Center for Global Development

CGD Brief

August 2002 Volume 1, Issue 3

Beyond TRIPS: A New Global Patent Regime

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Summary: A fierce dispute is raging over global pharmaceutical patents. The debate centers on a fundamental tension between pricing and incentives. Patents may raise the prices of pharmaceutical drugs paid by governments and consumers in poor countries, depriving millions of sick people access to medicine. Yet patents may also provide incentives for corporate investment in research on lifesaving drugs. Missing from the debate is an understanding that the costs and benefits of pharmaceutical patents vary with the characteristics of different drug markets. The incentives to invest in research on "global diseases" that are prevalent in developed and developing countries are very different from the investment incentives for diseases that primarily affect developing countries. A rational patent system would differentiate the extent of protection given to products in accordance with their extremely different global markets and existing research incentives. I present here a proposal for constructing such a global patent regime, which could be a reasonable compromise to the current bitter dispute. It allows the right line to be drawn between prices and incentives because different lines can be drawn for different products.

At the conclusion of the Uruguay Round in 1994, the founding members of the new World Trade Organization (WTO) signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which mandated the extension of patents on pharmaceuticals and other innovations in all member countries, including those in the developing world. This decision sparked fierce criticism, which has only intensified in recent years. While industry insists on the benefits of strong patents on all drug innovations in all countries, activists for the poor are equally adamant that inventors should have very limited rights to control pharmaceutical sales in the developing world, or no rights at all.

The debate centers on a fundamental tension between pricing and incentives. Patents may raise the pharmaceutical prices paid by governments and consumers in poor countries, depriving millions of sick people access to medicine. Yet patents may also provide incentives for corporate investment in research on lifesaving drugs. This debate has unfolded in a number of highly publi-

* This brief is based on two recent papers: (1) Lanjouw, Jean O. (2002a) "Intellectual Property and the Availability of Pharmaceuticals in Poor Countries," Center for Global Development Working Paper No. 5 and Innovation Policy and the Economy, vol. 3. (forthcoming); (2) Lanjouw, Jean O. (2002b) "A Patent Proposal for Global Diseases: U.S. and International Legal Issues," Harvard Journal of Law & Technology (forthcoming, Fall 2002).

cized court cases and international disputes that have hardened positions, absorbed considerable time and money, and made dialogue on the issue increasingly difficult. (Box 1 describes some of this history.)

What is missing from the debate is an understanding that the costs and benefits of pharmaceutical patents vary with the characteristics of different diseases. Many diseases are prevalent across the globe. For these "global diseases," the incentive to invest in research is derived predominately from developed countries because of the vast disparity in market size in comparison to poor countries. For products with global markets, extending patent rights will raise prices in poorer countries while contributing little to incentives. Other diseases primarily affect poor countries. Very little research has been devoted to these diseases, so increasing such investment is the primary policy challenge. While the prospect of obtaining patents will not itself attract substantial private investment since purchasing power in poor countries is low, even a small increase in incentives to invest may be a useful part of a larger strategy. Specific programs designed to boost research on products for the developing world will still be needed. The proposal described here to establish more appropriate patent rights should be viewed as complementary to those targeted efforts.

Regardless of one's views on the effectiveness of patents in poor countries, it is clear that some compromise will be necessary in the bitter dispute over global pharmaceutical patents. (Box 2 describes recent steps at Doha.) Given this, it would make sense to compromise on a system with a rational structure—one that differentiates the extent of protection given to products in accordance with their extremely different global markets and existing research incentives. I present here a way to construct such a global patent regime.

Why have patents in poor countries at all?

There is an urgent need for more investment in diseases that primarily affect developing countries. Many of these diseases afflict millions of people every year yet have received almost no research investment from the private sector and little from the public sector. In 2001, 2 million children in developing countries died from malaria, but spending on malaria research is less than one-half of one percent of what is spent annually on global private-sector R&D.[2] Just 1.5 percent of all references to diseases in scientific papers and 0.5 percent of pharmaceutical patents were related to diseases that are specific to developing countries in 1998. Only 8 of 1,233 drugs licensed from 1975 to 1997—less than one percent—were developed specifically for tropical diseases in humans.

