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Patented Drugs, Generic Alternatives and Intellectual Property Regimes in Developing Countries

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Section 1: Introduction

In the past decade, intellectual property rights have been the subject of intense international trade disputes, and the focus of an increasingly rich theoretical and empirical academic literature.³ The theoretical literature depicts a dilemma where stronger intellectual property rights entail a trade off between static monopoly inefficiencies and the dynamic benefits of increased research and innovation.⁴ Although global efficiency may benefit from a harmonized, strong intellectual property regime, the interests of countries diverge.⁵ Industrialized countries have strong intellectual property rights to encourage innovation. Developing countries may be better off--in the short-run--evading monopoly pricing and free-riding on current innovations through weak protection of intellectual property.

Three principal reasons have been offered for why developing countries should want an effective intellectual property regime. First, the monopoly prices paid by developing countries will sponsor more innovations,⁶ possibly for products geared to those countries such as tropical disease therapies.⁷ Second, if the developing countries do some innovation on their own, the rights protect and encourage local inventors.⁸ Third, stronger intellectual property rights might encourage foreign investment and provide opportunities to manufacture products that contain licensed foreign technology.⁹

Empirical studies provide at best weak support for these justifications.¹⁰ Profits from developing countries contribute little to OECD countries' research activities, particularly in pharmaceutical research.¹¹ The current controversy over parallel importation suggests that even profits from sales of patented drugs in Canada contribute little to pharmaceutical research in the United States. Moreover, potential profits from sales of drugs developed for exclusive use in developing countries, even assuming patent protection, are much too small to support their research and development.¹²

Second, very little patent-yielding innovation occurs in these countries. Lall (2001) lists only 23 countries in the world with any significant patenting activity in the United States in 1997. Finally, the empirical evidence suggests that intellectual property rights are uncorrelated to foreign direct investment. Certainly a system to enforce contracts and property rights are

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³ Important early papers include Chin and Grossman (1990); Deardorff (1992); Helpman (1993).

⁴ Gilbert and Shapiro (1990)

⁵ See also McCalman (2002), Scotchmer (forthcoming).

⁶ See, e.g., Deardorff (1992), McCalman (2002).

⁷ Diwan and Rodrik (1991).

⁸ Grossman and Lai (2002).

⁹ Helpman (1993).

¹⁰ See generally Maskus (2000a), Maskus (2000b).

¹¹ Abbott (2002)

¹² Hsu and Schwartz (2003), Lanjouw and Cockburn (2001).

valuable, but intellectual property is neither necessary nor sufficient. Brazil today, and Korea and Taiwan in the past, were notorious for weak enforcement of intellectual property, yet at the same time were the beneficiaries of heavy foreign direct investment. Overall, the empirical literature presents a puzzle as to why developing countries provide as much protection of intellectual property as they do.

In this paper we develop a model that offers a different explanation for why developing countries would want to protect foreign intellectual property. We focus on consumption rather than production, and show how the incentive to acquire a mix of products leads to a patent regime even if no innovative activity takes place in the South, and even if the purchase of patented goods in the South contributes nothing to innovation in the North.

Our model diverges from the literature in two respects. First, the quality of substitutes that are sold within the country measures the strength of the patent regime. In the pharmaceutical context, which for several reasons is most relevant for our analysis, the regime affects the availability of generic substitutes. Strong patent rights translate into availability of only low-quality alternatives. Weak patent rights permit sales of high-quality alternatives that are close substitutes to the patented product. We thus characterize the strength of patents by their scope, or the extent to which substitutes are covered by the patent grant. This characterization also provides a natural way to think about enforcement as a component of patent strength, so that functional intellectual property protection varies across types of products even when the legal structure is uniform.

Second, we model a heterogeneous population in the South, where consumers have identical preferences but different incomes.¹³ Some people prefer a cheap, low-quality generic version, while others prefer higher-quality drugs at higher prices. We assume that only a single generic version of the drug can be sold in the country at any time. Our results generalize to the case where a limited menu is available. The assumption is reasonable if production of the generic involves fixed costs and perhaps participation by the government itself. Finally, we abstract from the general equilibrium considerations and ignore dynamic income effects from trade, foreign direct investment or production. While our motivation for the abstraction is to acquire sufficient analytic simplicity to clarify and analyze the political economy questions posed here, we also note that governments as well as economists can be myopic. The simplifications do not necessarily detract from the applicability of our results.

Analytically our model draws from the quality ladder literature although we have rearranged some of the rungs.¹⁴ The patent-holder—a multinational company—can sell a drug of exogenously-determined quality. The developing country then establishes an intellectual property regime, which dictates the quality of the generic alternative that will be sold at cost. After the regime is established, the multinational company sets the quantity and price of the patented drug so as to maximize profits. Exiting the market is an option. Both of the drugs, one, or neither will be for sale. We assume initially that the government acts to maximize domestic welfare. Section 2 lays out our basic model.

In section 3 we show that the actions of the foreign company depend on three factors: the cost of the drug, the wealth of the developing country, and the level of intellectual property protection. There is a minimum intellectual property standard at which the patented good is made available. The minimum standard depends on the cost of the drug (more costly drugs require

¹³ By contrast, Diwan and Rodrik (1993) consider heterogeneous preferences for different products. Their conclusions depend only the mean of each country's distribution.

¹⁴ Ronnen (1991), Shepard (1991), Deneckere and McAfee (1996).

more stringent regimes) and the wealth in the country. As wealthier people will pay more for the high-quality patent drug, less patent protection is needed in order to support its market. In yet another injustice, poor countries need strong patent rights to insure the availability of patented goods, while rich countries get by with weaker intellectual property regimes.

In section 4 we consider how a welfare-maximizing country sets its intellectual property regime. Within certain income ranges and technology constraints, the intellectual property regime weakens as per-capita income increases. This prediction is consistent with the strong empirical regulatory that intellectual property rights tend to decrease with increases in national income in developing countries, rendering those with the middle income, rather than the poorest, with the weakest intellectual property protection. The relationship switches as countries become yet wealthier, and accelerates as they become fully developed. Maskus (2000) estimates that "the income at which patent protection becomes weakest is approximately \$2000 per capita in 1985 international dollars. Moreover, the expected patent index is the same for economies with per-capita GNP of \$500 and \$7750, indicating that there is a large range of income variation before protection becomes stronger than at its low-income levels." (2227)

The U-shape relationship between patent protection and national income is due in part to the large benefits from infringement in industrializing countries.¹⁵ Patents raise the cost of second-generation inventions.¹⁶ Industrializing countries infringe on patents to further innovate, rather than solely to avoid paying monopoly prices for existing goods. But while industrialization is important in explaining the left-hand side of the U-shaped relationship between national income and patent rights, it does not tell the whole story. Maskus (2000) and Maskus and Penubarti (1995) show that the U-shape relationship holds after controlling for industrializing and research activities.

