^S to send to the foreign market by maximizing expected profits. Next, the state of foreign demand (high or low) is revealed, after which, *n* symmetric parallel importing firms will enter the foreign market if there is a surplus volume above foreign consumer demand. Then, each parallel importing firm simultaneously ships a quantity *q* from the foreign market into the home market. In the final stage, the manufacturer sets the home price *p*.

Consider a manufacturer with a pharmaceutical patent that sells the drug in two markets, home and foreign. Demand at home is given by $D_H(p) = a - bp$. Since uncertainty exists with regard to foreign demand, let low demand abroad be $Q^L = h - g\bar{p}$ with

[7] Distortions may be resources wasted due to parallel trade activities, manufacturers no longer supplying to certain markets, inefficient vertical pricing, or free rider problems.

[8] See, among others "AstraZeneca Seeks to Limit Canada Sales" *Associated Press* April 22, 2003, "GSK Acts to Prevent Illegal, Potentially Unsafe Imports of Prescription Drugs" www.gsk.com January 21, 2003, and "Pfizer to Restrict Drug Sales to US from Canada" *Reuters* August 6, 2003.

[9] Such is the 2000 ruling from The European Court of First Instance on *Bayer AG versus Commission of the European Communities* case T-41/96. See also "GSK Given Green Light to Restrict Greek Drug Supply" *Pharmaceutical Business Review* 9/6/06.

probability β and let high demand abroad be $Q^H = h - y\bar{p}$ with probability $(1 - \beta)$ where $0 < \beta < 1$ and $g > y$. The manufacturer incurs marginal cost c in production[10].

Stage 5: Home Price Determination

In this stage, the relationship between home price and volume of parallel trade is determined. In a previous stage, *M* will have chosen the volume to supply to the foreign market and so the volume of parallel imports *Q* will have already been determined. The profit maximizing home price is the solution to

$$Max_p \Pi^M = (a - bp - Q)p \quad (1)$$

when quantity supplied exceeds foreign demand and

$$Max_p \Pi^M = (a - bp)p \quad (2)$$

otherwise.

Stage 4: PI Firms' Quantity Choice

When there is an excess volume in the foreign country, assume the government allows parallel trading firms to buy up the surplus only after foreign consumer demand is met.[11] Each parallel importing firm will simultaneously ship a quantity of the product to the home country. Each of these firms will maximize profits, taking the quantities of all other firms as given. Parallel trader firms face a fixed startup cost of *C*.[12] The marginal cost of transporting the goods between markets is *t*. Each PI firm will ship the quantity which solves

$$Max_q \Pi^{PI} = p(Q)q - (\bar{p} + t)q - C. \quad (3)$$

Stage 3: PI Firms' Entry

In this stage, the number of parallel importing firms is determined. The condition for free entry is

$$[p(n) - (\bar{p} + t)]q(n) - C \geq 0. \quad (4)$$

However, recall that the actual volume of imports is constrained by the quantity that *M* originally sends. Since the government will ensure that foreign consumer demand is met before allowing parallel trade, the maximum volume of imports is the difference between foreign supply and low demand.[13] For small startup costs, the volume available is less than the volume desired by PI firms (from equation 3).[14] Assume that startup costs are

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[10] For simplicity in analysis, *c* is set to zero.

[11] Since the government is interested in foreign consumer surplus, it will allow parallel traders to enter the market only after foreign consumer demand has been met. This assumption can be justified with real world evidence. In 2005, the (then) Canadian Minister of Health, Ujjal Dosanjh, proposed legislation regarding pharmaceutical export restrictions in times of shortage. "Canada to Restrict Exports to US of Prescription Drugs" *The Washington Post* 6/30/2005. If US consumers increasingly turn to other countries (e.g. the UK, New Zealand) as sources for pharmaceuticals, it would seemly likely that pharmaceutical export-limiting legislation in those counties would also be introduced.

[12] This could include costs such as getting licensed by the government or finding suppliers.