Can new patent rights improve the situation? One might argue that they will be irrelevant. Clearly, market-based incentives to invest are weak not just 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 (U.S.) per person annually on all health expenditures, not just pharmaceuticals. But it is equally clear that current policies have largely failed to generate innovation or products for the particular health needs of the poor.

The prospect of greater patent protection in the developing world is not going to cause industry to refocus research priorities dramatically and single-handedly resolve this problem. But private-sector skills and even a modest share of its resources could bolster more ambitious public and philanthropic efforts. Global private-sector R&D in pharmaceuticals topped $30 billion in 2001 and continues to grow. Patents that shift even a tiny fraction of that investment in the direction of products for poor countries would

Box 1: The Damaging Dispute over Pharmaceutical Patents

In the seven years since the TRIPS Agreement took effect, we have seen a pharmaceutical-industry coalition sue the South African government with the support of the vice president of the United States—support that was then retracted in response to domestic political pressure. We've seen the U.S. Trade Representative enmeshed in disputes with the Brazilian government over generic drugs; Pfizer and Glaxo Wellcome[1] have been targeted by major OXFAM campaigns ("Patient Rights before Patent Rights"); and TRIPS, debates over drug prices, and the tragedy of AIDS have been regular features in the world press and op-ed pages.

The continuing dispute damages everyone. Absent a consensus approach, pressure groups are driving changes in patent rules and using media campaigns to target the prices of particular drugs. This makes it impossible for firms to predict future markets in poor countries, forecasting that is crucial for making long-term investments in products for those markets. The negative publicity surrounding TRIPS feeds public suspicion of the purported benefits of drug patents. This has political repercussions, reflected in proposals to force down the price of the patented drug ciprofloxacin (Cipro) in the U.S., which was used to treat anthrax infections in 2001, and in support for legislation to allow the import of lower-priced versions of drugs that have patent protection in the U.S. The dispute breeds distrust among developing country governments, industry, and their advocates. This is particularly harmful now, since we will soon need far greater cooperation among these parties in order to cope better with the serious problem of illegal trade and drug safety in a world of Internet sales.

1 Now GlaxoSmithKline.
2 Total spending on malaria research was $100 million in 1998, according to the Wellcome Trust's latest report, "Malaria Research Capacity in Africa," http://www.wellcome.ac.uk/en/images/MIM_report99_2000.pdf.

be significant. Again, an appropriate patent system could complement programs that are directly addressing the lack of research through various financing schemes.

Different diseases, different markets

For diseases specific to developing countries, patents may help direct more research where it is so badly needed. But global diseases also impose heavy costs in poor countries. Consider: The disease burden in developing countries from two global diseases—cancer and heart disease—is four times the burden from malaria.[3] For these diseases, patent protection in rich-country markets already provides enormous incentives to invest in research. These incentives dwarf any possible contribution from the developing world. In Box 3, I articulate this point using the example of AIDS, a disease for which developed-country markets supply substantial incentives to invest despite the fact that the majority of those infected live in developing countries. Another example is heart disease, for which countries with about one-half of the world's population contribute less than two percent to spending on cardiovascular drugs.

While it may be important to give inventors protection in poor countries to increase research on diseases such as malaria, it is less obvious that the same policy should be used to promote or reward research on a global disease like cancer.

The Proposal

How, then, can we build a global system that links patent protection for pharmaceuticals to varying global market conditions?

The proposed mechanism involves a straightforward change in legislation in rich countries, and in the rare cases that it might require enforcement, it would use the existing infrastructure in those countries. The mechanism imposes no regulatory burden on developing countries. The idea is this: Whenever patent owners are dealing with a pharmaceutical innovation related to a listed global disease, the mechanism effectively requires owners to choose either protection in the rich countries or protection in the poor countries, but not both. Given this choice, such patentees would obviously choose to maintain patent protection in rich-country markets and allow competition in the poor countries.

Box 2: What Happened at Doha?