In addition to the overall weakening of intellectual property rights with increases in per capita income, we show that there is an inverted U pattern for prices, the quantity of trade and the profits of the multinational company. With higher per-capita income, a country demands more of the patented product (leading to an increase in its price) and at the same time improves the quality of the generic alternative (leading to increased competition and a decrease in the price of the patented drug). Eventually the second effect dominates. The wealthier among the developing countries thus pose a frustrating problem to multinational companies in foregone monopoly profits. The possibility of parallel importation creates yet another headache, as it is in these countries that patented goods are both available and cheap.

Section 2: Modeling Basics

A multinational drug company has a patent on drug R , with a per-unit cost of C_R . We do not model fixed costs here, but implicitly assume that some exist, as the drug will not be sold unless its price, P_R , is strictly greater than its cost. In addition to the patented drug, a generic good, G , may be offered for sale.

The quality of the drugs is given by $V(\cdot)$, where:

$$\begin{aligned} V(I) &= V_R = \text{the quality of the patented good } R \\ V(g) &= \text{the quality of good } G, \text{ where } 0 \leq g \leq I \\ V(0) &= V_O = \text{the quality of a free alternative remedy} \end{aligned}$$

¹⁵ Khan (2002).

¹⁶ See e.g., Heller and Eisenberg (1998).

We also index the strength of the country's intellectual property regime by g . If $g = 0$, the country fully protects intellectual property (no generic drug is available). When $g = 1$, the country does not protect intellectual property, moreover, the technology is not inherently protected, so that a perfect generic alternative is available to good R .

The cost of the generic good rises linearly in the index g , so that $C_G = gC_R$. The quality of the generic rises with g , but is subject to decreasing returns:

$$V'(g) > 0; V''(g) < 0$$

We assume that the generic good is sold at a price equal to its marginal cost, C_G .

Consumers have income t , which is uniformly distributed over the interval $[0, L]$. We will also characterize the income distribution or level of wealth in the country by L , although it technically refers only to the maximum income in the country. Following Shepard (1991), we assume that consumer t consumes at most 1 unit of drug, and her utility is defined by:

$$U(t) = \begin{cases} V_O t & \text{if she consumes the free alternative} \\ V(g)(t - gC_R) & \text{if she consumes } G \\ V_R(t - P_R) & \text{if she consumes good } R \end{cases}$$

Consumers choose which (if either) good to consume so as to maximize utility.

The definition of utility implies that there exist "tipping points" t_1 and t_2 such that consumer t consumes good O if $0 \leq t \leq t_1$; consumer t consumes good G if $t_1 < t \leq t_2$ and consumer t consumes good R if $t_2 < t \leq L$. These tipping points are given by:

$$E1 \quad t_1 = \frac{V(g)gC_R}{V(g) - V_O}$$

$$t_2 = \frac{V_R P_R - V(g)gC_R}{V_R - V(g)}$$

The marginal cost of production for the patent drug is an important feature of the analysis, and is assumed to be substantial. Some areas of intellectual property, notably copyright, seek to protect property with extremely low marginal costs. Our model yields few insights in these cases. However, the analysis is relevant to important categories of modern pharmaceuticals, where even countries that have established mandatory licensing for foreign technology and produce patented drugs themselves sometimes find the cost of treatment to be in excess of per-capita income.

Section 3: What the Drug Company Does

The drug company has a product of fixed quality V_R , and decides whether to sell the drug in the country and if so, at what price. We first characterize the monopoly solution, and then investigate how it varies with country conditions.

Lemma 1: The profit-maximizing price for good R , P_R , is given by:

$$\text{E2} \quad P_R = \max \begin{cases} \frac{1}{2V_R} \{L(V_R - V(g)) + C_R(V_R + gV(g))\} \\ C_R \end{cases}$$

All proofs are contained in the appendix.

When the intellectual property regime is weakened, a better generic comes on the market to compete with the patented good. The price of the generic drug increases along with its quality. Some consumers switch to the free alternative. That brings no relief, however, to the monopolist. The better generic, notwithstanding its higher price, takes away customers from the patented good. The multinational finds that its profit-maximizing strategy is to recoup some of the lost demand by lowering the price of the patented good, as is established in Lemma 2.

Lemma 2: Suppose that for some range of prices $P \geq C_R$ the multinational company can sell its drug R at a profit. Then the profit maximizing price, P_R , declines when the intellectual property regime is weakened.

Sales of patented drugs depend on the relative values of production cost, maximum income and the extent of patent protection. The patented good will not be sold if its price exceeds its cost, or, rearranging E2, if:

$$\text{E3} \quad C_R \geq C_1(g, L) = L \frac{V_R - V(g)}{V_R - gV(g)}$$

The relationship among the different parameters is established in the following theorem and corollary.

Theorem 1: There exists a cost of production $C_1(g, L)$ such that the multinational will not provide good R when its cost is greater than $C_1(g, L)$. For $0 < g < 1$, $C_1(g, L)$ is such that:

$$\text{E4} \quad \frac{\partial C_1(g, L)}{\partial L} > 0 \quad \frac{\partial C_1(g, L)}{\partial g} < 0$$

Not surprisingly, for a given intellectual property regime g , as the country's income increases, the multinational will offer for sale more costly drugs. The increasing income means a larger demand for the patent good. The multinational can charge more for the drug, and the mark-up will be sufficient to cover costs (and then some) for more expensive drugs. The second part of the theorem is more subtle. Note that we hold the quality of the patented drug constant. As a result, the mark-up on less-expensive patented drugs is higher than the mark-up on more

expensive versions. When an increase in the generic quality causes price to decline, as is established in Lemma 2, the reduction squeezes out expensive drugs first.

