

## A Patent Policy Proposal for Global Diseases<sup>1</sup>

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*There are two identifiable types of diseases in developing countries. Some, such as malaria, are specific to poor countries, but many others, such as cancer, have a high incidence in all countries. These differences give rise to quite distinct drug markets. In particular, for global diseases, pharmaceutical industry profits derived from having a monopoly over sales in poor countries make only a marginal contribution to total world-wide profit and therefore the incentives 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 paper describes a policy that could improve on the current patent regime by acknowledging these differences in markets and what they imply for optimal patent protection. It allows protection to strengthen for diseases specific to developing countries where a clear argument can be made that some form of new incentives are*

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*warranted. At the same time, it effectively keeps protection at its current level in situations where increased profits are less likely to generate new innovation.*

## **I. Introduction**

We are in the midst of a global expansion in the extent to which pharmaceutical innovations are protected by 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 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. Given the tradeoff between prices and innovation that is inherent in supporting R&D through a patent system, can the system be structured to elicit the same amount of innovation at a lower welfare cost? Note that, 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 and others 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. Surveys in India, for example, found that of about 12,000 deaths in rural areas (over age 14), 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 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.

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.<sup>2</sup>

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.*

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<sup>2</sup> 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.

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 policy described here 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. The following section outlines a mechanism that is simple to implement and has useful revelation and self-enforcement features that resolve these problems. The idea can be understood from this section alone. Section III addresses parallel imports and the continuance of ‘low cost sources of supply’. Discussions of some important details are found in Section IV-VI (and further discussion may be found in Lanjouw 2001). A brief discussion of some of the ways in which the proposed policy might be preferable to alternatives involving compulsory licensing and price control is in Section VII.

## **II. The Policy**

The mechanism I propose is remarkably simple to describe, and to implement. However, it is not directly obvious why it works and conveying this requires some explanation. Therefore, before turning to the idea itself, I outline its attractive features.

### ***Features***

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. 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.

### ***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.<sup>3</sup>

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. 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. There is a Cancer product based on a single innovation. This innovation is protected by a U.S. and an Indian patent, both owned by PharmaUS. PharmaUS obtains marketing approval in both countries and sells the

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<sup>3</sup> 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,

product. Now CiplaIndia (or USGeneric) enters the Indian market with its own version of the same product. PharmaUS could do one of two things. First, it may do nothing. Making this choice, PharmaUS no longer obtains monopoly profit from its Indian patent. At the same time, however, its profits from the vastly larger US market are not affected. The competition introduced by the entry of CiplaIndia lowers prices in India and the goal of the policy is obtained. But PharmaUS could make a second choice. After all, the company has a valid patent in India, may sue CiplaIndia for infringement, and will win. Nothing prevents the company from choosing to protect its monopoly profits 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.<sup>4</sup>

Suppose now that the innovation is for a Malaria product. In this case, the firm also has two choices when confronted by entry. Again it can do nothing. Again its

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the UK, Belgium, Germany, Denmark, Finland, Luxembourg, Russian Federation, and Sweden.

<sup>4</sup> 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.

alternative is to sue CiplaIndia for infringement. Now, however, the suit gives no grounds for rendering the U.S. patent unenforceable. The declaration made by PharmaUS to obtain the foreign filing license does not say anything 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. Given this choice, 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. Given this choice, it will sue in India for 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.

### **III. Parallel Imports and Low Cost Sources of Supply**

Firms have a legitimate concern about ‘low cost sources of supply’ and seepage across borders, particularly into their major markets. On the face of it, this proposal does not seem helpful in this regard since its intention is precisely to encourage low drug prices, for some products, 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 the adequate availability of drugs to poorer people. The rich world does not show any sign of being willing to supply levels of aid that would make purchases at U.S. prices feasible. Thus, the only appropriate response to the firms’ concern is to address the possibility 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 markets by suing their customers.<sup>5</sup> Internet sales also pose a safety threat to consumers. How is

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<sup>5</sup> 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

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](http://www.fda.gov/ola/2000/internetsales.html) for a discussion of current FDA concerns and efforts to combat this problem.<sup>6</sup>)

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

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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.

<sup>6</sup> 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.”

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.<sup>7</sup> 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 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.

#### **IV. Linkages**

As noted in Section II, 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***

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<sup>7</sup> See <http://ftp.fedworld.gov/pub/irs-regis/td8659.txt>

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. 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. 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

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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 must refer back to the U.S. 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 II, where a single patent protects a single product, is rare. We next consider how the mechanism would work in more complex settings.

### ***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. 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).

### ***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-participants. 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.<sup>8</sup> 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.

### ***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

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<sup>8</sup> 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.

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 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 II 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, and a procedure is needed to determine them.

They could be specified by an expert committee. However, a better alternative 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. One advantage of the latter is that the outcome would be less easily influenced by interest groups.

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. 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 coming from the poor country markets is less than some threshold value  $z$ .

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). A practical approach would be to first define a several sets of increasingly poor countries  $\{P\}$  and then determine appropriate sets of diseases for each. The use of several groups would lessen the ‘you’re in or out’ nature of the policy, and help reduce lobbying efforts.

One issue is to decide 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. 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 subsection). 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 decision criterion. The first is to measure profits. 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 vendor. These countries encompass 94.4% of 1998 world GDP measured in purchasing power parity terms (World Bank 2000 and IMS, personal communication). 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.<sup>9</sup> That said, relative gross sales figures do differ from relative profits in ways that will need to be taken account of when designing the decision criterion (see Lanjouw 2001 for a discussion.)

The fundamental decision, of course, is the choice of the threshold 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  $z$  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. Other Policy Options**

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<sup>9</sup> 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.

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 that suggested by the criterion 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 the decision criterion above. 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.

### **VIII. 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 pursuing 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**

<b>Disease</b>	<b>DALYs (Thousands, 1998)</b>	<b>Deaths per Year (Thousands, 1998)</b>
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**

	<b>Of Low and Middle Income Countries' Total DALYs Lost, Share of Disease</b>	<b>Of Global DALYs Lost, Rich Countries' Expenditure-Weighted Share</b>
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**

	<b>Rural</b> <b>Percent of Sample</b> <b>By wealth group</b>		<b>Urban</b> <b>Percent of Sample</b> <b>By wealth group</b>	
	<b>Low</b>	<b>High</b>	<b>Low</b>	<b>High</b>
<b>Cancer:</b>				
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)
<b>Cardiovascular:</b>				
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)
<b>Percent of Population</b>	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 and others. (2001).

**Table 4  
Drug Expenditure Patterns in Rich and Poor Countries**

<b>Country Percent of Total Spending in Therapy Area</b>				
<b>Country/Group</b>	<b>Cardiovascular</b>	<b>Anti-infectives</b>	<b>Parasitology</b>	<b>Total</b>
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
<b>Therapy Area as Percent of Total Spending by Country</b>				
<b>Country/Group</b>	<b>Cardiovascular</b>	<b>Anti-infectives</b>	<b>Parasitology</b>	<b>Total</b>
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
<p>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 <a href="http://www.ims-global.com">www.ims-global.com</a>.</p>				

**Table 5**  
**Income, Size and Drug Expenditures Across Countries**

<b>Country/Group</b>	<b>PPP per-capita 1998</b>	<b>Population 1998 Millions</b>	<b>Population as percent of Total</b>	<b>Country Drug Expenditure as percent of Total</b>	<b>Predicted Cardiovascular as percent of Total Cardiovascular</b>
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 cardiovascular 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](http://www.ims-global.com) and personal communication; Population and PPP statistics: World Bank, 2000.



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