Pharmaceutical patents were the main source of friction at the WTO Ministerial Conference held in Doha, Qatar, at the end of 2001. After extensive debate, ministers adopted the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), in which they affirmed that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to…promote access to medicines for all." Although it does not change the legal provisions in the TRIPS Agreement, the declaration will provide an influential interpretation of imprecise obligations. From a political standpoint, the Doha Declaration shifts the burden of proof onto patent holders who want to exercise control over sales of their innovative drugs in developing countries. The declaration also extends from 2006 to 2016 the deadline for the full implementation of pharmaceutical patent protection in the least developed countries—49 of the poorest countries with small markets.

These recent steps implicitly recognize that the trade-offs associated with patents are different for many poor countries. The proposal described in this brief builds on the same fundamental idea. The mechanism would allow even greater recognition of the relative merits of patent rights in different circumstances and would institutionalize these basic ideas without requiring burdensome administration or continued political negotiations.

Box 3: AIDS: Incentives for Investment

Perhaps the highest-profile global disease is HIV/AIDS. The vast majority of those infected with HIV live in developing countries. Yet countries with per capita incomes of less than $2,500 together contributed less than one-half of one percent to global spending on anti-retroviral drugs in 1999 (IMF and World Bank data; author's calculation). The incentive to invest in research rests squarely in developed countries, regardless of the patent regime in poor countries. In fact, the drug industry points out that it often does not patent products in the poorest countries even when the opportunity is available since there is so little prospect of profit. This is supported by a report on the status of 15 anti-retroviral drugs in 53 African countries in mid-2001. Outside of South Africa, where 13 of the 15 drugs had been patented, the median number of anti-retroviral drugs under protection was found to be just three per country.

3 Disease burden in DALYs (disease adjusted life years lost), a measure capturing mortality and morbidity.

Owners of patents related to nonglobal diseases, on the other hand, would be provided protection worldwide.

Here is how the mechanism could be implemented by the U.S.[4]

The policy would use an already existing regulation that requires inventors in the U.S. to request a "foreign filing license" from the U.S. patent office before filing patent applications abroad; under the proposed reform, a patentee who petitions for this license would sign a declaration along these lines:

> *I, the undersigned, request a license to make foreign patent filings covering the invention described in U.S. patent application 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."*

"Cancer" is a proxy here for lists of global diseases, and "India" is a proxy for related lists of poor countries.

Why does it work?

Suppose that an innovating firm has signed the declaration and has obtained patents in the U.S. and in poor countries. If a generic competitor began to sell a patented product in a poor country, the firm that owns the patent would have three options. It could

- compete
- exit the market, or
- sue for infringement.

If the firm chooses to compete or exit, it does not make use of its patent rights in the poor country. If it chooses to sue, it protects its poor-country market on the basis of its patent there. However, if the firm's product is for a listed global disease, by filing a suit it will have falsified its declaration to the U.S. patent office, making its U.S. patent unenforceable and allowing generics to be sold in the U.S. market. This is the trick that makes the declaration work. Because of the enormous difference in the size of the markets, the firm will choose not to enforce its rights in the poor countries, and generic competition will be allowed to lower prices.

For products that are not for listed global diseases, the policy would have no effect: protection would be available worldwide, encouraging research.

What is a global disease?

A simple and objective procedure would be needed to distinguish global from nonglobal diseases. It is important to stress here that the terms global and nonglobal refer to the market for a disease treatment, not to the disease's incidence. The patent office would update the license declaration periodically—say, every two years—following the stated procedure and would not make any of its own judgments about the declaration's content.

A practical approach would be to set up a procedure with two steps, the first identifying increasingly broad groups of poor countries, and the second identifying appropriate global diseases for each group. For example:

Step 1: Ask countries whether they object to being included on the declaration. Place those with a GDP per capita that is less than $500 (constant U.S. dollars) in group A; those with less than $2,500 in group B; and those with less than $5,000 in group C. (Note that the poorest countries in group A are also in B and C, and so on.)