The monotonic partial derivatives in E4 mean that inverse functions exist to $C_I(g, L)$. We can characterize the minimum income $L_I(g, C)$ necessary for sale of a drug of cost C given an intellectual property regime g ; and we can characterize the minimum intellectual property regime $g_I(C, L)$ necessary to insure the sale of a drug of cost C given maximum income L . The existence of the second inverse function has two substantive implications. First, the less wealthy a country is, the more stringent its intellectual property regime needs to be in order for sales of patented drugs of a given cost C . Second, for a given income distribution L , availability of more expensive drugs requires better intellectual property protection. Corollary 1 summarizes the conditions.

Corollary 1: There exists a function $g_I(C, L)$ defined over $[C_I(0, L), C_I(L, L)]$ such that g_I is the weakest intellectual property rights regime that a country with income L can sustain in order for a patented drug with cost C to be offered for sale, and such that:

$$\frac{\partial g_I}{\partial C} < 0 \quad \text{and} \quad \frac{\partial g_I}{\partial L} > 0$$

Corollary 1 shows that wealthier countries can "afford" weaker intellectual property regimes. The weak regime provides two benefits to the wealthier parts of the country: a high-quality generic is sold at cost, and the price of the patented drug is lower than it would be in a more stringent regime. Poor countries, alternatively, will have none of the patented drug unless they protect patent rights to the extent that only low-quality generic drugs are available.

Section 4: What the State Does

The country socially optimizes the intellectual property regime at g , generating a single generic drug of quality $V(g)$. If both G and R are available, welfare in the country is given by the integral:

$$W(g) = \frac{1}{L} \left[\int_0^{t_1} V_0 t dt + \int_{t_1}^{t_2} V(g)(t - gC_R) dt + \int_{t_2}^L V_R(t - P_R) dt \right]$$

If $g \geq g_I(C, L)$, then $t_2 = L$, and the third term above is missing.

To optimize welfare¹⁷, the country sets:

$$\begin{aligned} \frac{\partial W}{\partial g} = & V_0 t \frac{\partial t_1}{\partial g} - V(g)(t_1 - gC_R) \frac{\partial t_1}{\partial g} + V(g)(t_2 - gC_R) \frac{\partial t_2}{\partial g} - V_R(t_2 - P_R) \frac{\partial t_2}{\partial g} \\ & + \int_{t_1}^{t_2} (V'(g)(t - gC_R) - V(g)C_R) dt + \int_{t_2}^L -V_R \frac{\partial P_R}{\partial g} dt = 0 \end{aligned}$$

Substituting from the definitions of t_1 and t_2 :

$$\text{E5} \quad \frac{\partial W}{\partial g} = \int_{t_1}^{t_2} (V'(g)(t - gC_R) - V(g)C_R) dt + \int_{t_2}^L -V_R \frac{\partial P_R}{\partial g} dt = 0$$

Define g_{max} to be the value of g that satisfies equation E5.

The following restriction on the production function V is sufficient to establish existence of a unique maximum.

Condition A. Let g_0 be a solution to equation E5, i.e., a point where the first order conditions for a welfare maximum are satisfied, and $0 \leq g_0 \leq 1$. Condition A is satisfied when either:

$$\left| \frac{xV'''(x)}{6} \left(\frac{x^2}{g^2} \right) \right| \leq |V'''(g)|$$

for all x such that $0 \leq x \leq g \leq 1$, or $V'''(g_0) \geq 0$.

This condition is satisfied for any concave quadratic or cubic function, and also for any logarithmic function defined on the interval $[0,1]$.

Theorem 2: (existence) Suppose the production function $V(g)$ satisfies Condition A. Then there exists a level of g that maximizes welfare in the LDC over the interval $(0,1)$ in the presence of imports of the patented good and in its absence.

Our analysis so far contemplates two regimes: one where the country maximizes welfare conditional on sales of the patented good, and the other where the country maximizes welfare assuming that the patented good is not for sale. We first consider comparative static results for the optimal patent strength in each of the two regimes. In both cases, an increase in L causes the optimal patent strength to weaken, and a more expensive patent drug is dealt with by strengthening patent rights.

Consider first the case where $g_{max} < g_I(C, L)$, so the expression in E5 has two terms. Increasing L involves two reinforcing effects: the price charged by the monopolist increases when the country becomes wealthier. As a result, t_2 will increase, as people at the former tipping point will no longer purchase the patented drug. These people now purchase the generic drug G . G now caters to a (slightly) wealthier clientele on average who prefer a (slightly) higher quality generic drug. In addition, notwithstanding the increase in t_2 , a greater share of the population is in the high-income category, and benefits from the reduction in P_R that follows an increase in g . It follows that as long as $g_{max} < g_I(C, L)$, the optimal IP regime is weaker, *ceteris paribus*, in wealthy countries.

For the case where no patented good is sold in the country (whatever the level of g) the analysis is straightforward. An increase in L means that more people want a better quality generic, and hence the optimal patent regime becomes weaker.

¹⁷ A natural extension of this model is to consider other government objective functions, e.g., a median-voter model or different welfare weights.

Reducing the cost of the drug -- in effect, improving the technology, as we leave its value $V(g)$ untouched -- has the identical effect to increasing the wealth of a country. The population shifts toward consumers who prefer either a higher quality generic or the patented drug itself. Both groups are advantaged by a weaker intellectual property regime. These results are summarized in Theorem 3.

Theorem 3: Let g_{max} be an interior welfare-maximizing intellectual property regime. Then the optimal intellectual property regime weakens as income increases, and strengthens for more expensive drugs:

$$\frac{\partial g_{max}}{\partial L} > 0 \quad \frac{\partial g_{max}}{\partial C} < 0$$

Let $g_1(C_R, L)$ be the maximum value of g at which R is available in the country, $g_2(C_R, L)$ be the level of g that maximizes welfare in the absence of the patented good and $g_3(C_R, L)$ be the level of g that maximizes welfare conditional on the availability of R . We allow g_2 to be defined even where $g_2 < g_1$ -- that is, where the defined intellectual property rights are strong enough to support the importation of the patented drug. In this case, g_2 is optimal only if some other condition has restricted the importation of the patented drug. We can then compare g_2 and g_3 : how does the optimal patent regime change when trade expands and drug R is introduced in the country? The availability of good R creates an incentive to improve the quality of the generic, in order to lower the price of R . However, the introduction of the patent drug also means that two drugs are now available, and a lower quality of generic will create greater quality dispersion. As the following theorem proves, the second effect dominates. Thus, we expect the expansion of trade or the licensing of intellectual property for local manufacture to be accompanied by strengthening of intellectual property rules in developing countries.

