

Jean O. Lanjouw

A Patent Policy Proposal for Global Diseases

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

Public concern over the price of HIV/AIDS drugs in Africa has focused 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 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 being tailored to these different markets.

This policy brief outlines a proposal that would lower the price of pharmaceuticals that treat important global diseases in developing countries, while at the same time allowing patent 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 U.S. patent law—and would cost very little to implement.

When is the Extension of Patent Rights Important?

The crux of the debate over the extension of rights in poor countries is the unavoidable tradeoff between new products and lower prices that is part of supporting research and development through a patent system. Weaker rights allow generic competition to develop, which lowers the price of existing products. Clearly this benefits current disease sufferers. On the other hand, more extensive rights give firms greater reason to invest in the creation of frontier products. However, the extension of rights to new countries varies in importance. It encourages new research investment when (i) the profits available before the addition of the new countries are very low, and (ii) the countries introducing patent protection represent a sizeable market. New rights will not have much effect when they add only a small increment to an already substantial world market.



Jean Lanjouw is a visiting fellow in Economic Studies at the Brookings Institution and associate professor of economics at Yale University. She is also a research fellow at the National Bureau of Economic Research.

The International

Two Types of Drug Markets: Global Diseases, Specific Diseases

From this perspective, the crucial observation is that there are two very different and identifiable types of drug markets. Some diseases, such as malaria, are specific to developing countries. At least twenty diseases have more than 99 percent of their disease burden in low-income countries. Without patent protection in the developing world there has been little prospect of profit from therapies for these diseases and therefore almost no private investment. New patent laws in the developing world may encourage greater research on diseases of this type.

Global diseases are those like cancer, which are widespread in both rich and poor countries. These diseases have received less attention in development debates over intellectual property because they are not specific to developing countries. However, this does not mean that they are not important causes of disability and mortality among the poor. According to a 1999 World Health Organization report, cancer and heart disease together account for 15 percent of all 'disability adjusted life years' lost in the low and middle-income countries (a statistic that combines quality of life and mortality). This is four times higher than the disease burden due to malaria. 'Rich country' diseases also cut across the income spectrum. A recent survey in India found that cancer and heart disease were the cause of 12 percent of all adult deaths in the bottom quintile of the wealth distribution.

A significant share of developing country drug expenditure goes to global diseases, which reflects the high incidences of these diseases. Spending on cardiovascular drugs alone was 8 percent of total drug expenditure in Mexico, and 13 percent of total expenditure for Mexico, Argentina, and Brazil in 2000.

At the same time, given their limited resources, spending by poor countries represents a remarkably small part of worldwide expenditure on global diseases. For example, poor countries with 46 percent of the world's population—including China, India, Indonesia, and Pakistan—collectively are estimated to account for less than 2 percent of spending on drugs for cardiovascular disease worldwide.

The disparity in spending between rich and poor countries is important. It means that the profit derived from having a patent-based monopoly over sales in poor countries makes a very limited contribution to the worldwide profits realized by pharmaceutical companies and therefore to their incentives to invest in research. Sizable incentives to invest in cancer products already exist, due to demand in rich countries. At the same time, monopolies that lead to even small drug price increases can greatly reduce the number of poor

Drug Patent Problem

people able to purchase patented drugs and the income available for other purposes among those who do.

The Proposal: Limited Patent Use

My proposal is novel in that it tailors protection to fit the vastly different worldwide markets for drugs aimed at different types of diseases. It sets up a mechanism that would only affect inventors whose patents relate to a global disease. Those patentees would effectively be required to choose to make use of their patent protection either in rich countries or in poor countries, but not both.

Because the profit potential in rich countries is much greater, owners of patents related to global diseases will naturally choose to relinquish protection in poor countries. Thus, the policy would lower prices in poor countries where greater incentives are not needed, such as in the treatment of diseases like cancer. At the same time, it would keep intact patent-based incentives for diseases such as malaria that are specific to poor countries, where there is a clear argument to be made that new incentives are warranted.

How Does It Work?

Patents are national in coverage. Obtaining protection in France or Brazil, for example, requires an application for a French or Brazilian patent. When an innovation is made in the United States, the inventor is required to apply first for a U.S. patent. To make subsequent foreign applications, the inventor must obtain a “foreign filing license” from the U.S. Patent and Trademark Office (USPTO). This rule is in place to protect military secrets, and variants are found in patent regulations in other countries.

