For many years, governments, drug companies and a variety of advocacy groups have been battling over patent protection for pharmaceuticals in poor countries. In particular, the fight involves the standards required for membership in the World Trade Organization – requirements known as Trade-Related aspects of Intellectual Property, or TRIPS, rules. These provisions were a source of bitter controversy during the Uruguay round of trade negotiations in the 1980s.

The pharmaceutical industry resolutely insisted that worldwide protection was crucial to sustain research on drugs. Poor countries, for their part, were equally adamant that patent rights should not limit their ability to produce or buy lower-cost generic versions for their own local markets. In the mid-1990s, the force of the AIDS epidemic moved this controversy out of the obscure realm of trade negotiations and onto the front pages of the newspapers as a major health and economic development issue to be fought out in the public arena.

Today, that sense of urgency has waned. Rich countries are beginning to earmark significant funds to purchase antiretroviral drugs, used for treating AIDS, for distribution to low-income countries. And last August, on the eve of the WTO ministerial meeting in Cancun, an agreement was reached on rules governing the export of drugs under compulsory license to supply countries lacking the

JENNY LANJOUW is a senior fellow at both the Brookings Institution and the Center for Global Development in Washington, and is an associate professor in the agricultural and resource economics department at the University of California (Berkeley).
ability to manufacture their own. Meanwhile, GlaxoSmithKline and Boehringer Ingelheim announced that they would license the production of their patented antiretrovirals for distribution in South Africa – ground-zero of the AIDS pandemic.

Thus, after years of frustrated efforts to reach a sensible resolution to the patent controversy, it is now tempting to declare victory and turn to other policy challenges. There are, after all, many barriers to drug access in poor countries ranging from income to transportation to health care infrastructure, and it may seem a distraction to continue arguing over protection of intellectual property rights.

Not quite. Moves to increase access to lifesaving drugs are surely good news, but the patent problem has hardly been solved. The complex and uncertain rules that define the current system for protecting intellectual property will continue to be a source of international tension. And it would be a shame to let reforms drift off the proverbial radar screen. Building health infrastructure in poor countries will never be easy – it will take time and sizeable resources. Improving the patent system just takes political will.

WHAT IS THE CURRENT SYSTEM?

Some developing countries that are members of the WTO have until January 2005 to implement TRIPS standards; others have until January 2016. The Doha Declaration on the TRIPS Agreement and Public Health, issued two years ago, allows a specified group of “least developed countries” to defer, or not enforce, pharmaceutical patent rights for more than a decade. Taking advantage of these opportunities for extension, however, is at the discretion of individual nations’ governments, and some countries have been urged to choose faster implementation. Cambodia and Nepal, the first of the least developed countries to join the WTO after its creation, did not opt for the extension, instead agreeing to a 2007 date.

Moreover, some countries are being pressed to implement so-called “TRIPS-plus” provisions that extend beyond the WTO minimum standards as the price of invitations to bilateral trade deals with rich countries. The tensions involved in this process are perfectly captured in the 2002 law that set priorities for United States negotiators.

That law requires U.S. negotiators to ask for accelerated implementation of TRIPS and mandates that any multilateral or bilateral trade agreement entered into by the United States “reflect a standard of protection similar to that found in United States law.” At the same time, negotiators were told to respect the Doha Declaration.

What’s more, some of the flexibilities built into TRIPS to assuage poor-country concerns are problematic. In principle, they allow countries to issue licenses for the production and sale of generic versions of patented drugs to address public health problems. But, as the case of South Africa shows, the system is a tangle.

For its own political reasons, South Africa’s health ministry refused to issue compulsory licenses for the sale of generic antiretrovirals for AIDS treatment. But in October, the country’s Competition Commission took an indirect route to getting generics into use, attacking the monopoly inherent in patent rights by upholding a claim that patentees had engaged in excessive pricing. This ruling elicited the licensing offer by GlaxoSmithKline and Boehringer Ingelheim, noted above, as an out-of-court settlement.

South Africa will thus get antiretrovirals at well below the price charged in rich countries. But it took years of focused campaigning,
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persistent media attention, and legal and regulatory wrangling to get there. This process can hardly serve as a template for resolving the tensions inherent in property rights in most pharmaceuticals. Because patents are national in scope – there is no such thing as a global patent – a generics firm hoping to achieve economies of scale in production by supplying a group of, say, 20 poor countries would need to obtain a license on relevant patents in each of those countries as well as at home.