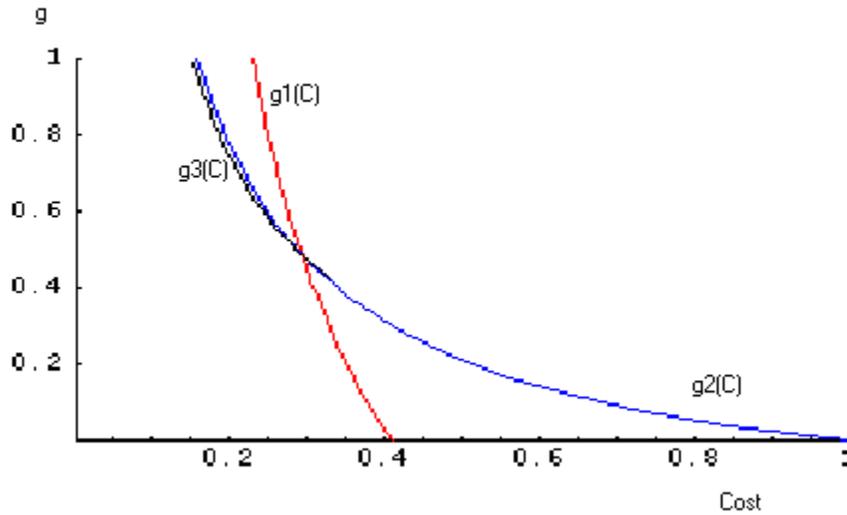
Theorem 4: For all values of C_R and L such that good G is sold, $g_3(C_R, L) \leq g_2(C_R, L)$. Whenever both G and R are sold, $g_3(C_R, L) < g_2(C_R, L)$.

We now turn to choosing conditions for g_2 or g_3 to optimize welfare. We first establish two technical lemmas.

Lemma 3: There exist inverse functions $C_1(g, L)$, $C_2(g, L)$, $C_3(g, L)$ dual to g_1 , g_2 , g_3 defined over $(0, 1)$ such that $C_1(g, L)$ is the maximum cost at which R is sold given patent regime g , $C_2(g, L)$ is the cost at which patent regime g maximizes welfare for the country in the absence of patented good R , and $C_3(g, L)$ is the cost at which patent regime g maximizes welfare for the country conditional on availability of patented good R . The derivatives of all three functions with respect to g are negative over the range $(0, 1)$.

Lemma 4: g_1 , g_2 , and g_3 intersect at a single point $(g^*, C^*/L)$ where $0 < g^* < 1$. Lemma 4 is illustrated in Figure 1. The figure depicts the curves where $L = 1$, and $V(g) = 1 + \log(1+g)$.

Figure 1



Theorem 5: There exists a regime-switching cost C^* such that $0 < C^* < L$ and:

- (i) if $C_R > C^*$ then the country maximizes welfare by choosing a level of intellectual property protection g_2^* such that R is not offered for sale in the country and $g_2^* < 1$.
- (ii) if $C_R < C^*$ then the country maximizes welfare by choosing an level of intellectual property protection g_3^* such that both R and G are offered for sale and $0 < g_3^* \leq 1$.

The theorem follows immediately from Lemma 4. When $C > C^*$, R is not available in any of the three cases. By definition, g_2 maximizes welfare in this event, and thus a weaker IP regime is preferred to that which is just weak enough to marginalize the patented drug. When $C < C^*$, even if R were not available, the optimal intellectual property level g_2 would be set at a sufficiently strict level to allow its sale at a profit. g_2 with R is pareto preferred to g_2 without R : consumers retain the option to purchase G_2 at the same price as before, but some defect to purchase R instead. But by construction and Theorem 4, g_3 with R is strictly preferred to g_2 with R , so g_3 is the optimal regime when $C < C^*$.

The relationship between the cost of the patent drug, the country's maximum income level and the choice of regime also follows directly from Lemma 4:

Corollary 2: The regime-switching cost C^* is higher in wealthy countries; alternatively, given a drug of cost C , there exists a regime-switching level of wealth, L^* , such that a country will set intellectual property levels stringent enough to attract entry of the patent drug if and only if $L > L^*$.

The weaker intellectual property regimes in wealthier countries mean that better generic drugs are available. They do not necessarily imply that the price of the patented drug is lower. Suppose the country has chosen g_3 to maximize welfare. Increasing L holding g constant would cause the company to raise the profit-maximizing monopoly price of the patented good. However, the increase in L also causes an increase in the welfare-maximizing level of g , which increases competition for the patented drug and induces a decrease in its price:

$$E6 \quad \frac{dP}{dL} = \frac{\partial P}{\partial L} + \frac{\partial P}{\partial g} \frac{dg}{dL}$$

The effect of an increase in wealth on the price of the drug reflects these countervailing influences. Close to L^* , an increase in wealth causes the price of the drug on net to rise. Eventually the second component dominates, and heightened competition from G overwhelms the income effect. As we show in Corollary 3, a similar inverted-U pattern holds for the drug company's profits and sales volume.

Corollary 3 Let $L \geq L^*$. For L close to L^* , the price of the patented drug, the profits to the drug company, and sales volume increase as L grows. For a sufficiently high level of L , further increases in wealth result in reductions in three variables.

Corollary 3 is illustrated in figures 2 and 3, where C is set constant at .35, $V(g) = 1 + \log(1 + g)$, and L varies along the x-axis from 1.2 (where $L = L^*$, equivalent to the intercept point in figure 1) to $L = 2.3$, where the optimal intellectual property regime, g^3 , goes to 1. In between these two limits, the intellectual property regime is given by $g^3(C, L)$. Figure 2 shows that up to about $L = 1.7$ the wealth effect dominates, and the price of the patent rises with increasing demand.

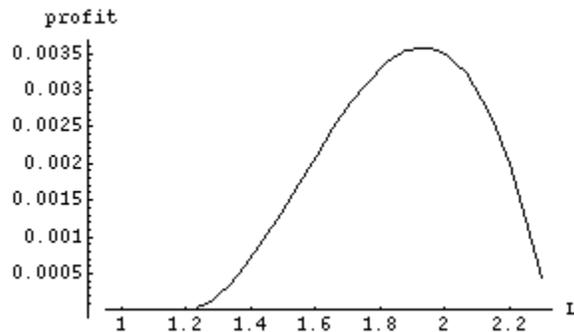
Figure 2



Above $L = 1.7$, the weakening of the intellectual property regime (that is, the increase in g) and increased competition from a generic of increasingly higher quality causes the price of the patent good to fall, notwithstanding continued increases in L . At $L = 2.3$, the IP regime limits to $g = 1$, so that generic quality approaches the quality of the patented good, the price of the patented good approaches its cost of 0.35.

