

## Beyond TRIPS: A New Global Patent Regime Frequently Asked Questions

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### 1. Doesn't this policy create a problem of gray market imports into the rich countries?

Any policy alternatives or global IP regime that offers drugs at lower prices to poor countries will have the potential for illegal arbitrage, including this one. Adoption of the policy could help with this concern in the following way. First, it is difficult for countries working individually to block illegal imports when a product is light and easy to transport (consider narcotics). Successfully controlling international drug flows will require the cooperation of governments in countries that are the source of low cost drugs. Settling the dispute over TRIPS could improve conditions for such cooperation. Second, being a beneficiary of the policy could be linked to specific efforts on the part of a developing country to prevent illegal exports. For example, health authorities could require that manufacturers use specific markers to identify drugs sold in poorer markets. Possible ideas could be drawn from firms' experiences in separating different market segments in the developed world.

It is also important not to over-emphasize this issue. There have been huge price differentials across countries for decades *without* massive movements of pharmaceuticals from poor to rich markets. Consumers have strong safety concerns and pharmaceutical supplies in the developed world are closely regulated. Together these limit the potential gray market.

### 2. Isn't this policy just a give away to firms and consumers in the newly industrializing countries (NICs)? Don't companies lose out if developing countries become richer?

No. This proposal is specifically designed to evolve, automatically, as countries grow richer. For example, consumers in countries with the lowest levels of GDP per capita obtain the greatest benefits. As a country becomes richer and represents a greater part of the global market its patent protection effectively widens to cover more diseases, until the point where the country moves off of the declaration all together. Most NICs have

income levels sufficiently high that they would be above the highest cutoff and would therefore have full protection.

Firms based in any country can choose to take advantage of the ability to produce under competitive conditions in the poorer countries. These firms can be from the NICs, but they can also be generic or pharmaceutical producers from the US, Europe or elsewhere

### 3. How does this policy prevent countries from deciding to weaken domestic patent protection for drugs by broadly licensing for generics production?

All existing TRIPS provisions regarding to the acceptable scope of compulsory licensing would remain unchanged. However, the interpretation of these provisions is an on-going political process. The desire for a weak interpretation is driven largely by rejection of the idea that all countries should have U.S.-style patent laws. The argument that patents should be respected because of their importance to research incentives would be more compelling with a system where it was more clearly true. This policy generates a system where patents become effective in countries precisely when their markets become significant enough to contribute in a non-trivial way to research incentives, but not before that point.

### 4. What about the poor in the rich countries who cannot afford drugs? Why should we subsidize rich people in poor countries?

The prices paid by a consumer in this country do not depend on how much an African patient pays for his drugs. For-profit firms naturally price to obtain maximum profit in each of their important markets and that calculation does not change with patent laws elsewhere. Thus lowering the price of pharmaceuticals to poorer consumers in the United States cannot be done by raising prices in Africa. It would require changes in other domestic policies.

Patent laws are national in scope. Therefore, the global patent regime is not suitable for the detailed targeting of benefits within countries. It is true that all policies have some leakage to unintended beneficiaries. But this must be kept in perspective. There are some rich people living in India, for instance, but it is a country of over a billion people and most of them are extremely poor. The *average* income is just \$1.30 a day.

**5. Why would a pharmaceutical company ever support this policy?**

Unless a satisfactory solution is found to the TRIPS debate it will continue to fester and give critics reason to attack the industry. There are other political battles at hand that are of far greater moment to the industry. Tarnishing its image by appearing unreasonable about patents in the developing world does not help them in this wider context. Taking up this policy would be a clear positive step by the industry that would not appear to be caving in to the demands of advocates. It would create a system that is clearly more sensitive to the concerns of developing countries and one that they would have reason to enforce with more enthusiasm.

In addition, certainty about future property rights is essential to firms engaged in long term research. In the current state of uncertainty, patents in poor countries are of no value to anyone. This policy recognizes the importance of certainty by clearly delineating what protection will be available at the time of patent application. It protects the firm's important markets by automatically expanding the scope of protection as a country grows richer.

**6. How does this policy solve the problem of too little research on tropical diseases?**

By itself it does not. Clearly patents are not valuable where there is no income. However, there is an enormous gap between the need for treatments for tropical diseases and current R&D investment. Other policy options to support research are available: public funding for R&D, prizes, a purchase fund. Patent-based incentives are complementary to other methods of increasing research. Even with *every* instrument in place we will probably not bridge the gap. The availability of patent rights over tropical disease innovations across all countries (save the poorest) could make a positive contribution to bettering this situation. How big is unknown because it has not been tried. But given current, meager, levels of investment, even a small contribution to incentives could give a powerful boost to the generation of new product innovations.

**7. Right now in many poor countries companies do not request patents for their innovations and still the people do not obtain drugs. How does this policy solve that problem?**

It is true that the poorest often cannot afford drugs even at marginal cost pricing. For the poorest, even a system allowing generic production will not give them access to drugs. There needs to be more money, period. That said, whatever pot of money is available will go much further if drugs are available in poor countries at competitive prices. Then, aid money used for drug purchases would go that much further. Furthermore, in some poor countries the lower prices associated with generic production would bring drugs within reach of a sizable segment of the population.

**8. Won't this policy create high prices for developing country-specific drugs?**

Possibly, since this plan gives the patentee monopoly rights and therefore the ability to avoid direct competitive pressure on prices. But the patentee may choose not to exercise these rights, especially if it is a non-profit entity. The National Institutes of Health, for example, hold many patents. With tropical disease innovation this will often be case because donor dollars will finance much of the research. A public entity can choose to make its patented technologies freely available and then the patents would have no effect on prices.

The patent system gives for-profit firms an added incentive to join the search for new products because they are allowed to charge a mark-up over costs. Low purchasing power in the poor countries acts as a natural limit on this mark-up. Again, the primary policy problem for poor country-specific diseases is to develop products. Once developed, those products can be purchased by the international community or domestic government rather than poorer consumers.

**9. Who would need to implement the policy?**

The United States, or other country, could do it unilaterally. However, to be effective and fair it should be implemented, at minimum, by the eight or ten developed countries having potentially significant pharmaceutical research sectors.