A Patent Policy Proposal for Global Diseases[1]

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We are in the midst of a dramatic extension in the global reach of the patent system. Until recently, most developing countries did not grant patents on new pharmaceutical products in an effort to keep their prices low. Today, however, most countries have extended their patent laws to include pharmaceutical innovations. The rest will soon follow in order to fulfill World Trade Organization membership requirements.

Public concern over the price of HIV/AIDS drugs in Africa has focussed attention on this new global system and generated a debate between those who support the establishment of strong patent laws to protect pharmaceuticals in developing countries, and those who, in various ways, would weaken them. The choice does not, however, have to be limited to strong versus weak. The worldwide markets for drugs to treat cancer and malaria are very different and the global patent system would be improved by a recognition of this fact.

This paper outlines a policy that would lower the price of pharmaceuticals in developing countries on important global diseases, while at the same time allowing protection to increase where it is most likely to lead to the creation of new products. The proposal requires no changes in international treaties, only minor changes to our own patent law, and would cost very little to implement.

I. Introduction

We are in the midst of a dramatic expansion in the global reach of the patent system. Previously, most developing countries (LDCs) treated such innovations as non-patentable or at best offered only minimal protection for new manufacturing processes. Today, as the result of bilateral pressure and World Trade Organization membership requirements, they are in the

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process of implementing new patent laws that look very similar to those in the U.S. and Europe, granting full protection to all inventions in this area.

The public attention now focused on patents and the price of HIV/AIDS drugs in Africa has created an opening and a demand for creative thinking about ways to improve this new global system. The crux of the debate over the extension of rights in poor countries is the inevitable tradeoff between new products and lower prices that is part of supporting research and development through a patent system, which raises the question of whether the system be structured to elicit the same amount of innovation at a lower welfare cost. In answering this very basic question, it would be a mistake for international and domestic policy discussions to focus only on AIDS, despite the undoubted importance of this specific disease. The U.S. patent office granted over ten thousand patents related to pharmaceutical innovations in 1998, spanning thousands of diseases. No policy designed to address the current AIDS crisis is likely to be the best policy for the system as a whole, nor is it necessary to think in those terms. The AIDS epidemic is an international emergency of the first order. It can be treated as exceptional, and deserves its own policies.

An analysis of the implications of extending protection to additional countries is very closely analogous to that of granting protection for more years (see Nordhaus, 1968; Deardorff, 1992). Fundamental determinants of the optimal extent of protection are the degree to which the prospect of greater profits leads firms to increase research investment, and the degree to which further investment results in innovation of benefit to the public. These responses tend to decline at higher levels of R&D investment. Thus one can expect relatively more benefit from increasing protection where incentives are initially low.

From this perspective, it is important to recognize that there are two very different and identifiable types of drug markets. Some diseases are important worldwide, being found in both poor and rich countries, and therapies for such diseases have global markets. Others are more specific, with almost their entire market in the developing world (for example, malaria). Table 1 shows twenty diseases for which at least 99% of the global burden is in developing countries.

There has been almost no investment in the latter category outside of the public sector. Without protection in the developing world, there has been little prospect of profit anywhere and therefore little interest on the part of firms to invest in therapies for these diseases (see Lanjouw and Cockburn, 2001). The new regime may draw resources into the creation of drugs to prevent and treat diseases specific to poor countries. Of course, even with effective patent systems the group of LDC markets may not, by themselves, be very attractive given the prices that they can support. The goal of recent initiatives to “make a market” is to put more money into these poor

country markets via a dedicated fund or tax credit to subsidize purchases of specified products (see Kremer, 2001, and World Bank, 1999, for details). This type of policy is appropriate for stimulating private investment in research on 'Malaria'-type diseases: those which have small markets in the West, but which are of great importance in the developing world.

Consider, however, global diseases: those that are widespread in poor countries but *also* in rich countries. These diseases are the focus of the proposal described here. They have received less attention in development debates over intellectual property because they are not specific to LDCs. However, this does not mean that they are not important causes of disability and mortality amongst the poor. The first column of Table 2 indicates, for example, that cancer, heart disease, and diabetes together account for 16 percent of the total 'disability adjusted life years' (DALYs) lost in a group of poorer countries with annual per-capita expenditure of just U.S. $1,250 (World Health Organization estimates. Similar percentages were found using mortality). This is four times higher than the share of their total burden coming from malaria. Not only are 'rich country' diseases important in poor countries, they appear to cut across the income spectrum. Table 3, for example, presents data from a Pakistan health survey designed to gather information on the prevalence of strong risk factors for cardiovascular disease and cancer (see Pappas, *et. al.*, 2001, for details). These data are unusual in having information from direct health examinations of the sampled individuals, rather than simply statements about disease incidence, together with at least some measure of household wealth. Fifty percent of the Pakistan population falls in the lowest defined asset owning group. The table shows that smoking among males is both widespread and significantly higher amongst the poor in Pakistan than the better off. Further, while those in the bottom half of the distribution have relatively lower rates of the risk factors associated with cardiovascular disease, the rates are still high with about a quarter suffering from hypertension and fifteen percent having high cholesterol. Other data exist giving self-reported, and therefore less reliable, disease incidence, but with better measures of household wealth.[2] Surveys in India, for example, found that of about 12,000 adult deaths in rural areas, 11% of those occurring in the lowest 20% of the all-India wealth distribution were ascribed to cancer or heart disease. This is well below the 35% rate in the highest quintile ascribed to these causes – but still a very substantial source of mortality (Deon Filmer, World Bank, personal communication). The evidence is not plentiful, but what evidence there is suggests that 'rich country' diseases are

[2] The problem with such data is that respondents may not know the true cause of death. This is clear from the fact that by far the largest reported single cause is 'Old Age'. However, the upper and lower income group comparisons seem somewhat more reliable in light of the fact that both groups had similar allocations to 'Old Age': 32 and 36%, respectively.

widespread in poor countries, and that they are important among the poor and not just the relatively rich in those countries.

At the same time, almost all of the potential market for global diseases is found in the West. Return to Table 2. The second column gives rough measures of the relative market size in rich and poor countries based on disease incidence as measured by DALYs. The column figures are rich country DALYs divided by total DALYs for each disease, where rich and poor country DALYs are weighted by a rough estimate of their relative drug expenditure levels. On this measure, almost all of the market for cancer, heart disease and diabetes is in the rich countries. This is in stark contrast to malaria. [3]

Tables 4 and 5 go directly to drug expenditure patterns. Like Table 2, the top panel of Table 4 suggests that poorer countries contribute little to total world expenditure on drugs for global diseases, but at the same time can be a significant major source of demand in some therapy areas (here parasitology). The bottom panel of Table 4 indicates, again, that a very significant share of the total spending by poor countries goes to global diseases even though their spending is of little importance in world demand for drugs for those diseases. Table 5 ranks selected major countries by their 1998 purchasing power parity adjusted per-capita GDP (those included are the largest LDC drug markets). We see each country's share of total worldwide drug expenditure and an estimate of their individual shares of total worldwide spending on drugs for cardiovascular disease. These numbers are remarkably small. In particular, the subtotal in the middle of the table indicates that about 46% of the world's population is found in countries representing less than 2% of total expenditure on drugs for cardiovascular disease.

Thus global diseases are worthy of attention for the following reason:

For such diseases, the profit derived from having a monopoly over sales in poor countries makes only a marginal contribution to the total world-wide profit of pharmaceutical firms and therefore only marginally increases their incentive to invest in research. At the same time, even a small price increase due to such a monopoly in a poor country can greatly reduce the number of people able to purchase patented drugs and the welfare of those who do. This is particularly true given that drug purchases are largely paid directly by consumers in LDCs, without the benefit of insurance.