Figure 3 gives the results for profits. As wealth increases, demand for the patented good grows. Eventually competition from the generic drug causes the price of the patented drug to decline. Notwithstanding the price reduction for the patented drug, further generic competition reduces demand for the patented good so that profits fall, approaching zero as g goes to one and imitation is complete.

Figure 3



Section 5. Conclusions

Pharmaceutical patents are among the most valuable of patent classes, in part because it is difficult to protect the property using other means--reverse engineering is possible--and in part because it is easy to establish infringement in court. Companies have been eager to obtain patent protection for pharmaceutical products in developing countries, but to date their success has been tempered by financial and humanitarian concerns.

We consider when, and how much, a country will unilaterally protect intellectual property when it does no patentable innovation of its own. We frame the patent strength problem as one of patent scope, which translates functionally into the extent to which substitute treatments resemble in quality the patented drug. We analyze the impact of varying production costs of the drug and the wealth of the country on its incentives to strengthen or weaken patent rights. We find that developing countries do have an incentive to limit the quality of generic substitutes when the cost of the patent drug is high. By establishing a bound on imitation, the country can obtain both the patented drug and lower cost alternative drugs; in a poor country, this may be an optimal solution.

The model yields a number of predictions. We predict that formal patent rights will be stronger in the poorest developing countries, and weaken with increased wealth. The patent drug will not be for sale in the poorest countries, but among those where it is for sale, its price initially increases, then decreases, with further increases in wealth. The reason for the decrease is that the country develops an aggressively high-quality alternative drug. In the event of parallel importation, these relatively wealthy countries constitute a major problem for multinational companies, as the developing country can provide not only a high-quality generic drug but also an inexpensively-priced patented version.

The model also provides an argument for licensing patented drugs. If a multinational enters the developing country market, the availability of the patent drug will, in some cases, discourage development of a high-quality generic. Specifically, it will cause the country to degrade its own drug program, so that lower-cost generics are available as well as the high-quality patented drug. With increasing international trade in pharmaceuticals, discouraging the production of higher-quality generic versions is valuable to multinational companies.

We abstracted from any impact the developing country might have on a multinational's research program, claiming the small profits in developing countries as authority. However, parallel importation renders the activities in developing countries less benign. Our model suggests that the multinational company should react differently in the case of drugs with

different costs. Expensive drugs, according to our model, obtain protection in the developing world irrespective of international treaties. Inexpensive drugs, on the other hand, spell trouble. Relative to the cost of inexpensive treatments, more countries are wealthy enough to want to develop close imitations of the drug. Here the coordinating benefits of a treaty may be important. While an individual country may lack incentives to strengthen its intellectual property regime, the combined efforts of many nations might provide a pareto efficient move with stronger intellectual property rights for the developing countries.¹⁸ Our analysis suggests that while including developing countries in multilateral intellectual property treaties may be of only marginal use in encouraging research on expensive drugs, their inclusion may be critical for the development of inexpensive therapies.

¹⁸ The case is analogous to that analyzed by Romero (1991).

References

- Abbott, Frederick, "WTO TRIPS Agreement and its Implication for Access to Medicines in Developing Countries," Study Paper 2a (2002)
- Chin, Judith and Gene Grossman, "Intellectual Property Rights and North-South Trade," in R.W. Jones and A.O. Krueger, eds, *The Political Economy of International Trade*, Cambridge MA: Basil Blackwell Publishers, 1990.
- Deardorff, Alan V., "Welfare Effects of Global Patent Protection," *Economica*, 59: 35-51 (1992)
- Deneckere, R. and R. McAfee, "Damaged Goods," *Journal of Economics and Management Strategy*, 5 (2): 149-174 (Summer 1996).
- Diwan, Ishac and Dani Rodrik, "Patents, Appropriate Technology, and North-South Trade," *Journal of International Economics*, 30: 27-47 (1991).
- Gilbert, Richard and Carl Shapiro, "Optimal Patent Length and Breadth," *RAND Journal of Economics*, 21 (1) : 106-112 (Spring 1990)
- Grossman, Gene M. and Edwin L.-C. Lai, "International Protection of Intellectual Property," *manuscript*, September 2002.
- Heller, Michael A. and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science*, 280: 698-701 (1998)
- Helpman, Elhanan, "Innovation, Imitation, and Intellectual Property Rights," *Econometrica* 61 (6): 1247-1280 (Nov. 1993).
- Hsu, Jason C. and Eduardo S. Schwartz, "A Model of R&D Valuation and the Design of Research Incentives," *National Bureau of Economic Research Working Paper 10041*, (October, 2003).
- Khan, Z., "Intellectual Property and Economic Development: Lessons from American and European History," Study prepared for *Integrating Intellectual Property Rights and Development Policy*, CIPR, London. <http://www.iprcommission.org/>
- Lai, Edwin L.-C. and Larry D. Qiu, "The North's intellectual property rights standard for the South?" *Journal of International Economics* 59:183-209 (2003).
- Lall, Sanjaya, "Indicators of the relative importance of IPRs in developing countries," *draft*, UNCTAD/ICTSD, November 2001.
- Lanjouw, Jean O. and Iain M. Cockburn, "New Pills for Poor People? Evidence after GATT," 29 *World Development* 265-89 (2001)
- Maskus, Keith E. and Mohan Penubarti, "How trade related are intellectual property rights?" 39 *J. Int'l Econ.* 227, (1995).
- Maskus, Keith E., "Lessons from studying the international economics of intellectual property rights," 53 *Vand L. Rev.* 2219, November 2000.
- Maskus, Keith E., *Intellectual Property Rights in the Global Economy*, Washington D.C.: Institute for International Economics, (2000).
- McCalman, Phillip, "The Doha Agenda and Intellectual Property Rights," *manuscript*, Department of Economics, UCSC, October 2002.
- McCalman, Phillip, "National patents, innovation and international agreements," *J. Int. Trade and Economic Development* 11 (1): 1-14 (2002).
- Nogues, J. J., "Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries," *Developing Economies* 31: 24-53(1993)
- Romero, Richard, "When excessive consumption is rational," *American Economic Review* 81 (3): 553-564, 1991.
- Ronnen, Uri, "Minimum Quality Standards, Fixed Costs and Competition," *RAND Journal of Economics*, 22 (4), Winter 1991.
- Scotchmer, Suzanne, "The Political Economy of Intellectual Property Treaties," *forthcoming*, *Journal of Law Economics and Organization*.
- Shepard, Andrea, "Price Discrimination and Retail Configuration," *Journal of Political Economy*, 99(1): 30-53, (February, 1991).