[13] The firm would not choose to send a volume greater than Q^H to the foreign market. At its maximum, foreign demand is equal to Q^H so sending a larger amount will always result in PI competition in the home market.

[14] $C < \frac{\left[a - 2b(\bar{p} + t) - Q^S + Q^L\right]^2}{2b}$

small.[15] Parallel trader firms will observe this maximum volume before making their decision to enter the market and thus fewer will enter than if there was no supply restriction.

Stage 2: Choice of Foreign Supply

Now, *M* chooses how much to ship to the foreign market. The firm would not choose to send a volume less than Q^L because parallel trade competition would not occur even if it were permitted. Thus, profits are increasing until low demand is met. Similarly, *M* has no incentive to send more than Q^H because any excess would end up back in the home market as competition. Expected profits will therefore be maximized at some point over the range $Q^L \leq Q^S \leq Q^H$. If *M* sends Q^L when the actual demand is Q^H, then *M* would be forgoing some foreign sales. Assume that *M* can alleviate the foreign shortage by supplying out of its inventories. Assume that it is not costless to supply out of inventories and *M* incurs a cost of $K + \varphi\left(Q^H - Q^S\right)$. Let *K* be some fixed cost of keeping inventories and φ is the cost per unit of shortage.

The relevant profit function is

$$Max_{Q^S} E[\Pi] = \beta\left[\frac{\left(a-\left(Q^S - Q^L\right)\right)^2}{4b} + Q^S \overline{p}\right] + (1-\beta)\left[\frac{a^2}{4b} + Q^S \overline{p} + \left(Q^H - Q^S\right)(\overline{p} - \varphi) - K\right]. \tag{5}$$

The simplified first order condition is

$$\frac{\partial E[\Pi]}{\partial Q^S} = -\beta\left(\frac{a-(Q^S - Q^L)}{2b}\right) + \beta\overline{p} + (1-\beta)\varphi \ . \tag{6}$$

When the size of the home market is less than the volume of parallel imports, the first term becomes positive and entire expression is greater than zero. In such a case, expected profits would rise as more is supplied so it would be optimal for the firm to supply $Q^{S*} = Q^H$. This will happen when the foreign market is very large relative to the home market, and therefore is a larger source of revenue. This is also the case when φ is large. When the size of the home market is larger than the volume of parallel imports the first term is negative, making expression (6) negative as well (as long as the marginal cost of fulfilling a shortage is not too large). Expected profits would be falling as the firm supplies more than Q^L. Thus it would be optimal for the firm to supply $Q^{S*} = Q^L$. Since the firm always limits supply to some degree, the home price is only affect some of the time. With probability (1 – β), the home price is unchanged because there is no excess supply in the foreign market. With probability β, the home price is reduced as the manufacturer faces PI competition.

Stage 1: Foreign Price Negotiation

The government and manufacturer enter in to a Nash bargaining game to negotiate the

[15] According to IMS Health (2004), in March 2003, there were 99 internet pharmacies catering to US patients and by January 2004 there were 214. Since the number doubled in less than a year, it is likely that startup costs for parallel traders of pharmaceuticals would indeed be small.

foreign price. The government's objective is to maximize expected consumer surplus while the firm's goal is to maximize expected profits. If no agreement is reached, the firm does not sell in the foreign market so foreign consumer surplus would be zero and the firm would receive home profits only ($a^2/4b$). The negotiated foreign price is the solution to

$$Max_{\bar{p}}\left[E[CS(\bar{p}^*)]-0\right]^{\lambda}\left[E[\Pi(\bar{p}^*)]-\frac{a^2}{4b}\right]^{1-\lambda} \tag{7}$$

where λ is the foreign government's degree of bargaining power.