[3] These figures are provided to give an impression of the very distinct differences in the global distribution of markets for the two types of diseases highlighted here. They have some weaknesses and should not be taken too literally. For example, DALYs lost fall with pharmaceutical consumption and on this account the percentages in the second column are under-estimates of the importance of rich country markets. The interpretation of drug expenditure data is discussed below in Section V.

In this paper I propose a policy that could improve on the current regime by acknowledging these differences in markets and what they imply for optimal patent protection. It allows protection to continue increasing worldwide in most areas of pharmaceutical innovation (as envisioned in TRIPs, the intellectual property section of the GATT treaty). In particular, and in contrast to other proposals being discussed such as indiscriminate compulsory licensing, it allows protection to strengthen for diseases specific to LDCs where there is a clear argument to be made that some form of new incentives are warranted. At the same time, it effectively keeps protection at its current level in situations where an increase in profits is less likely to generate new innovation. To do this, the policy requires inventors choose either to avail themselves of protection in the rich countries or, alternatively, in the poor countries, but not in both, whenever a patented product is for a global disease. Because the profit potential offered by rich country markets is far greater, firms will naturally relinquish those in poor countries. Thus the policy would lower the price of drugs for global diseases, and should be seen as a complement to policies that target poor-country specific diseases.

The following section suggests ways in which the policy could benefit both the world's poor and research-based pharmaceutical firms. In particular, it addresses concerns over parallel imports and 'low cost sources of supply'. Section III outlines a mechanism that gives a feasible way to present patentees with the desired choice between protection in either rich or poor country markets in the limited situations where their patents relate to products for specific global diseases. Economists and policy makers have been reluctant to differentiate protection across types of innovation despite the fact that there is a strong theoretical basis for doing so (and Article 27 of the GATT treaty explicitly requires non-discrimination). There are good reasons for this. The information needed to decide how best to differentiate is limited, and any differentiation must be on features both easily identified and hard to change or resources will be wasted as everyone tries to fit into the better class.[4] The mechanism described is simple to implement and has useful revelation and self-enforcement features that resolve these problems. Discussions of some of the important details are found in Section IV-VII. A brief discussion of some of the ways in which

[4] The experience with 'orphan' drugs illustrates. The U.S. Orphan Drug Act gives tax benefits and exclusive marketing privileges to applicants for new drug approvals related to products that would otherwise be uneconomic to discover and bring to market. It identifies qualifying products as those with expected patient populations of less than 200,000. By defining diseases very narrowly, the industry has managed to get orphan drug designations on most forms of cancer, AIDs, asthma, and other diseases one would not expect to find under that heading. See testimony to the U.S. Senate, 1992, by James Love at http://www.cptech.org/ip/health/orphan/orphan92.html.

the proposed policy might be preferable to alternatives involving compulsory licensing and price control is in Section VIII.

II. Benefits for Firms and the World's Poor

Firms have a legitimate concern about 'low cost sources of supply' and seepage across borders, particularly into their major markets.[5] On the face of it, this proposal does not seem helpful in this regard since its intention is precisely to encourage low drug costs, in some areas, in poor countries. Firms may well object to it on these grounds. However, we must have 'low cost sources' if we to have any hope of ensuring anything like the adequate availability of drugs to poorer people. The rich world will not supply levels of aid that would make purchases at U.S. prices feasible. Thus, the only appropriate response is to address the problem of seepage. If firms are confronted with substantial international arbitrage, then they will naturally respond by selling at a uniform price – one that is quite likely to be far higher than even than the monopoly prices appropriate to poor countries. They may decide not to launch drugs in the poorest countries altogether. To prevent this, efforts should be directed towards helping firms to separate markets. This is true regardless of whether the policy proposed here is implemented.

A first step in easing firms' concern might be legislative confirmation that the U.S. does not have an international exhaustion of rights doctrine, in keeping with the more recent Federal Circuit Court interpretation of the law on exhaustion (see Adelman, *et. al.*, 1998). This would be a clear statement that holders of U.S. patents have the right to prevent products from coming into the U.S. from elsewhere, even if originally sold by their own licensees or subsidiaries.

The bigger issue, however, is the enforcement of rights in this area. Drugs are small and lightweight which makes it difficult to prevent products that have been sold cheaply in a country where consumers are poor from flowing back into markets where they are better off. The internet may greatly exacerbate this problem in the future. Consumers will be able to purchase drugs directly from around the world. Once LDC firms have developed sufficiently good reputations for quality that consumers feel comfortable with their products, one can easily imagine hundreds of thousands of packets crossing borders in separate envelopes in the regular post. Patentees will be hard pressed to identify such individual infringements and reluctant to enforce a separation of

[5] Parallel imports amongst poor countries is of second order importance to firms, and may improve welfare in some very poor but very unequal societies where firms target the elite. See Malueg and Schwartz (1994) for a theoretical assessment of some of the pricing, profit, consumer surplus, and overall welfare implications of global discrimination and uniform pricing regimes.

markets by suing their customers.[6] Internet sales also pose a safety threat to consumers. How is one to know that a web-based pharmacy is actually in North Carolina and not a counterfeit operation operating from overseas? (See www.fda.gov/ola/2000/internetsales.html for a discussion of current FDA concerns and efforts to combat this problem.[7])

It is difficult to see how the enforcement problems can be successfully resolved without better coordination and regulation of drugs at source. Thus the participation of poor countries in efforts to prevent illegal movements of drugs across borders will be key. The proposal described here is specifically designed to benefit developing countries, and in a way that would be very apparent to their populations. (This is contrast to the TRIPs agreement itself which, whatever its long run benefits in the form of new products, has engendered considerable resentment in LDCs.) It would seem reasonable to expect that they, in turn, make efforts to ensure that drugs priced for their consumers actually get to their populations and do not escape as exports to rich countries.

There are various ways that this might be done. One possible idea can be seen by analogy. The U.S. federal government taxes gasoline and diesel fuel at different rates depending on its intended use. This is difficult to enforce once distribution to users has occurred since the taxed and untaxed fuel looks the same. The solution has been to dye the untaxed fuel to make it more readily distinguishable.[8] Health authorities in all countries already specify features of drug appearance and packaging. One could ask poor countries that are candidates to be included under the policy to require that pharmaceuticals sold in their countries to be, for example, lime green. This would make it simpler to check bulk movements, and give consumers elsewhere a better chance of noticing that their drugs are not actually being manufactured in North Carolina, as they

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[6] This is an upcoming problem – the physical movement of product does not appear to be a primary concern of the industry now. The bigger block to tiered pricing currently is the reluctance of rich country consumers to tolerate poor countries having lower prices than they themselves receive, or what would appear to be their lack of awareness. Recent legislative efforts to remove FDA controls on imports, produced last year out of anger over Canadian prices, for example, do not distinguish between poor and rich source countries, nor were the potentially negative implications for poor countries noted in the public discussion. The political pressure and regulation that result from this public attitude cause prices in one country to spillover to prices in another – even if no product crosses country borders. Naturally, firms respond by being reluctant to price at lower levels in poor countries.

[7] Extracts from a statement to Congress by FDA commissioner Hubbard: "Internet technology can obscure the source of the product …[the Agency] believes that illegal online drug sales pose a significant public health risk. Consumers….may be targets of unscrupulous business practices, such as the selling of unsafe, unapproved, expired, counterfeit, or otherwise illegal drugs. The sale of drugs to U.S. residents via foreign websites is an extremely challenging area… FDA efforts are mostly limited to requesting the foreign government to take action."