Appendix

Lemma 1

The price of the patented drug, P_R maximizes $(P - C_R)(L - t_2)$ subject to the constraint that price exceeds cost. Substituting from E1 and solving the first order condition yields the identity in E2.

Lemma 2

By assumption,

$$\text{A1} \quad C_R < L \frac{V_R - V(g)}{V_R - gV(g)}$$

From Lemma 1:

$$\frac{\partial P_R}{\partial g} = \frac{1}{2V_R} \left\{ -LV'(g) + C_R V(g) + C_R gV'(g) \right\}$$

substituting from E3 and using the convexity condition:

$$\begin{aligned} \frac{\partial P_R}{\partial g} &< \frac{1}{2V_R} \left\{ -LV'(g) + L \frac{V_R - V(g)}{V_R - gV(g)} (V(g) + gV'(g)) \right\} \\ &= \frac{L}{2V_R} (V_R - gV(g)) \left\{ V'(g)(-V_R)(1-g) + V(g)(V_R - V(g)) \right\} \\ &< \frac{L}{2V_R} (V_R - gV(g)) \left\{ \frac{V_R - V(g)}{1-g} (-V_R)(1-g) + V(g)(V_R - V(g)) \right\} \\ &= \frac{L}{2V_R} (V_R - gV(g)) \left\{ (V_R - V(g))(-V_R + V(g)) \right\} < 0 \\ &\quad \text{q.e.d.} \end{aligned}$$

Theorem 1

The drug company makes positive profits only when demand for R is positive for some price $P_R \geq C_R$. Rearranging from Lemma 2, the drug company will not provide drug R when:

$$\text{A2} \quad C_R \geq C_1(g, L) = L \frac{V_R - V(g)}{V_R - gV(g)}$$

It is clear from Equation A2 that C_R^* must be increasing in L .

$$\begin{aligned}
\frac{\partial C_R^*(g, L)}{\partial g} &= \frac{L}{D^2} \left\{ [V_R - gV(g)]V'(g)(-1) + [V_R - V(g)][gV'(g) + V(g)] \right\} \\
&= \frac{L}{D^2} \left\{ -V'(g)V_R(1-g) + V(g)(V_R - V(g)) \right\} \\
&< \frac{L}{D^2} \left\{ -\frac{V_R - V(g)}{1-g}V_R(1-g) + V(g)(V_R - V(g)) \right\} \quad (\text{by the convexity of } V(g)) \\
&= \frac{L}{D^2} \left\{ (V_R - V(g))(V(g) - V_R) \right\} < 0
\end{aligned}$$

where $D^2 > 0$.

q.e.d.

Corollary 1

Theorem 2

By assumption, $t_2 = L$, and equation E5 has only one term. Without loss of generality we let $C_R = L$, and denote $t_1(g)$ by $t(g)$, so that g becomes the cost of the generic good. Note that this places a restriction on L for existence of an interior maximum, but the two parameters L and C_R are redundant parameters. Solving the integral in E5. yields the following first order condition:

$$A3 \quad \frac{\partial W}{\partial g} = (L - t(g))[V'(g)\left(\frac{1}{2}(L + t(g)) - g\right) - V(g)] = 0$$

Let g_o be a solution to A3. To establish a unique interior maximum it is sufficient to show that

$$\frac{\partial^2 W}{\partial g^2} < 0 \quad \text{at } g = g_o.$$

Differentiating A3 and substituting from the condition that $g = g_o$:

$$\frac{\partial^2 W}{\partial g^2} \Big|_{g = g_o} = V''(g) \frac{V(g)}{V'(g)} - V'(g) \left(2 - \frac{1}{2} t'(g) \right)$$

As $V'(g) > 0$ it is sufficient to show that:

$$A4 \quad V''(g)V(g) - [V'(g)]^2 \left(2 - \frac{1}{2} t'(g) \right) < 0 \quad \text{at } g = g_o.$$

Differentiating $t(g)$:

$$\text{A5} \quad t'(g) = \frac{V(g)}{V(g)-V_0} - \frac{V_0}{V(g)-V_0} \frac{gV'(g)}{V(g)-V_0}$$

Take the Taylor expansion of $V(g)$:

$$\begin{aligned} V_0 &= V(g) + V'(g)(0-g) + \frac{1}{2}V''(g)(0-g)^2 + \frac{1}{6}V'''(g)(0-g)^3 + \dots \\ \text{A6} \quad &= V(g) - gV'(g) + \frac{1}{2}g^2V''(g) + g^2\varepsilon \end{aligned}$$

$$\text{where } \varepsilon = \sum_{n=3}^{\infty} \frac{(-1)^n}{n!} g^{n-2} V^n(g)$$

and $V^n(g)$ denotes the n -th order derivative of $V(g)$

rearranging:

$$\text{A7} \quad \frac{gV'(g)}{V(g)-V_0} = 1 + \frac{1}{2} \frac{g^2V''(g)}{V(g)-V_0} + \frac{\varepsilon}{V(g)-V_0}$$

Substitute A7 into A4 and rearrange:

$$\text{A8} \quad V''(g) \left[V(g) - V_0 \left(\frac{gV'(g)}{V(g)-V_0} \right)^2 \left(\frac{1}{4} + \frac{1}{2} \frac{\varepsilon}{V''(g)} \right) \right] - (V'(g))^2 \left(\frac{3}{2} \right)$$

The second term in A8 is always negative, as $V'(g) > 0$. Turning to the first term, $V''(g) < 0$, $V(g) > V_0$, and $0 < \left(\frac{gV'(g)}{V(g)-V_0} \right) < 1$. Using the Lagrange Remainder to the Taylor Expansion,

$$\varepsilon = \left(\frac{xV'''(x)}{6} \right) \left(\frac{x^2}{g^2} \right)$$

for some x such that $0 < x < g$, hence a sufficient condition for the first term to be negative is that Condition A holds.

q.e.d.