In the simplest form, the degree of the government's bargaining power could be based on the uniqueness of the product. Assume that the more unique the product, the weaker the government's bargaining power. Let uniqueness U take values between 0 and 1 and be related to the degree of government bargaining power by $\lambda = 1-U$. If the manufacturer's product is completely unique and has no substitutes in the market (e.g. a blockbuster or breakthrough drug) then $U = 1$ and $\lambda = 0$.

Parallel Imports are Prohibited

As a benchmark, consider the case when parallel imports are not permitted. The firm will fully supply to the foreign market and will not face any competition in the home market. Recalling that $Q^L = h - g\bar{p}$ and $Q^H = h - y\bar{p}$, the firm's objective is to maximize

$$E[\Pi(\bar{p})] = \beta\left(\frac{a^2}{4b}+(h-g\bar{p})\bar{p}\right)+(1-\beta)\left(\frac{a^2}{4b}+(h-y\bar{p})\bar{p}\right) \tag{8}$$

by choice of foreign price and the government will maximize expected consumer surplus,

$$E[CS(\bar{p})] = \left[\beta\frac{(h-g\bar{p})^2}{2g}+(1-\beta)\frac{(h-y\bar{p})^2}{2y}\right]. \tag{9}$$

Consider then the extreme cases when either the firm has all of the bargaining power or the foreign government has all of the leverage. Expression (9) would be maximized when the foreign price is zero. When the foreign government has all of the leverage, it would push the firm into marginal cost pricing. The firm, however, would seek to maximize (8) and would choose a price of

$$\bar{p}^*_{NoPI} = \frac{h}{2[\beta g+(1-\beta)]} \tag{10}$$

if it possessed all of the bargaining power. One would expect that as the firm's leverage decreases, the government is able to force the price lower. Thus, the value of lambda (degree of bargaining power) will be a key determinant in the foreign price.

Parallel Imports are Permitted

Recall that the firm will deter PI competition when the size of the home market is larger than the volume of parallel imports and the marginal cost of fulfilling a shortage is small. When the firm deters, it maximizes

$$E[\Pi(\bar{p})] = \beta\left[\frac{a^2}{4b} + (h - g\bar{p})\bar{p}\right] + (1-\beta)\left[\frac{a^2}{4b} + (h - g\bar{p})\bar{p} + (g-y)(\bar{p}-\varphi) - K\right]. \qquad (11)$$

The firm will accommodate PI competition when the foreign market is large relative to the home market or if the marginal cost of fulfilling a shortage is large. When the firm accommodates, it maximizes

$$E[\Pi(\bar{p})] = \beta\left(\frac{(a - \bar{p}(g-y))^2}{4b} + (h - y\bar{p})\bar{p}\right) + (1-\beta)\left(\frac{a^2}{4b} + (h - y\bar{p})\bar{p}\right). \qquad (12)$$

How does the firm's optimal choice of foreign price change under the different PI regimes? Suppose that the firm has all of the bargaining power. When PIs are permitted and accommodated and the firm has all of the bargaining power, we find that $\bar{p}^*_{NoPI} > \bar{p}^*_{DetPI}$ as long as $h > \beta g + (1-\beta)y$ and also $\bar{p}^*_{NoPI} > \bar{p}^*_{AccPI}$ when the ratio of the foreign market size to home market size is large.[16] So, when the foreign market is large enough, the firm prefers a lower foreign price when PIs are permitted. However, when the foreign market is a large source of revenue for the firm, then it would like the low level of foreign demand to be as large as possible because expected profits are certainly rising until Q^L is supplied. Since $Q^L = h - g\bar{p}$ is increasing as the foreign price is falling, the firm prefers a lower foreign price in that case. Whether the firm deters or accommodates competition, the foreign government's optimal price is zero. The degree of bargaining power will determine if the actual price is closer to the firm's optimal profit maximizing price or if the actual price is closer to marginal cost.