[8] See http://ftp.fedworld.gov/pub/irs-regs/td8659.txt

had supposed. There may be related and better ideas on how to use form and packaging to differentiate products - firms have considerable expertise in this area and their advice will be valuable here. But the point is clear. The fact that the policy encourages low prices in LDCs certainly implies the continued existence of 'low cost sources of supply'. But the same policy also gives poor countries a positive reason to cooperate in resolving this looming, and extremely difficult, international enforcement problem. Seen from this perspective, the policy could help firms protect their more valuable markets.

In addition, the policy provides an alternative to untargeted policies now being suggested, such as across-the-board compulsory licensing of pharmaceutical patents or price control. Given the current climate of discontent with the new patent regime, and efforts to weaken it, some move away from the strongest level of protection will probably be necessary. This policy is be a controlled move designed to preserve incentives where they are most needed.

For precisely the same reasons the policy would benefit poor countries. They too stand to gain from the successful separation of markets. They too stand to gain from a policy that lowers prices on global diseases while at the same time maintaining incentives for firms to invest in products for diseases specific to poor countries. In addition, the policy involves only the patent laws and procedures in rich countries. Poor countries would continue to develop their patent systems fully and no questions would be raised about their compliance with WTO membership requirements. This would help shift international patent issues out of the realm of continuous dispute and put discussions on a more cooperative footing.

III. The Mechanism

The Mechanism

I will first describe how the policy works in the simplest possible terms, leaving details to the discussion that follows. Assume, initially, that there are only:

1. two countries, the U.S. (representing a set of rich countries) and India (representing a poor set);
2. two diseases, Malaria and Cancer, the first representing a set with no U.S. market and the second a set with a very large U.S. market and a substantial but much smaller Indian market; and

3. three companies, PharmaUS, CiplaIndia, USGeneric, where each represents a type of firm in the pharmaceutical market.

Bear in mind that patents are national in coverage. To obtain protection in France requires an application for a French patent. To obtain protection in Brazil requires an application for a Brazilian patent. Now, when an innovation is *made in the U.S.*, the inventor is required to apply *first* for a U.S. patent. To make subsequent, foreign, applications the inventor is required to first obtain a "foreign filing license" from the US patent office (USPTO). This rule is in place for the purpose of protecting military secrets, and variants of it are found in patent regulations elsewhere.[9]

The proposed policy is, very simply, to stipulate that when a patentee petitions for this license, he does so in the following form (exact language not important):

I, the undersigned, request a license to make foreign filings for patent no. X, with the understanding that this permission will not be used to restrict the sale or manufacture of drugs for 'Cancer' in 'India' by suing for patent infringement in 'India'.

Again, obtaining a license is one of the steps that any U.S. patentee already must take in order to file abroad anywhere, including in Europe and Japan (see Section VII for further details). Requiring this declaration to obtain the license is the entire policy. A provision that already exists in the patent law is used to serve an entirely unanticipated purpose. The mechanism will work because other features of the patent law and pharmaceutical regulation can also be turned to serve this new purpose. These are discussed below.

Basic Outline of Why it Works

Consider the simplest situation. PharmaUS has a Cancer product protected by a single patent in the U.S. and in India. The company obtains marketing approval in both countries and sells the product. Now CiplaIndia (or USGeneric) enters the Indian market with its own version of the same product. PharmaUS can choose to do one of three things. First, it may continue to

[9] High income countries that already have in their patent law some form of the domestic filing requirement for residents include at least: France, Greece, Italy, Portugal, Spain, the UK, Belgium, Germany, Denmark, Finland, Luxembourg, Russian Federation, and Sweden. For the first six the requirement covers all innovations, while for the last the requirement as currently stated covers only security-related innovations.

sell the product. Making this choice, it would need to lower its price to remain competitive with the new entrants. This is a strategy that multinationals have followed for decades in countries not offering them patent protection. On the other hand, PharmaUS might be uncomfortable selling at prices low enough to be competitive in India – perhaps because of international price comparisons – and it may choose to withdraw from the Indian market altogether. This is also a strategy that multinationals have followed. With this choice, PharmaUS would continue to exercise its rights in the U.S. market and entrants would supply the Indian market.

However, PharmaUS could make a third choice. The company has a valid patent in India, may sue CiplaIndia for infringement, and, if so, would win. Nothing prevents the company from choosing to protect its rights in India, on the basis of its patent there, in an Indian court, in exactly the same way that it would without the policy. But what happens then? At this point, either CiplaIndia or, more likely, USGeneric, can go to the USPTO and claim that, by attempting to stop CiplaIndia's sales of the Cancer product in India, PharmaUS has rendered its *U.S.* patent unenforceable. This is so because, by taking this action, PharmaUS has falsified the declaration it made to the USPTO to obtain the foreign filing license. Patentees have a duty to deal with the PTO in good faith and failure in this regard is clear grounds for rendering a patent unenforceable.[10]

Suppose now that the innovation had been for a Malaria product. Again PharmaUS could choose either to compete or to exit the market with the entry of CiplaIndia. Again its alternative is to sue for infringement. Now, however, the suit would give no grounds for rendering the U.S. patent unenforceable. The declaration made by PharmaUS to obtain its foreign filing license says nothing about Malaria.

So what is our result? In the case of a patent for a Cancer product, PharmaUS's two choices are effectively between protecting its profits in the U.S. or in India, but not both, just as desired. It will not sue *in India* for infringements of Cancer product patents because it will not want to jeopardize its *U.S.* patents. Knowing this, CiplaIndia will enter the market and prices in India will fall. In the case of a patent for a Malaria product, PharmaUS's two choices are effectively between protection in the U.S. or protection in *both* the U.S. and India. It will sue in India for

[10] Forfeiture is not generally favored by courts as a remedy for breach of contract. The more usual remedy would be damages. However, rendering a patent unenforceable is the standard remedy in this context. It has been put into effect, for example, in cases where a patentee knowingly misrepresented prior art to the patent office, or made a false declaration concerning the adequacy of the patent specification in revealing the invention. Note that 'damage' here would be to the integrity of the U.S. patent system, not to the developing country in question.

infringements of Malaria product patents. Knowing this, CiplaIndia will avoid the suit by not entering the market – retaining the incentive for investment in Malaria products.

One might say, "With this policy PharmaUS may not even bother to get a patent in India for Cancer." This is true and it is fine. One of two strategies will be followed. Either PharmaUS will continue to market its patented Cancer product in India, on a competitive basis, or it will leave the market to CiplaIndia and USGeneric. Both strategies have been followed by multinationals over the past decades in countries that have not granted them patent protection. Both LDC firms and developed country generics manufacturers have shown themselves to be adept at rapid imitation and entry. This was, after all, the point of pressing for TRIPs in the first place, as well as domestic legislation to control generic entry. Lanjouw (1998) presents evidence indicating that, over the past two decades, major patent drugs arrived on the Indian market typically within 7 years of their world launch, and often much sooner. Watal (2000) suggests an increase in arrival speed. For ten drugs launched in the U.S. after 1985, she finds an average time lag to availability in India of just two years. Thus, there does not appear to be any reason to be concerned about which strategy the patentee chooses to follow.

The mechanism is designed to be triggered by a lawsuit. Why do we go this route? Because when infringement suits are filed to prevent the sale of a *product* it is on the basis of a set of *patents*. In order to be successful in prosecuting his suit, the patent owning firm has an incentive to correctly announce which patents it believes best protect the product in question. This resolves the otherwise intractable problem of how to identify the use of particular patents. It allows the mechanism work without a bevy of scientists trying to identify patents that might someday be for Cancer.