Theorem 3

Let $0 < g_{max} < g_1$

By assumption g_{max} is an interior maximum, so $\frac{\partial^2 W}{\partial g^2} < 0$ at $g = g_{max}$. Totally differentiating and rearranging E5 yields:

$$\frac{dg}{dL} = -\frac{\partial^2 W / \partial g \partial L}{\partial^2 W / \partial g^2} \text{ at } g = g_{max}$$

Thus it is sufficient to show that $\partial^2 W / \partial g \partial L > 0$ at $g = g_{max} < g_1$.

We use the following substitutions:

$$\text{from E2: } \quad \frac{\partial P_R}{\partial L} = \frac{V_R - V(g)}{2V_R} \quad \frac{\partial^2 P_R}{\partial L \partial g} = \frac{-V'(g)}{2V_R}$$

$$\text{from E1 and E2: } \quad t_2 = \frac{1}{2}L + \frac{1}{2} \frac{C_R(V_R - gV(g))}{V_R - V(g)} \quad \frac{\partial t_2}{\partial L} = \frac{1}{2}$$

$$\frac{\partial^2 W}{\partial g \partial L} = [V'(g)(t_2 - gC_R) - V(g)C_R] \frac{\partial t_2}{\partial L} + V_R \frac{\partial P_R}{\partial g} \frac{\partial t_2}{\partial L} - V_R \frac{\partial P_R}{\partial g} + \int_{t_2}^L -V_R \frac{\partial^2 P_R}{\partial g \partial L}$$

substituting and simplifying:

$$\text{A9} \quad \frac{\partial^2 W}{\partial g \partial L} = \frac{3}{4} \{V'(g)L - C_R(gV'(g) + V(g))\}$$

If $g_{max} < g^*$, by E4.:

$$\text{A10} \quad C_R < L \frac{V_R - V(g)}{V_R - gV(g)}$$

substituting A10 into A9:

$$\frac{\partial^2 W}{\partial g \partial L} = \frac{3}{4} \frac{L}{(V_R - gV(g))} \{2gV'(g)(V_R - V(g) + V(g)(V(g) - V_R) + (1-g)V_R V'(g)\}$$

by convexity, $V'(g)(1-g) > V_R - V(g)$, hence:

$$\begin{aligned} \frac{\partial^2 W}{\partial g \partial L} &> \frac{3}{4} \frac{L}{(V_R - gV(g))} \{2gV'(g)(V_R - V(g)) + V(g)(V(g) - V_R) + V_R(V_R - V(g))\} \\ &= \frac{3}{4} \frac{L}{(V_R - gV(g))} \{2gV'(g)(V_R - V(g)) + (V_R - V(g))(V_R - V(g))\} > 0 \end{aligned}$$

q.e.d.

Theorem 4

If the optimal IP regime g_2 is weaker (i.e. larger) than the level at which R is sold by the MNC, then the lemma holds trivially, as by construction $g_3 < g_1 < g_2$. Suppose g_2 is sufficiently small that the MNC would be willing to sell R , so that $t_2(g_2, C_R) < L$, and suppose that $g_3 = g_2$. Then from E5:

$$\frac{\partial W}{\partial g} = 0 = \int_{t_1}^{t_2} (V'(g)(t - gC_R) - V(g)C_R)dt + \int_{t_2}^L -V_R \frac{\partial P_R}{\partial g} dt = \int_{t_1}^L (V'(g)(t - gC_R) - V(g)C_R)dt$$

substituting from Theorem 2:

$$\Rightarrow \int_{t_2}^L (V'(g)(t - gC_R) - V(g)C_R)dt = \int_{t_2}^L (V'(g)(L - C_R) - V(g)C_R)dt$$

As $t_2 < L$, the condition cannot hold, that is, at g_2 , the benefits to the average consumer of G from reducing g outweigh the disutility to average consumers of R from the increase in the price of R that results from a decrease in g . Thus g_2 is too high (the patent regime is too weak) to be optimal in the presence of sales of R , and $g_2 > g_3$.

q.e.d.

Lemma 3

The existence of $C_1(g)$ comes by definition from Corollary 1. The derivative of C_1 with respect to g is shown there to be negative everywhere on the interval $(0,1)$, which establishes the existence of its inverse $g_1(C)$ over the range $(C_1(0), C_1(1)^*)$.

By Theorem 3, both g_2 and g_3 have negative derivatives with respect to C over the ranges where g is feasible $((0,1))$ and where they solve for an interior maximum. For g_2 solutions exist for $g \in (0,1)$. For g_3 the relevant range is $(0, C^*)$ for some $C^* < L$ (see Theorem 5, below). At C^* , $g_3 = g_1$; for larger values of C , g_3 by definition equals g_1 , hence g_3 has a negative derivative with respect to C over the relevant range. Thus C_2 and C_3 are defined over $(0,1)$, and all three functions decrease over the range of $g = (0, 1)$.

Lemma 4

We prove this using the dual functions C_1 , C_2 , and C_3 defined above, and show that :

- (1) the curves defined by C_1 and C_2 cross such that for small values of C , $g_1 > g_2$ and vice versa for large values of C .
- (2) C_1 and C_3 are such that for all C less than some C^* , $g_3 < g_1$ and for larger values of C , g_3 is set at the boundary g_1 .
- (3) C^* must be the same point where g_1 and g_3 cross, so all three curves intersect at a single point

(g^*, C^*) . This is shown in figure 1 below for the case where $L = 1$ and $V(g) = 1 + \log(1+g)$.

proof of (1)

By E3 and substituting from the definition of t_l into A3:

$$\text{A11} \quad \frac{C_1(g)}{L} = \frac{V(1) - V(g)}{V(1) - gV(g)}$$

$$\frac{C_2(g)}{L} = \frac{V'(g)(V(g) - V(0))}{2V(g)(V(g) - V(0)) + 2gV'(g)(V(g) - V(0)) - gV'(g)V(g)}$$

$$\text{At } g = 0: \quad \frac{C_1(0)}{L} = \frac{V(1) - V(0)}{V(1)}$$

By l'Hospital's Rule, the limit as $g \rightarrow 0$

$$\frac{C_2(g)}{L} = \frac{V'(g)V'(g)}{2V(g)V'(g) + 2gV'(g)V'(g) - V'(g)V(g)} = \frac{V'(g)V'(g)}{V'(g)V(g)} = \frac{V'(0)}{V(0)}$$

$$\text{A12} \quad C_2(0) > C_1(0) \Leftrightarrow \frac{V'(0)}{V(0)} > \frac{V(1) - V(0)}{V(1)} \Leftrightarrow V'(0)V(1) > (V(1) - V(0))V(0)$$

$V(1) > V(0)$, and by convexity, $V'(0) > V(1) - V(0)$, hence $C_2(0) > C_1(0)$.