3. Discussion

While a PI-permitting policy may have the desired effect on home price some of the time, it negatively affects the firm's profits all of the time. To verify that expected profits from accommodating PIs are lower than when PIs are not permitted, we can show that expression (8) is larger (12).[17] To verify that expected profits from deterring PIs are lower than when PIs are not permitted, we can show that expression (8) is larger than (11).[18] No matter if the firm chooses to accommodate or deter PIs, moving to a PI-permitting regime results in lower profits.

This model may offer some insight into the consequences of allowing parallel trade in pharmaceuticals between Canada and the United States. Since the US market is so much larger than its Canadian counterpart, the model suggests that the firm would strictly limit supply to Canada in an attempt to deter parallel import competition.[19] Thus the model suggests that the volume of PIs coming into the US would be zero. Therefore a policy meant to lower the US price by integrating the US and Canadian markets would not be effective. The model also suggests that if parallel imports were allowed, the firm's

[16] This is true when $\frac{h}{a} > \frac{2\beta a(g-y)[\beta g + (1-\beta)y]}{\beta(g-y)^2 - 4by + 4b[\beta g + (1-\beta)y]}$.

[17] This is true as long as the home market is of sufficient size. That is, when $a > 2b\bar{p}\left(1 - \frac{(g-y)}{4b}\right)$.

[18] This is true as long as *K* is positive.

[19] Recall that several pharmaceutical firms have already limited supply to Canada.

profits would fall.

It costs roughly $800 million to bring a new prescription drug to market.[20] In the United States, firms are allowed to recoup some of this expense by charging monopoly prices while the drug is under patent. Perhaps as a result, consumers in the United States enjoy more newly-launched drug choices and more drug choices overall than consumers in other markets.[21] If the US permits low-priced imports, the implications may extend beyond current savings on drug spending. A reduction in profits could have a profound impact on the pharmaceutical market. Internal cash flows are an important source of financing for pharmaceutical R&D activities. A reduction in profits reduces cash flows which leads to a reduction in pharmaceutical R&D.[22] Reduced R&D may lead to a reduction in the number of new products developed in the future.

In addition to Canada, US legislators have proposed importing drugs from the European Union, Australia, Israel, Japan, New Zealand, Switzerland, and South Africa.[23] If PIs can originate in all of these markets, the potential volume entering the US market could rise substantially (the EU alone is a larger market than the US). In such a case, the model suggests that the firm would accommodate PI competition but would also prefer a higher foreign price to offset the loss of sales. Again, the firm's profits would be expected to fall. An extension in which the firm must negotiate foreign prices with many governments could speak to the potential additional consequences of a PI-permitting policy in such a context.

4. Conclusion

In this note I developed a model of parallel imports with endogenous price controls. The foreign price depends on the degree of bargaining power that the government has, which in turn is based on the uniqueness of the firm's pharmaceutical product. Moving to a PI-permitting regime from one prohibiting PIs results in a lower foreign price when the firm chooses to deter competition but the firm actually prefers a higher price when accommodating competition. A monopoly manufacturer will choose to limit its foreign supply to reduce the quantity available for parallel trade competition. The volume of (potential) PI competition is constrained by the quantity originally sent to the foreign market. The firm faces a tradeoff between the possibility of parallel import competition and the cost of filling a foreign shortage out of inventories. When the foreign market is a relatively larger market, the firm will supply a high amount and will possibly face PI competition. When the home market is relatively larger (and the cost of filling a foreign shortage is small) the firm will choose to deter parallel imports through a strict supply limit. Thus, home consumers can enjoy lower prices only when the foreign market is large, foreign demand is low, and the manufacturer accommodates parallel trade by sending a high amount to the foreign market. The manufacturer will have lower profits when PIs are permitted.

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[20] See DiMasi et. al. (2003).

[21] HHS Task Force on Drug Importation (2004).

[22] Grabowski and Vernon (2000), Giaccotto, Santerre, and Vernon (2005), and Vernon (2005) all find evidence that cash flows are a significant determinant of pharmaceutical R&D.

[23] See the text of HR-2427 and S-2328. www.congress.org

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