Advantages of the Policy

1. It does not contravene existing treaties (Paris Convention, Article 4bis; the TRIPs component of GATT, Article 27).
2. It can be implemented unilaterally, although it would be most effective and acceptable to all parties if the EU, Japan and the U.S. were to move together. (Note: for simplicity, I will comment below as though only the U.S. implemented the policy. The comments would be equally true for other rich countries and one could read 'France' or 'Japan' in place of 'U.S.' if those countries were to participate.)
3. *It does not require any changes whatsoever to new LDC patent systems or the development of their enforcement procedures.* In fact, better functioning patent office and court systems in

the LDCs will only improve the working of this policy. At a time when there is concern to nurture budding TRIPs compliance it seems a great advantage of this mechanism that it will not in any way 'muddy the waters'.

4. As detailed below, the mechanism relies almost entirely on the quality and reliability of U.S. institutions and not on those in the LDCs themselves.
5. This policy would be fully controlled by the U.S. government. This is in contrast to the sanctioning of compulsory licensing by LDC governments, where pressure by local interests to expand coverage to all diseases will be difficult for the domestic government to resist.
6. The mechanism does not require information that is clearly not available. In particular, and crucially, it does not require that patents be examined and identified as covering innovations *for* a particular disease. Such a task would be infeasible. Even ignoring the expense, at any moment in time the patent owner himself may not know the future uses of a patented innovation. The policy mechanism induces firms to volunteer the link between patents and products when the information becomes known and only as necessary.
7. No one is told what to do. Incentives are aligned to make use of the greater information that firms have about the relative size of global markets for different products. They behave as desired without outside control or monitoring.
8. Because it uses existing institutions and procedures, is largely self-monitoring and does not require the collection of information for each patent, the policy would cost very little to administer and enforce. One potentially important implication is that this policy need not be seen as an alternative to other policies within the constraints of fixed health or development budgets.

IV. Linkages

As noted in Section III, a case filing identifies the Indian patents that protect a particular product. This section considers the two remaining links that need to be made.

Linking Products to Diseases

One of the stated advantages of the mechanism is its reliance on U.S. institutions. But it is triggered by a court case in India. This may seem surprising. However, it is the filing of a suit that is the trigger – the effectiveness of the policy does not rely in any way on the subsequent legal proceedings in India. Using the Indian case for this purpose does raise two issues, however.

First there must be a clear procedure for determining, on the basis of U.S. institutions, whether the Indian product which is the subject of the suit corresponds to a particular disease. CiplaIndia or USGeneric will always have an incentive to claim that a disputed product is for Cancer in order to render unenforceable the U.S. patent of PharmaUS, while the latter will claim all products are for Malaria.

I suggest the following. All products marketed in the U.S. are approved by the FDA for specific indications.[11] To render unenforceable PharmaUS's patent, USGeneric must take the Indian product and apply to the USFDA for an abbreviated new drug approval (ANDA). In this, it would claim the Indian product's equivalence to one already marketed in the U.S. with a Cancer indication. This procedure is exactly the same as that already followed for any generic on the expiry of a patented product so our own generic companies are well versed in following it through. If the USFDA issues tentative approval, or a preliminary letter of bioequivalency, the case that the Indian product is for Cancer is made and the U.S. patent rendered unenforceable.[12] At this point USGeneric or CiplaIndia can, and will, request final marketing approval from the USFDA, since obtaining access to the U.S. market was the point of rendering PharmaUS's patent unenforceable. The bioequivalence report is the basis for that approval. Thus there is no net increase in resources expended by either the companies or the government as a result of using the USFDA ANDA process for our purpose. It also means that the FDA has a serious interest in the quality of the bioequivalence report as it has direct implications for the integrity of the U.S. system of safety regulation.

Linking Patents to Patents

The second issue that arises is that the Indian patents supporting the suit need to be linked to their U.S. equivalents. Fortunately, this is a standard output of international patent procedures. Having first filed in the U.S., a subsequent Indian application typically refers back to the U.S.

[11] Until October, 2000, products were assigned to one or more detailed therapeutic classes. This coding has been stopped for budgetary reasons but may resume in the future and would clearly be most useful for our purpose. Alternatively, the written descriptions could be used. Other OECD country health authorities code products so there may be scope for making use of their systems as an additional method of identification.

[12] The current rules concerning ANDA applications are complex and it is currently unclear to me whether a minor alteration would be needed. It is sufficient for our purpose that a firm be allowed to file an ANDA, and for the FDA to issue a statement of bioequivalence, regardless of whether the pioneer patent protecting the product is valid and in force. Actual approval is not necessary. It is important here that the patent-product link declared to the U.S. FDA, which defines the pioneer patent(s) in the ANDA legislation, *not* be

application to establish the owner's global priority over the innovation and the time limit for related foreign filings. The global links between patents covering the same innovation that are exposed by this process can be found in publicly available databases.

V. More Complex Settings

The simple situation described in Section III, where a single patent protects a single product, is rare. We next consider how the mechanism would work in more complex settings: with multiple uses of a single patent; multiple patents on a single product; multiple patents on multiple products; and patents on research tools. From these examples it will be clear how other extensions would look.

Single Patent – Multiple Uses

Suppose, first, that an innovation made by PharmaUS, and patented both in the U.S. and in India, leads to a product which is found to be useful against two diseases: Cancer and Malaria. PharmaUS obtains marketing approval in the U.S. for Cancer and Malaria indications. Suppose, too, that PharmaUS requests marketing approval for the product in India, but only for the Malaria indication. Now let CiplaIndia or USGeneric enter the Indian market. If PharmaUS files an infringement suit, the U.S. patent would be vulnerable because the Indian product is bio-equivalent to a U.S. product approved for Cancer. The disease indications claimed in the Indian marketing approvals process are of no consequence. Given this, PharmaUS will refrain from enforcing its Indian patent regardless of the ostensible use of the product in India. Together with some profit derived from sales in the U.S. for its Malaria use, the valuable U.S. Cancer market will be the source of support for R&D investment on dual use products. (See Section VI for how this might affect the choice of diseases to include under the policy.) Of course PharmaUS could protect markets in *both* countries by requesting marketing approval of the product in the U.S. only for the Malaria indication. However, this would prevent the firm from legally advertising the Cancer use of the product to doctors and the public, and therefore will not be an attractive option when the Cancer market is expected to be significant (which is exactly what we want).

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pivotal. There is no clear incentive for patentees to be forthcoming in identifying pioneer patents as there is to identify relevant patents when winning an infringement suit is at stake.

Multiple Patents – Single Use

Let us return now to the situation where we have a pharmaceutical that is only useful against Cancer, but now the drug requires several patents to produce. If each of the patents is owned by a different patentee, and each of the patentees is subject to the policy, then this situation does not differ from the simple one presented in the previous section. Suppose, alternatively, that one of the patents is owned by PharmaUS, and the rest by non-participatants. Then the policy will affect only the single patent owned by PharmaUS and will be less effective as a result. This is one reason that a joint adoption of the policy by members of the EU, the U.S. and Japan would be useful.[13] If the other patents were owned by CiplaIndia, the policy shifts remaining profits to Indian inventors and would support the development of research capacity there.