The policy proposed here is simply to require something like the following declaration in the request for a foreign filing license:

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’.

In reality, rather than ‘cancer’ and ‘India,’ the declaration would specify one or more groups of poor countries and corresponding groups of diseases.

For global diseases, the profit derived from having a patent-based monopoly in poor countries makes a very limited contribution to the worldwide profits realized by pharmaceutical companies.

To understand how the proposal would work, suppose there were three hypothetical pharmaceutical companies: PharmaUS, a research-based multinational, CiplaIndia, an India-based firm, and USGeneric, a generics producer. PharmaUS has a cancer drug protected by a single patent in the United States and a corresponding patent in India, and the company sells the product in both countries. Then CiplaIndia (or USGeneric) enters the Indian market with its own version of the same product. PharmaUS can choose to do one of three things:

- compete
- withdraw from the Indian market
- sue CiplaIndia for patent infringement.

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Under my proposal, nothing prevents PharmaUS from choosing to protect its rights in India. But if it does, then either CiplaIndia or, more likely, USGeneric, can go to USPTO and claim that, by attempting to stop CiplaIndia's sales of the cancer drug in India, PharmaUS has rendered its U.S. patent unenforceable. This is so because, by taking this action, PharmaUS has falsified the rich-or-poor declaration it made to USPTO to obtain the foreign filing license.

Patentees have a duty to deal with the patent office in good faith, and failure in this regard is clear grounds for rendering a patent unenforceable. If the drug innovation had been for a malaria product, however, a 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 the likely result? PharmaUS will not sue in India for infringement of cancer product patents because to do so would jeopardize its U.S. patents, and the United States is a much bigger market for cancer drugs than India. Knowing this, CiplaIndia will enter the market and prices in India will fall. However, PharmaUS 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 pharmaceutical companies to invest in malaria products.

Advantages of the Proposal

The proposed policy has several key advantages:

- It does not contravene existing treaties.
- It can be implemented unilaterally, although it would be most effective and acceptable to all parties if the industrialized countries were to coordinate and adopt similar policies.
- It does not require any changes whatsoever to less developed countries' (LDC) new patent systems or the development of their enforcement procedures.

- The mechanism relies on the quality and reliability of institutions in the countries implementing the policy and not on the institutions in developing countries.
- The policy would be fully controlled by those governments implementing the policy, which would protect it from domestic political pressures in less developed countries. This is in contrast to compulsory licensing by LDC governments, where pressure by local interests to expand coverage to all diseases would be difficult for the domestic government to resist.
- The mechanism does not require information that is not available. Most important, it does not require that patents be examined and identified as being for a particular disease. The policy mechanism induces firms to volunteer the link between patents and products when the information becomes known and only as necessary (i.e., in the event of a lawsuit).
- Firms are free from outside control or monitoring. Rather, incentives are aligned to make use of the better information available to firms about the relative size of global markets for different products.
- 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. It need not be seen as an alternative to other policies within the constraints of fixed health or development budgets.

Choosing Countries, Measuring Profit Potential

Under the policy, the U.S. Patent and Trademark Office would have a transparent and objective procedure to determine the composition of the groups of countries and diseases included, and would update the license declaration periodically as markets evolve and countries develop. For a specified group of poor countries, the procedure would identify a group of truly ‘global’ diseases—those for which the percentage of the total potential profit coming from the group of poor country markets represents less than some threshold share.

The proposed policy would be flexible regarding whether to restrict coverage to just the very poorest countries and include a broad set of diseases, or to target a wider group of countries and define the diseases more narrowly. A practical approach might be a combination: to specify several sets of increasingly poor countries and then determine appropriate diseases to include for each.

In order to implement the procedure, USPTO would need a measure of ‘potential profits,’ which could be estimated from pharmaceutical sales data that are already collected regularly. The patent office also would need to know the market share threshold for drug sales in poor countries. A small, 2 percent share, for example, would cause a disease to fall under the policy if expected profits from sales of treatment drugs in poor countries represented less than 2 percent of total global profits. Increasing the threshold share would allow the policy to cover a larger number of diseases and confer greater benefits on the poor, but would begin to more significantly dampen research incentives.