To take another example, consider the international agreement last August in Cancun that allows firms to produce pharmaceuticals for export under compulsory license in cases where recipient countries cannot produce their own. The deal was greeted with
relief after nine months of diplomatic deadlock. However, its terms include a remarkable list of conditions on all parties trying to follow the letter of the agreement – conditions that are likely to make it unworkable in practice.

What’s more, the terms of the August agreement are so vague – as are the procedures and timing for complaints by patent-holders – that uncertainty will make exporters of generics reluctant to enter foreign markets. The Canadian prime minister has declared that Canada will take a first step toward implementing the agreement by allowing its manufacturers to respond to export requests. But the proposed Canadian legislation enabling generic drug exports adds yet further restrictions to those imposed by the August WTO agreement.

The Canadians would, for example, limit coverage to a defined set of eligible pharmaceuticals. The WTO agreement does not require that. The proposed Canadian legislation would also give patentholders a chance to match the price offered by any generic manufacturer, and thereby forestall issuance of a license. This reduces the incentive for generics makers to bid to enter markets in the first place.

**How Did We Get Here?**

Most people recognize both the value of the contributions to global health that have come from private pharmaceutical research and the fact that the patent system plays a pivotal role in supporting that research. By the same token, most recognize that markets in the poorest countries are not a significant part of this incentive equation. But it has proven very difficult to draw lines separating the markets that matter from the perspective of innovation incentives and those that do not – and to do it in a way that is both clear and reasonable. “Everyone agrees we should do something for the very poorest countries,” Daniel Vasella, the chief executive of Novartis, acknowledged. “But if we expand that to cover all countries other than the richest and to cover all diseases, that will completely undermine intellectual property.”

Confronted with a situation in which it is hard to draw lines, the industry has understandably tried to obtain the strongest protections possible using whatever means were available. Inevitably, they have overreached, provoking the ire of economic development activists, poor-country governments and public opinion at home.

There is a way to resolve the dilemma – a way to create a mechanism for defining and implementing a more rational structure of global protection. It would give the fullest protection where research incentives are currently weak (e.g., drugs for malaria), while at the same time facilitating competition from generic drugs in poorer countries for treating diseases like cancer and heart disease, where developed-country markets already provide strong research incentives. What’s more, the mechanism would evolve automatically in response to the economic maturity of countries and changes in market opportunities.

**The Foreign-Filing License Solution**

The proposed mechanism involves a straightforward change in legislation in rich countries and – in the rare cases where it might require enforcement – uses existing infrastructure in those countries only. It imposes no regulatory burden on developing countries.

Under the plan, some countries would be allowed access to generics immediately, but only as long as their markets represent a very small portion of global demand – say, no more than 2 percent of sales in the aggregate. Which countries qualified would depend on
income level – the poorest would benefit the most – and on the disease.

For example, drugs aimed at malaria would be protected in most countries, because the low-income countries are a more significant share of the market. Drugs to treat, say, high blood pressure, prostate cancer or acid-reflux disease are mostly sold in the rich countries, so many poor countries could be open to generics. For countries above some average income threshold – perhaps $5,000 a year – all patented drugs would receive full protection, regardless of demand.

Arguably, the most important part of the plan is how little it asks of developing-country governments. They do not need to change their patent laws or enforcement procedures, or make complex decisions about compulsory licensing. Although the regulatory approach

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is aimed at changing access to drugs in poor countries, it would not require them to regulate anything. In fact, their obligations under TRIPS would stay just as they are now.

The mechanism is exceedingly simple. Take the example of a drug that has been invented in the United States and is freshly patented. Under current U.S. regulations, the owner of the patent is obligated to obtain permission from Washington before it can apply for parallel patent protection in other countries (the foreign filing license). The proposal would simply require the patent holder to sign a declaration in order to obtain this permission – a declaration that the permission being sought would not be used to restrict the sale of the drug in poor countries with minimal demand. If the patent owner later reneged by pressing its patent claims against competitors in a proscribed market, it would put at risk its right to enforce the patent in the United States, where it really mattered.

Adjustments in coverage would follow automatically from changes in market conditions. So, for example, India would be allowed easy access to generics initially, but the country would grow into patent protection as its economy blossomed. This extension in protection would not require the Indian government to change its laws or to invest additional resources in policing patents. All of the institutions required to implement and operate the system are already in place in the rich countries.

Note that the approach does not limit protection for intellectual property actually created in low-income countries; nor does it undermine incentives to invest in home-grown R&D. The policy would apply only to inventions in high-income countries; inventors in poor countries would continue to enjoy whatever protection is offered by their own governments. To put it another way, it would give local inventors a chance to develop an appreciation of the patent system, and would give governments an incentive to build the enforcement capability necessary for a patent system to really work.