Finally, suppose that each of the multiple patents is owned by PharmaUS. If there are two subsets within this group of patents that are similarly effective in protecting the innovation, then PharmaUS can sue on the basis of one subset in India and use the remaining patents to protect its market in the U.S. In this case the policy would be ineffective. How much this type of situation would reduce the overall effectiveness of the policy depends, of course, on how common it is for pharmaceutical innovations to be covered by sets of "redundant patents". This deserves investigation. However, one might expect that, in most instances, limiting the number of patents enforced in India to those not useful in protecting the U.S. market would substantially reduce protection in India and make it considerably easier for a competitor to sell a related product there without triggering an infringement suit.[14]

Multiple Patents – Multiple Products

Next consider a situation with two patents and two products. Suppose that PharmaUS has a patent on a basic innovation that contributes to products for both Cancer and Malaria. In addition, PharmaUS has a second patent that protects an adaptation of the basic innovation to make the product more useful against Malaria. Production of the Malaria product requires use of

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[13] Another reason is to make it difficult for firms to avoid the policy by claiming to invent in subsidiary locations outside of the U.S. There is well developed case law related to the identification of 'inventors' that limits firms' flexibility to simply chose any employee who is convenient to designate as the inventor.

[14] One might also worry that a patentee would try filing on the basis of the least important patent and then amending the complaint to bring in the important patents only later, as a way to delay any actions in the U.S. However, the Indian court can refuse to admit such an amendment and this strategy could also be prevented with an equitable estoppel defense (see section VII, below).

both patents, while production of the Cancer product requires only the first. As we saw above, since the first patent relates to a Cancer product the firm will choose not to enforce it in India. However, the second patent does not relate to Cancer. Thus PharmaUS will choose to enforce the second patent in both countries. Incentives to invest in research directed towards adapting innovations for LDC-specific uses are maintained, and any profits made from sales of Malaria products in India now accrue solely to the developmental research that leads to their discovery.

Research Tools

Research tools are innovations used in the process of doing further research, such as a process for inserting genetic material into cells. Because there is no product associated with the use of these innovations, the patents would not be directly affected by the policy. However, the licensing fees that tool owners can charge depend, at least indirectly, on the size of the profits that those who use the tools can obtain on resulting products (with 'reach-through' royalty contracts that give the tool owner a percentage of final product sales, this relationship is direct). Where patented research tools are important, the outcomes described above simply move back a step to those investing in the creation of new tools.

VI. *What is 'Cancer'? Where is 'India'?*

In Section III we simplified the discussion by assuming that there is a single poor country, India, and a single disease with a predominantly rich country market, Cancer. These were stated in the foreign filing license declaration. The declaration would, in fact, specify a set of diseases and a set of poor countries. Before discussing how to specify these sets, it is important to emphasize why we would not want to simply pick the poorest countries and then apply the policy to *all* diseases. It is true that if we were to do this the design of the mechanism would ensure that firms' own choices would automatically keep incentives roughly in order. For products where potential profits were greater in the U.S., patent holders would refrain from enforcing Indian patents. For products more valuable in India they would choose to prosecute infringements there and give up the U.S. market. Thus, responding on the basis of their knowledge of global market opportunities, firms' behavior would reflect the relative demand for new products, as one would want. The problem is, of course, that unless markets are concentrated, in either the rich countries or in the poor, restricting inventors to the choice between making use of patent protection in one or the other could have a substantial effect on the overall

level of their returns. For this reason - to maintain research incentives - the policy should be limited to diseases with markets concentrated in the rich countries and a procedure is need to determine which diseases these are.[15]

The set of poor countries and the set of diseases to go into the filing declaration could be specified by an expert committee basing its judgements on experience in the pharmaceutical field. The committee could meet periodically to update the listings. A better alternative, however, would be to devise a straightforward, transparent and objective procedure to determine these groups. The PTO could then be given the procedure and asked to update the license declaration periodically, without the need to convene committees or for the PTO to make any judgements of its own. [16] One advantage of the latter is that the outcome would be less easily influenced by interest group lobbying.[17]

Before turning to the kind of information available on which to base such a procedure, it is useful to clarify what we would like to do. Denote the set of poor countries by {P}, profit in country j from sales of patented products for disease d as $p_j(d)$, and total global monopoly profits for those products as $p(d)$. The goal is to identify a set of countries {P} and a set of diseases {D} such that, for each of the diseases in {D}, the percentage of the total potential profit $p(d)$ coming from markets in {P} is less than some cutoff value z. That is:

$$(1) \qquad [\ _{j\ \{P\}}\ p_j(d)\ ]\ /\ p(d)\ <\ z \quad \text{for all } d \in \{D\}.$$

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[15] The fact that firms choose the better market, rich or poor, when a disease is included in the policy makes it self-correcting against large mistakes. Suppose, for example, that there is a rare form of Cancer only found in Africa. If this type of cancer were not separately classified then products treating it would be included along with all other Cancer products under the policy. However, for products treating this form of cancer, patentees would choose to protect their patents in Africa and any profits that ever would be available would be realized. No harm would be done.

[16] One might consider making the license declaration refer to a lists maintained by the PTO, rather than specifically-named countries and diseases. The content of the lists could then change over the life of a patent. However, the lists are unlikely to change very rapidly so the benefits would be small. At the same time, this approach would introduce an uncertainty that is costly to both the patent owning firm and those considering infringing entry. In particular, note that withdrawing coverage for a disease in a country midway through the life of a patent would force previous entrants under the policy to either exit immediately or negotiate with the patent owner from a very weak position unless they had prepared an estoppel defense.

[17] Which is not to say that it would be immune. Lobbying may be less damaging here than in some other situations, however. Larger and relatively well to do poor countries are likely to spend more lobbying for inclusion, but industry will work hardest to keep precisely these countries out. No one will lobby over the

This equation encapsulates the basic decisions that have to be made in order to implement the policy proposed here. The equation may be viewed as the basis of a procedure for the PTO to follow mechanistically or as guidance for an expert committee.

Clearly the smaller is the set {P} the larger can be the set {D} and vice versa. Thus there is a choice to be made about whether to have the policy benefit only the very poorest countries by lowering prices of products treating a broad set of diseases or to include a wider group of countries and define the diseases more narrowly. The one requirement is that a sufficient number of countries be included in {P} to cover the fixed costs of launching an imitative product in their competitive environments. This is not a particularly stringent condition given that the largest fixed cost in this industry, the expense of discovery R&D and large-scale clinical trials, is not relevant to imitating entrants. It is instructive that the vibrant and competitive pharmaceutical industry in India developed entirely under such conditions (see Lanjouw, 1998).[18] A practical approach to using equation (1) would be to first define a several sets of increasingly poor countries {P} and then determine appropriate sets of diseases for each based on (1). The use of several groups would lessen the 'you're in or out' nature of the policy, and help reduce lobbying efforts.

One issue in using this equation is deciding how to deal with the existence of products that are useful against a number of diseases. If most of them are in the set {D} then the policy applies appropriately. Suppose, however, that only one of the diseases is in the set {D}. The policy would apply on the basis of that one indication, while the relevant market for such products in each country is actually the combined market for the diseases. In some cases, the share of potential profit in the poor countries across all uses of the product might add up to something significant, even when their share of profit related to one disease taken alone is relatively small. It would be important to gauge the frequency of this type of multiple product situation – and consider, for example, whether using some classification systems or aggregations of 'diseases' might help minimize them. Note that to some extent profits for diseases not included in {D} could still be obtained by enforcing patents on adaptations (see the previous

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smaller markets, so those countries we are most interested in including will be politically least controversial.