Which Patents Protect a Product?

The proposed mechanism is triggered by a lawsuit. One important reason for this feature is that when an infringement suit is 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 its suit, the patent owning firm has an incentive to correctly announce which patents it believes best protect the product in question. Thus, the link between products and patents is made automatically, which resolves the otherwise intractable problem of how to identify the use of particular patents.

Which Products are for Which Diseases?

The patent office also needs a clear procedure for determining when a particular Indian product corresponds to a particular disease. In my hypothetical example, CiplaIndia or USGeneric will always have an incentive to claim that a disputed product is for cancer so as to render unenforceable the U.S. patent of PharmaUS, while the latter will claim all products are for malaria.

All products marketed in the United States are approved by the Food and Drug Administration (FDA) for specific indications. Therefore, the problem could be resolved as follows: to render unenforceable PharmaUS's patent, CiplaIndia, (or USGeneric) must take the Indian product and apply to the U.S. FDA for an abbreviated new drug approval. In doing this, CiplaIndia would claim the Indian product's equivalence to one already marketed in the United States with a cancer indication (or other global disease). The procedure would be precisely the same as that already followed for any generic drug on the expiration of a patent on the original. If the FDA issues tentative approval, or a preliminary letter of bioequivalency, the case that the Indian product is for cancer would be made.

Preventing Arbitrage from Poor to Rich Countries—Advantages for Firms

Firms have a legitimate concern about 'low cost sources of supply' and seepage across borders 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. Pharmaceutical firms may well object to it on these grounds. However, there must be 'low cost sources' if there is to be any hope of ensuring the adequate availability of drugs to poorer people. The rich world will not supply levels of aid to developing countries that would make purchases at U.S. prices feasible. Thus, the only appropriate response is to devise means to enable the separation of markets, not to raise prices throughout the world.

A first step might be legislative confirmation that the United States does not have an international exhaustion of rights doctrine, which would state clearly that holders of U.S. patents have the right to prevent products from coming into the United States from elsewhere, even if the products were originally sold by the patentholders' own licensees or subsidiaries.

Enforcement is the bigger issue, however. Drugs are small and lightweight, which makes it difficult to prevent products sold cheaply in a country where consumers are poor from flowing back into markets where people will readily pay more for them. This is certain to be a far greater problem in an era of Internet sales, with hundreds of thousands of pills crossing international borders in small, inconspicuous packages. Patentees will be hard pressed to identify such individual infringements and reluctant to enforce a separation of markets by suing their customers. Internet sales also pose a safety threat. How is one to know that a web-based pharmacy is actually in North Carolina and not a counterfeit operation based overseas?

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 in a way that would be apparent to their populations. It would seem reasonable to expect that leaders of these countries, in turn, would make efforts to ensure that drugs priced for their consumers do not leave their countries. This could be accomplished in a variety of ways. For example, health authorities in all countries already specify features of drug appearance and packaging. One could ask poor countries that are candidates for inclusion under the policy to require that pharmaceuticals sold in their countries have certain identifiable characteristics.

The proposal has other advantages. It provides an alternative to untargeted policies now being suggested, such as across-the-board compulsory licensing of pharmaceutical patents or price controls. Given the climate of discontent with the current patent regime, and efforts to weaken it, some move away from the strongest level of protection will probably be necessary. The simple policy proposed here—which requires only a modest change in the patent laws of rich countries—would be a controlled move designed to preserve incentives where they are needed most. Meanwhile, poor countries would continue to develop their patent systems fully and no questions would be raised about their compliance with World Trade Organization membership requirements. This would help shift international patent issues out of the realm of continuous dispute and put discussions on a more cooperative footing.

Conclusion

This brief has outlined a policy for lowering the price of pharmaceuticals in developing countries for important diseases while at the same time maintaining the research and development incentives of research-based firms. The policy requires no changes in international treaties, only minor changes to our own legal code, and would cost little to implement.

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The diseases to which this policy would apply are not viewed as 'poor country diseases,' because they are not exclusive to poor countries. As a result, they have not received attention in development debates over patent policy. They should. If industrialized countries used some creativity in redesigning their patent systems, they could give a big welfare boost to poor countries while supporting the full implementation of patent systems in the developing world.

There are also 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.

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