Note, too, that the plan avoids the objectionable process of designating countries as part of the very-poor group. The only income-based dividing line would be between countries with incomes above $5,000 per capita and those below. And since the approach would not alter the text of the TRIPS agreement, existing flexibility in TRIPS would remain to address public health concerns in countries falling outside the scope of the policy.

In sum, both existing rights and obligations would remain in place. Companies would simply forego exercising their rights in the poorest countries, thereby removing the major area of disagreement.

**DIFFERENT DISEASES, DIFFERENT MARKETS**

The key to the proposal is, of course, the real-
ity that pharmaceutical markets are extremely different, depending on the disease that is treated. Consider truly global diseases first – those that are prevalent worldwide. Global diseases impose an enormous health cost on poor countries. HIV/AIDS is the first that comes to mind, but there are many others. For example, the World Health Organization estimates that the health burden in poor countries from two global diseases, cancer and heart disease, is four times the burden on those countries due to malaria. Yet the incentives for industry to develop drugs to treat such diseases lie almost exclusively in demand from affluent economies. To take one example, countries with about one half of the world’s population contribute less than 2 percent to spending on cardiovascular drugs.

On the other end of the spectrum, there is an urgent need for more investment in diseases that primarily affect poor countries. In 2001, two million children died from malaria, but spending on malaria research represents less than one-half of 1 percent of the total investment in drug R&D globally. It should be no surprise, then, that only 8 of 1,233 drugs licensed by the United States Food and Drug Administration from 1975 to 1997 were developed specifically for tropical diseases in humans. If there is to be a market for drugs treating these diseases, much of it must lie in low-income countries.

Would enforcing strong patent rights in developing countries further the research effort on diseases that bedevil these countries? Incentives to invest are weak not only because of limited patent protection in the developing world, but also because people there are poor. In 1998, 17 countries spent no more than $10 per person annually on all health expenditures. But it is equally clear that current policies have largely failed to generate products for the particular health needs of the world’s poor.

The prospect of strong patent rights in poor countries world would not cause industry to reorient its research priorities toward developing-countries’ needs. But global private-sector R&D in pharmaceuticals is enormous – $32 billion in 2002 – and it continues to grow. So even a modest shift in priorities in response to the modest increase in poor-country demand for new drugs would represent a significant gain.

**PIE IN THE SKY OR COMMON SENSE?**

Although the fight over defining the scope of patent rights for drugs is proving extremely persistent and difficult to settle, it does not stem from inherently conflicting goals. The pharmaceutical industry wants, above all, to protect its rights in rich economies, and it would like to see effective protection evolve in poorer countries as they grow into more
attractive markets. Making profits in the low-income countries is simply not an industry objective.

For their part, the economic development community is primarily concerned with keeping drug prices low in the poorest countries. These are not opposing objectives.

This proposal offers a fix that respects the underlying logic of the patent system. The right lines can be drawn in the trade-off between prices and investment incentives because different lines can be drawn for different products.

The mechanics of implementing this proposal are straightforward. The industry must decide that a virtually costless compromise on a more acceptable patent system is a whole lot better than trench warfare over drug access in low-income countries. There remain divergent views within and between organizations on this point. Those who have been most involved in the debate would have to be convinced that the solution described here does not create dangerous precedents. And this would require some thinking outside the box.

If consensus can be reached, the governments of countries with research-based pharmaceutical sectors would probably want to coordinate the implementation – though it could be done unilaterally. This group includes the United States, Canada, the European community and Japan. Each country would revise its patent code to add a foreign filing license provision (if one is not already there), with the requirement to sign the declaration and other details.

The approach would plainly not solve every problem associated with disparities in access to lifesaving drugs. Moreover, controversy over the strength of patent rights would continue with respect to countries above the income cutoff. There might still be an argument, for example, over whether Eastern European transition states should be held to different standards than the richest countries. What the policy would do is provide a simple way to remove the poorest countries from the patent debate, so that their access to new pharmaceuticals would not be needlessly complicated by rules made to protect other markets.

Some analysts have suggested that efforts to define such a middle ground on drug patent protection are hopeless because both sides have dug in. But compromise is happening in an ad hoc fashion in the context of specific disputes. This proposal offers a fix that respects the underlying logic of the patent system.

The right lines can be drawn in the trade-off between prices and investment incentives because different lines can be drawn for different products. The proposal asks pharmaceutical companies to take a more defensible position on global patents, but one that protects their significant markets. It asks lower-income countries to give private enterprise meaningful patent rights where those rights can possibly contribute to innovation.

Sometimes, it seems, free lunches really can be almost free.