Step 2: Using data on pharmaceutical sales by disease class, calculate for each class the total world sales and then determine the sales in each of the country groups A, B, and C. Include on disease list A all classes for which the sales for country group A are less than two percent of world sales, and similarly for disease lists B and C.

For the poorest of poor countries in group A, all disease classes would probably qualify as global and, effectively, no protection would yet be afforded pharmaceuticals in those countries. Moving to B, the country group gets larger and also somewhat richer. Some disease classes may no longer qualify as global, and firms would be able to obtain patent protection for products related to those. For the largest group, the group that includes C, only a few diseases would qualify, and patent protection would widen further. This example illustrates how the procedure could be structured, though other GDP cutoffs and more country groups could be chosen. Similarly, a number other than two percent might be appropriate.

Linking products and diseases

If the patent-owning firm chooses to sue for infringement, a clear procedure is needed to determine whether a generic product sold in the poor-country market is for a listed global disease. In practice, this could work as follows: All products are approved for marketing for specific indications. The generic firm would be required to apply to the U.S. FDA (or similar European authority) for an abbreviated new-drug approval of its product. The firm would claim the product's equivalence to one already marketed for a listed global disease. The procedure would be precisely the same as the procedure already followed by makers of generics when patented products expire. A report confirming bioequivalence from one of these authorities would establish the generic as a global-disease product.

4 Legal issues for the U.S. and other countries, as well as other details, are in Lanjouw 2002a and 2002b.

Advantages of the policy

This approach would have several advantages:

- **Compatible with the WTO TRIPS Agreement.** No amendment of TRIPS is required.

- **Low cost.** The policy is self-enforcing. Because doing so would put major markets in jeopardy, firms would rarely choose to trigger an event (a suit) that would make it necessary to classify a product. Should a suit arise, only information available through existing administrative and legal procedures is needed to determine if the declaration has been falsified. Monitoring would be done by generic firms having a strong interest in entering the U.S. market. As a result, the policy would require almost no government expenditure on administration or enforcement.

- **Limited lobbying opportunities**. Clear procedures determine the country and disease groups that are listed in the declaration, and the legislation to establish the procedures is required only in the developed countries and only at the time of implementation. This insulates the policy from the effects of subsequent lobbying by firms and by patient groups in the developing world.

- **Uses market information**. The policy utilizes firms' knowledge of the relative importance of markets. For example, suppose that AIDS were a listed global disease but that there were a particular form of AIDS specific to Africa or, alternatively, a drug-delivery system particularly suited to African conditions. For products treating this specific form of AIDS, or for products related to this delivery system, inventors could choose to protect their markets in Africa, and any profits available to support innovation would be preserved.

- **Combines certainty with flexibility**. The effective patent rights available to a firm with respect to a particular innovation are determined by the content of the declaration when it is signed. These remain the same throughout the life of the patent, and the firm can make its marketing decisions accordingly. At the same time, the content of the declaration evolves. A country starting out in group B, for instance, would move to group C as it grew richer, and eventually it would not be included in the declaration. The result would be a global patent regime that would automatically evolve in line with the development level of countries and the importance of different product markets

Moving beyond the roadblocks

The global debate over access to medicines and patent rights is deadlocked. Positions are hardened and the stakes are high. Firms still believe they are in control, and they are reluctant to depart from a strategy of crisis management. Advocates see people dying and throw their energy into the fight for dramatic change. They have little appetite for reforms that take time. Guardians of the patent system worry about what they see as "tinkering" with the system to pursue social goals, even though that is its rationale in the first place. As is only natural, people are hesitant when confronted by new ideas.

Many have suggested that efforts to find middle ground are pointless because neither side will give any ground when it comes to patent rights. But compromise is unavoidable. The real question is whether we want to accept a global patent framework that is the product of political horse-trading. This proposal provides a reasonable compromise. The right line can be drawn between prices and incentives because different lines can be drawn for different products. The proposal asks firms to take a more defensible position on global patents, but one that protects their significant markets. It asks developing countries to give firms meaningful patent rights where those rights can possibly contribute to innovation. It can be implemented at almost no cost.

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For research and other background on global patent and intellectual property rights issues, go to www.cgdev.org.

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