[18] Another factor that one might want to consider is the likely ability of patentees to prevent patent infringing imports into the different countries. If India were included in {P}, for example, and Brazil were not, can we expect Brazilian patent owners to be successful in preventing imports from India? If barriers are likely to be weak, it would point in the direction of including a larger set of countries {P} and fewer diseases. It should be possible to get a reasonable answer to this question by looking at current experience. Since developing countries have been adopting the new laws over an extended time, we can see whether

subsection). But nevertheless, this concern would suggest erring on the conservative side in defining the set of diseases {D}.

There are two main parts to implementing the threshold criterion in equation (1). The first is to measure $p_j(d)$. The second is to determine a reasonable threshold z. Regarding the first, the most important problem is that profit figures are easily manipulated and there is no consistent, comprehensive, source for such data. Moreover, the data that are available are not broken out by disease categories. The closest, and fortunately quite reasonable, approximation is information on the value of pharmaceutical sales. These data are available for very disaggregated therapy classes and across some 70 countries from IMS HEALTH Global Services, a private database vender. These countries encompass 94.4% of 1998 world GDP measured in purchasing power parity terms (World Bank, 2000, and IMS, personal communication).[19] [20] The value of sales of pharmaceuticals for a particular type of disease is very directly related to what we want to measure, as compared to information on disease incidence, another obvious contender. Because countries differ to a surprising extent in their use of drug therapies relative to other medical treatments, cross-country statistics on disease incidence would give a very imprecise indication of the relative size of potential drug markets.[21]

That said, gross sales figures differ from what we would like in an important respect. Sales reflect a combination of costs and a profit margin. Since the price-cost margins are typically much higher in richer countries, looking at gross sale values will understate the importance of rich country markets as a source of profit. This is particularly true when profit is a small component of total sales, as it would be for drugs no longer under patent protection. In all

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imports have flowed from India, say, into countries that adopted early, infringing the rights of patentees there.

[19] Therapy classes and diseases are not synonymous, and in principle either could be used to define products on the foreign filing declaration. For the ANDA identification to be useful in identifying relevant products, 'diseases' should correspond to a classification used by the FDA. The relation between IMS data classifications and the FDA system of defining indications would need to be understood. Some assumption would also be needed regarding the markets in those countries, all very small, for which data are not currently available.

[20] It would increase the plausible candidates for inclusion in {D} if veterinary uses of patented innovations were included in the determination of the potential size of country markets. It might make it possible to include, for example, products for some parasitic and worm diseases. Whether the marketing data on veterinary sales and USFDA treatment of such products would allow them to be incorporated in a simple way is something to be determined.

[21] There are two other problems with disease incidence and mortality figures. First, they can be strongly affected by current drug consumption. Thus, the larger the market the lower the incidence and mortality – HIV/AIDS provides a good example. Second, like profits, these data do not exist in anything like the comprehensive and consistent form necessary.

countries many, if not most, sales in any given disease category are of drugs whose patents have expired, and these drug products are not easily distinguished in the data from those still protected by patents. (Recall that this is precisely the reason that we are using court cases to make the link between products and patents). Being sold under competitive conditions, sales figures relating to generic products cannot reflect the potential monopoly profits available in different markets. To the extent that they are important in a disease category, the left-hand side of equation (1) calculated with sales data would be larger than the ratio calculated with potential monopoly profits. We would (conservatively) allow too few diseases to qualify for any specified set of poor countries {P}. An alternative would be to use sales data to compute the left-hand side of equation (1) adjusted by an estimate of the relative price-cost margins in rich and poor countries.

A related issue arises for those products still under patent protection in the West. We want to know the relative profit that could be obtained from the sales of drugs in rich and poor countries assuming that the seller has a monopoly in each country. But many poor countries are only now beginning to offer patent protection and have had very competitive pharmaceutical markets. As a result, for products still under patent, sales figures in the rich countries include a monopoly profit margin while those in the poor often do not. The lack of mark-up would tend to make the poor country markets look less important than they would if the owner had a patent everywhere. However, the opposite may also be true. Competitive prices mean more output is sold so that 'sales' can actually be larger under competition than with a monopoly despite the lack of mark-up.

It is worth noting, however, that if prices in a country are relatively low due to price controls (rather than competition), it is not a concern for us. Price controls are not restricted by any treaty agreements and many rich countries have both strong patent systems and extensive regulation of pharmaceutical prices. The same will be true in many of the developing countries that are now implementing new patent systems. Any assessment of the profits that a patentee could potentially obtain in each country, whether rich or poor, should certainly take its price control regime into account. That sales data reflect the operation of price controls is thus an advantage rather than a drawback.[22]

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[22] The move to a regime where patent owners have the right to prevent sales of a product in a country gives them a far stronger bargaining position in negotiations with price regulators. Thus price controls may not constrain the future profits of patentees to the extent reflected in current sales data. If important, the relative profit to be gained from patent protection in poor countries would be greater than suggested by these data.

One might worry that this policy might push an LDC government to implement stricter price controls in order to get more diseases to qualify. This would be limited by the strength of their own

The fundamental decision, of course, is the choice of the cutoff level, *z*. A small value for *z*, say 0.02, implies that a disease class will fall under the policy if, for drugs in that class, expected profits from sales in the set of poor countries are less than 2% of total global profits. Increasing the cutoff value of *z* would allow the policy to encompass a larger number of diseases and confer greater benefits on the poor, but would begin to more significantly dampen research incentives.

VII. Legal Issues

This section discusses a number of legal issues.

Delayed Case Filings

Recall that the reason that PharmaUS does not choose to sue CiplaIndia for a Cancer patent infringement in India is that PharmaUS does not want to jeopardize the corresponding U.S. patent. However, the process for rendering the U.S. patent unenforceable is not instantaneous. Suppose it were to take, on average, two years. Then one could imagine PharmaUS allowing CiplaIndia to infringe until two years before the expiration of its own U.S. Cancer patent. It could then file an infringement suit in India, requesting an injunction to prevent further sales and claiming damages for past infringement, without losing any protection that it would otherwise have had in the U.S. If PharmaUS could succeed with such a strategy it would effectively destroy CiplaIndia's incentives to enter in the first place and render the policy largely ineffective. Fortunately, PharmaUS would not succeed. CiplaIndia would have a clear defense of 'equitable estoppel' against delayed lawsuits as long as it kept records that would allow it to demonstrate that it had informed PharmaUS of its intention to begin the infringing action in India and that PharmaUS had indicated its agreement by not responding at that time (see Adelman, Rader, Thomas and Wegner, 1998).

The Foreign Filing License Requirement

The foreign filing license requirement is found in U.S.C. Title 35, Sections 181-5. Its current justification rests on national security. Implementing the policy would require enabling

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domestic producer interests and the fact that tighter price controls in a single country would have only a marginal effect on overall sales for the set of countries {P}.

legislation allowing the U.S. PTO to require a declaration as part of obtaining this license. The basis of the legislation could remain national security, if security is construed broadly enough to encompass global health concerns (as suggested by the title of the U.S. Institute of Medicine, 1997, report: "America's Vital Interest in Global Health: Protecting our People, Enhancing our Economy, and Advancing our International Interest"). Otherwise a new justification will be required. The actual procedure for determining the content of the declaration would go in the Code of Federal Regulations.

The U.S. code currently states that the requirement for a foreign filing license applies *up to six months* after the application of a U.S. patent. Thus under current rules a patentee can circumvent the need for a license by delaying his foreign applications for six months. This is easily done. In fact foreign filings may be delayed, without loss of priority, as long as thirty months with use of a PCT application. (The only cost is some restriction on the inventor's ability to obtain injunctions and damages during that period.) Because of this, effective implementation of the policy would require that the six month limit indicated in Section 184 be increased to at least 30 months.