Using a similar construction, the limit as $g \rightarrow 1$

$$\frac{C_1(g)}{L} = \frac{V'(1)}{V(1) + V'(1)}$$

$$\frac{C_2(g)}{L} = \frac{V'(1)(V(1) - V(0))}{2V(1)(V(1) - V(0)) + 2V'(1)(V(1) - V(0)) - V'(1)V(1)}$$

With appropriate simplifications,

$$C_2(1) < C_1(1) \iff V'(1)V(0) < V(1)(V(1) - V(0)).$$

$V(0) < V(1)$ and by convexity, $V'(1) < V(1) - V(0)$, hence $C_2(1) < C_1(1)$. Thus $C_1(g) = C_2(g)$ for some $0 < g < 1$, or $g_1(C) = g_2(C)$ for some $C \in (C_1(1), C_1(0))$.

proof of 2:

We know from Theorem 1 that there if $\frac{C}{L} \geq \frac{V(1)-V(0)}{V(1)}$, then R will not be available for any value of g . Thus, g_3 cannot have an interior solution for a range of costs $C < L$, where by definition $g_3 = g_1$; alternatively, for g sufficiently small, there is no positive cost of R such that welfare is maximized conditional on the availability of both G and R .

By Theorem 4, $g_3(C) < g_2(C)$ for all C such that $g_2(C) < g_1(C)$. By part 1 of this proof, positive values of C exist such that $g_2(C) < g_1(C)$. Hence, for a range of C , $g_3 < g_2 < g_1$.

proof of 3:

Solving the integral in E5 and substituting for P_R , t_1 and t_2 yields the following condition for C_3 when $g_3 < g_1$:

$$\begin{aligned}
 & \left\{ \frac{1}{2} + \frac{1}{2} \frac{C_3}{L} \frac{V(1)-gV(g)}{V(1)-V(g)} - \frac{C_3}{L} \frac{V(g)g}{V(g)-V(0)} \right\} \\
 \text{A13} \quad & * \left\{ \frac{1}{2} V'(g) \left[\frac{1}{2} + \frac{1}{2} \frac{C_3}{L} \frac{V(1)-gV(g)}{V(1)-V(g)} + \frac{C_3}{L} \frac{gV(g)}{V(g)-V(0)} \right] - gV'(g) \frac{C_3}{L} - V(g) \frac{C_3}{L} \right\} \\
 & + \frac{1}{2} \left\{ \frac{1}{2} - \frac{1}{2} \frac{C_3}{L} \frac{V(1)-gV(g)}{V(1)-V(g)} \right\} \left\{ V'(g) - gV'(g) \frac{C_3}{L} - V(g) \frac{C_3}{L} \right\} = 0
 \end{aligned}$$

Let g be such that $C_1(g) = C_3(g)$ and A13 is satisfied, so that maximizing welfare subject to availability of R results in $t_2 = L$, $P_R = C_R$, and the patented drug just barely unavailable.

Then $\frac{C_3}{L} = \frac{C_2}{L} = \frac{V(1)-V(g)}{V(1)-gV(g)}$. Substituting into A13 yields:

$$\text{A14} \quad \left(1 - \frac{C_3}{L} \frac{V(g)g}{V(g)-V(0)} \right) \left(\frac{1}{2} V'(g) \left(1 + \frac{C_3}{L} \frac{gV(g)}{V(g)-V(0)} \right) - gV'(g) \frac{C_3}{L} - V(g) \frac{C_3}{L} \right) = 0$$

The first term in A14 cannot be zero as $0 < g < 1$, hence the second term must be zero. Solving the term for C_3 yields an expression identical to the equation for C_2 in A11. Hence, $C_3(g) = C_2(g)$ when $C_3(g) = C_1(g)$, and there is a value $g = g^*$, and associated cost C^* , such that the two maximizing strategies converge and the intellectual property level set such that the price of the patented good is set exactly equal to its cost.

q.e.d.

Corollary 2

The expressions in A11 and A12 show that C and L occur as a ratio in all three equations defining g_1 , g_2 and g_3 . Hence an increase in L , accompanied by a proportionate increase in C , will maintain the identities $g_1 = g_2 = g_3$, or the regime-switching cost C^* increases with L , while the regime-switching wealth L^* increases with cost.

Corollary 3

Near L^* the net effect in A14 must be positive: at L^* , the price of the patented good is set equal to its cost, C . An increase in L results in maximum welfare at $g_3 > g^*$, but by Theorem 5, $g_3 < g_1$ at $L > L^*$, so positive amounts of the patented good are sold and $P_R > C$.

While the price of the patented good remains above its cost as long as $g < 1$ and $L > L^*$, at some point it begins to decline. We consider the limit of dP/dL as g approaches 1.

From E2:

$$\text{A15} \quad \lim_{\{g \rightarrow 1\}} \frac{\partial P}{\partial L} = \frac{V(1) - V(g)}{2V(1)} = \frac{V(1) - V(1)}{2V(1)} = 0$$

As is shown in Theorem 5, $C_3(g) < C_1(g)$, and

$$\lim_{\{g \rightarrow 1\}} \frac{C_3(g)}{L} < \lim_{\{g \rightarrow 1\}} \frac{C_1(g)}{L} = \frac{V'(1)}{V(1) + V'(1)}$$

Hence, for g sufficiently close to one,

$$\text{A16} \quad C_3(g)(V(1) + V'(1)) < LV'(1)$$

By A16 and E2:

$$\begin{aligned} \text{A17} \quad \frac{\partial P}{\partial g} &= \frac{1}{2V(1)} \{-LV'(g) + CV(g) + gCV'(g)\} \\ &\underset{g=1}{=} \frac{-1}{2V(1)} \{V'(1)L - C(V(1) + V'(1))\} < 0 \end{aligned}$$

From A9 and A16,

$$\text{A18} \quad \text{sign} \frac{dg}{dL} = \text{sign} \{V'(1)L - C(gV'(g) + V(g))\} > 0$$

Substituting A15, A17 and A18 into E6 establishes that for sufficiently large values of $g < 1$, $dP/dL < 0$.

q.e.d.