Takings

The proposed policy raises a potential legal 'takings' issue. Not, however, in the same way that it typically arises in association with the foreign filing license. In the normal situation, a potential takings occurs when a foreign filing license is denied. The patent holder can sue the government to recover damages caused by the order of secrecy (Title 35, Section 183). But a foreign filing license is *never* denied as a result of the mechanism proposed here. Further, if the policy ever results in a U.S. patent being rendered unenforceable, it is because the patentee has failed to deal with the PTO in good faith. This is not a basis for claiming compensation. Thus, if there is a takings case to be made it is at the level of the procedural change itself and not with respect to its operation in any individual situation.

VIII. Other Policy Options

One response to the proposal outlined here is to ask, 'Would it not be simpler for the developing countries to use existing provisions in TRIPs to lower their prices?" Most countries, rich and poor, control the prices of pharmaceuticals. Such control is not restricted by treaty. The TRIPs agreement also allows countries to issue compulsory licenses to attain public health goals.

Compulsory licenses are non-exclusive licenses granted to domestic producers that allow them to use a protected innovation in return for reasonable royalty payments to the patentee. The treaty puts various conditions on their use. (See Scherer and Watal, 2001, for a detailed discussion.) These conditions include: treating license requests on their individual merits; considering a compulsory license only after negotiations with the patentee have failed; and allowing decisions to be subjected to independent review. Further, the output produced under a compulsory license must be primarily for domestic consumption. This section considers briefly these two policy options, as well as a "compulsory license" variant of my proposal.

Across-the-board Compulsory Licensing and Price Controls

If the only goal were to attain lower prices on products developed for rich country markets, then either price control or compulsory licensing *might* be adequate. The proviso for price control is that patentees would retain control over sales in the LDC market and a firm could, if the controlled price were viewed as too low, simply keep its patented product off the market altogether. Compulsory licensing avoids this problem by allowing domestic producers to sell a patented product, but this only helps in countries with some R&D and manufacturing capacity (since no one can produce under a compulsory license for export under current rules, there would be no source of imports). Because of the procedural conditions noted above, reliance on a compulsory license system could also mean substantial delay in new drugs' arrival on the market.

More importantly, neither price control nor compulsory licensing offers what the proposal here was designed to provide – a feasible way to allow competitive pricing in some areas while keeping in place incentives for private firms to invest in research on diseases specific to poor countries. The last seems important. Private firms currently do very little research on products for the developing world (see Lanjouw and Cockburn, 2001, for evidence). There is little doubt that the lack of patent protection in major developing country markets has contributed to this disinterest. While it is true that the public sector can be a source of research effort, resources there are limited by the priorities of government sponsors (just 0.8% of the 1999 U.S. National Institutes of Health budget went to tropical diseases, for example) and we should probably not expect an explosion of new funding there. Given this, engaging the private sector could be of real benefit. With the extension of patent protection across all developing countries we may see the private sector developing products of specific interest to them. How responsive firms will be is hard to predict. However, it seems certain that compulsory licensing or stringent

price control regimes that limit the returns to discovering new products specifically designed to treat poor country health problems would prevent any beneficial redirection of research.

Note that this problem does not arise when compulsory licensing is used by developed countries. Occasional and non-systematic compulsory licensing, as practiced in the U.S. for instance, does not affect firms' R&D priorities. Nor does blanket compulsory licensing when introduced by a country (such as Canada) with demand patterns are similar to those of countries with strong patent regimes. The former can, to a large extent, free-ride on the incentives provided by the latter. By contrast, if developing countries were to implement comprehensive compulsory licensing, firms probably would purposefully avoid areas of special interest to those countries. There is no free ride for Malaria.

Targeted Compulsory Licensing and Price Controls

Could compulsory licensing or price control regimes be structured so as to constrain most tightly the prices of products for global diseases, while allowing higher profit margins for inventors of Malaria products? A number of considerations suggest that the answer is probably no, at least not in a feasible manner. There are two main problems. As noted below, compulsory licensing is only meaningful if it can be done quickly. Firms considering competitive entry will not even begin the process of investment that entry requires until they know that they will be able to proceed with production and sales. For this reason, Scherer and Watal (2001), in a discussion of compulsory licensing experience, commend the approach that was taken by the Canadians, who set 4% as the reasonable royalty payment for all such licenses. By doing this, the licensing board avoided having to investigate R&D costs and market conditions before setting each fee. The average licensing approval time of only ten months was possible precisely because no attempt was made to differentiate across products.

In order to differentiate effectively, one would need to define categories of products to receive different royalty or pricing treatments, and then have a quick method for identifying into which category a particular product or set of patents should fall. This brings one directly to the difficult identification problems addressed above. Further, unlike the proposal outlined above, where firms would rarely trigger an event making it necessary to classify a product, with compulsory licensing there is no self-enforcement. Under a differentiated compulsory licensing or pricing scheme the correct allocation of every single patented product would have to be determined, with firms' having every incentive to make this as hard as possible. Such a regime

would create clear opportunities for lobbying by firms, and produce confrontations unlikely to contribute in a helpful way to the already acrimonious discussions in this area between countries.

Beyond the informational problem, the more difficult aspect of treating products for different types of diseases differently might well be political. Having seen a compulsory license granted for a global disease product with a "reasonable royalty" of one percent, those suffering from malaria might well object to a "reasonable royalty" of 30 or 50% being required of producers of their drugs, regardless of the sound economic logic. Domestic political pressure might make differentiation along the lines required by efficiency untenable (that is, with higher rates on patents for LDC-specific diseases), and result in a structure of incentives far from those suggested by equation (1) above.

My proposal with a royalty payment

Under my proposal and for the specified set of global products, firms effectively obtain either full protection in the poor countries or no returns at all (a zero percent royalty), depending on their choices. A variant would be to reformulate the declaration so as to enable firms to preserve monopoly rights in the rich countries and at the same time obtain some return from the poor countries. For example, they might declare that they "will not prevent the manufacture or sales of drugs for Cancer unless they obtain less than a 5% royalty." Although this appears, on the face of it, to be preferable in the sense of striking some type of middle ground, it is not. From the firm's perspective, there may be no difference between being held to a zero percent royalty in three countries (my proposal) or a 5% royalty in ten countries. Of course, if one did not change the countries {P} and diseases {D} falling under the proposal when going from a zero to a five percent royalty the latter would be preferred by firms. But it would no longer accord with equation (1). With a 5% royalty, either more diseases or more countries should qualify – in fact just to the point where firms would be indifferent between my proposal and this variant. From the broader perspective of being able to include more countries, which might be attractive on political grounds, the positive royalty is also not necessary – one can increase the size of {P} as far as one is likely to want to by reducing the set of diseases {D}.

It is a very important aspect of my proposal that the actions that make a U.S. patent vulnerable are crystal clear and immediate. Crystal clear because the punishment for falsifying the declaration is large and there should be no room for a patentee to do so by mistake. Immediate because patents are time-limited. It is of no use to have a mechanism where the procedure to obtain recourse takes so long that the U.S. patent is close to expiring anyway,

because then the threat of loss of the U.S. market does not inspire firms to behave as desired. Under my proposal, proceedings to render a U.S. patent unenforceable can begin on the day that a suit is filed in India. A declaration such as the one above would have to be falsified on the basis of the *outcome* of a suit in India – that is, only after CiplaIndia had successfully proven that royalties of at least 5% had, in fact, been paid. Court proceedings can be slow moving anywhere, and particularly so in a developing country, so there would appear to be considerable scope for the patentee to delay the progress of such a case.

IX. Conclusion

In this paper I have outlined a policy for lowering the price of pharmaceuticals in developing countries on important diseases while at the same time maintaining the R&D incentives of research firms. Aspects of patent law, such as the foreign filing license, rules of estoppel and priority procedures; features of litigation and the drug approvals process; as well as available data sources are all used in ways not originally intended, to arrive at a mechanism that serves our purpose. The new rules would give firms new incentives, and in responding to these they would choose not to suppress competition in markets where the profit potential is small. Rarely would the procedure to render a patent unenforceable be observed, because firms would alter their behavior to avoid this outcome. Never would an outside body have to make the difficult judgement about what a patent is for, because the patentee is given an incentive to provide this information whenever it is needed (in the event of an infringement suit). The policy requires no changes in international treaties and only minor changes to our own legal code and, as a result, it is straightforward to implement.

How beneficial would this policy be? This is a difficult question to answer given our very vague understanding of the importance of any change in patent laws, including the very major changes currently underway as countries become TRIPs compliant. However, the tables showed that 'rich country' diseases are a significant source of the disease burden in the poorest countries of the world and weigh heavily on the poorest in those countries. Clearly, too, allowing these countries to have competitive suppliers would allow consumers to obtain lower prices. Absent the policy they would face either the domestic monopoly price or a yet higher world market price if global pricing concerns make patentees reluctant to tier prices. The gain from allowing competition depends on the availability of substitute products and the demand conditions in the poor countries for these diseases. Data are available that would allow the

estimation of the detailed demand models needed to make plausible estimates of price reductions and their effect on the welfare of consumers in poor countries. This work remains to be done.

Not being exclusive to poor countries, the diseases to which this policy would apply are not viewed as 'poor country diseases' and therefore have received little attention in development debates over patent policy. They should. With some creativity in designing our own patent system, we can use the excellence of our scientific research to give a big welfare boost to poor countries while supporting the full implementation of TRIPs in the developing world.

The policy can also be used in our own self-interest. There are large issues at stake in the enforcement of both intellectual property and safety regulations in a world of global internet sales. Resolving these will require cooperation at an international level and therefore a turn away from the type of polarized discussions of recent years. Positive initiatives are needed to demonstrate that the developed world can be flexible and thoughtful in pursing the interests of its own constituencies. This policy could provide one.

Table 1
Diseases for Which 99% or More of the Global Burden Fell on Low- and Middle-Income Countries in 1990

Disease	DALYs (Thousands, 1998)	Deaths per Year (Thousands, 1998)
Chagas Disease	588	17
Dengue	558	15
Ancylostomiasis and Necatoriasis	Na	na
Japanese Encephalitis	502	3
Lymphatic Filariasis	4,698	0
Malaria	39,267	1,110
Onchocerciasis-river blindness	1,069	0
Schistosomiasis	1,696	7
Tetanus	12,950	409
Trachoma	1,255	0
Trichuriasis	1,287	5
Trypanosomiasis	1,219	40
Leishmaniasis	1,707	42
Measles	30,067	882
Polio	213	2
Syphilis	4,957	159
Diphtheria	181	5
Leprosy	393	2
Pertussis	13,047	342
Diarrhoeal Diseases	72,742	2,212

Sources: Global burden from World Health Organization (1996); Figures from WHO (1999). DALYs are estimates of years of life lost or lived with a disability, adjusted for its severity.

Table 2
Disease Adjusted Life Years (DALYs) Lost

	Of Low and Middle Income Countries' Total DALYs Lost, Share of Disease	**Of Global DALYs Lost, Rich Countries' Expenditure-Weighted Share**
Cardiovascular	10%	91%
Cancers	5%	94%
Diabetes Mellitus	1%	96%
Malaria	4%	0%

Note: Low and middle income countries have a weighted average annual GDP per capita of US $1,250 and rich countries, $25,510. Weighted percentages in column 2 use 1990 per-capita drug expenditure in India and the U.S. to represent the poor and rich countries, respectively, times DALYs in 1998.
Sources: The World Health Report 1999, WHO, for disease statistics. OPPI (1996) for expenditures.

Table 3
Chronic Disease Risk Factors by Wealth – Pakistan

	Rural Percent of Sample By wealth group		Urban Percent of Sample By wealth group	
	Low	**High**	**Low**	**High**
Cancer:				
Male Smoking	35.5 (2.3)	33.7 (5.0)	57.0 (5.0)	33.0 (3.3)
Female Smoking	4.0 (0.7)	2.3 (1.2)	9.1 (2.1)	2.4 (1.0)
Cardiovascular:				
Hypertension	22.0 (1.8)	52.1 (4.7)	29.7 (4.2)	46.0 (3.8)
High Cholesterol	13.7 (1.8)	33.7 (5.7)	22.1 (3.7)	27.8 (4.0)
Percent of Population	42.0	6.0	8.0	9.0

Notes: Wealth groups are defined by the number of assets owned. Low is <3 and High is >5. Assets include items such as a fan, iron, radio, tape recorder, television. 18,315 people were surveyed and examined. Estimated standard errors are in parentheses.
Source: Pappas, *et. al.* (2001).

Table 4
Drug Expenditure Patterns in Rich and Poor Countries

	Country Percent of Total Spending in Therapy Area			
Country/Group	**Cardiovascular**	**Anti-infectives**	**Parasitology**	**Total**
6 Developed Countries	95.7	92.3	65.4	93.6
3 Developing Countries	4.3	7.7	34.6	6.4
Mexico	1.0	4.1	13.5	2.4
Country/Group	**Therapy Area as Percent of Total Spending by Country**			
6 Developed Countries	19.6	10.0	0.1	100
3 Developing Countries	12.8	12.2	1.0	100
Mexico	8.0	17.5	0.9	100

Notes: Percentages are based on expenditure for 12 months to October, 2000. Developed countries included are: U.S., Japan, Germany, France, the U.K., Italy. Developing countries are Mexico, Brazil, Argentina. This choice of countries has no significance beyond the availability of detailed spending data.
Source: Expenditure data: IMS HEALTH Global Services at www.ims-global .com.

Table 5
Income, Size and Drug Expenditures Across Countries

Country/Group	PPP per-capita 1998	Population 1998 Millions	Population as percent of Total	Country Drug Expenditure as percent of Total	Predicted Cardiovascular as percent of Total Cardiovascular
Pakistan	1715	131.6	2.2	0.30	0.12
India	2077	979.7	16.7	1.13	0.47
Indonesia	2651	203.7	3.5	0.27	0.11
Egypt	3041	61.4	1.0	0.30	0.13
China	3105	123.9	21.1	2.07	0.86
Philippines	3555	75.1	1.3	0.39	0.16
Subtotals			45.8	4.0	1.85
Venezuela	5808	23.2	0.4	0.43	0.18
Columbia	6006	40.8	0.7	0.43	0.18
Brazil	6625	165.9	2.8	1.72	0.72
Mexico	7704	95.8	1.6	1.59	0.66
South Africa	8488	41.4	0.7	0.31	0.13
Saudia Arabia	10158	20.7	0.4	0.38	0.16
Argentina	12013	36.1	0.6	1.14	0.47

Notes: Expenditure is for the year 1999. PPP is GDP per capita converted to U.S. dollars using a constant purchasing power parity index. The estimated percent of all cardiovascular expenditure represented by a given country is its percent of total expenditure multiplied by the ratio of cardivascular to total expenditure for Mexico found in the first panel of Table 3, (1.0/2.4) = 0.41.
Sources: Expenditure data: IMS HEALTH Global Services at www.ims-global .com and personal communication; Population and PPP statistics: World Bank, 2000.

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