



Outline of the Foreign Filing License Approach

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This article outlines a policy reform aimed at creating a more broadly accepted global patent system for pharmaceuticals. It addresses concerns amongst the development community that patents might impede drug access in poor countries, and industry concerns that R&D incentives be preserved in markets where profits are available. The proposed mechanism - working through the foreign filing license - balances the dual objectives in a clear and straightforward way.

In essence, the policy would have inventors in developed countries make legally binding commitments to their own governments not to enforce patent rights in certain proscribed pharmaceutical markets. These markets would be defined as those constituting the bottom percentage of global drug sales in each disease class.

Firms have been willing to make a voluntarily commitment not to exercise patent rights in the poorest countries. One can think of the policy as taking the spirit of these commitments and translating it into a reliable rules-based system that would apply equally to all firms or public enterprises doing pharmaceutical research.

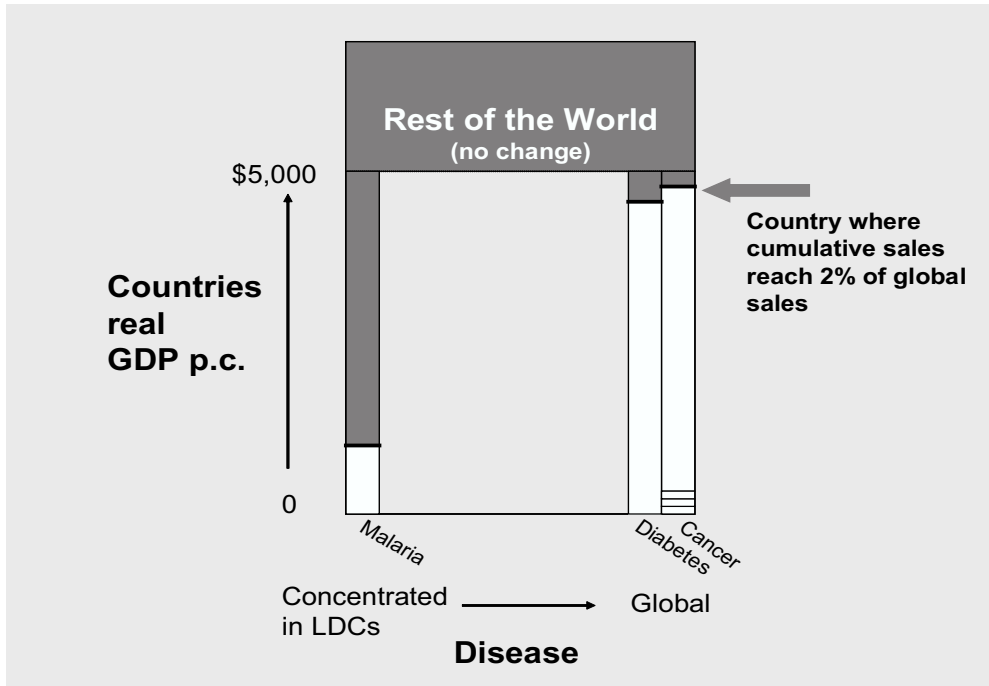
The proposal is most easily understood in two steps. First I will describe the result and then the mechanism itself.

The Result

On the left-hand side of the first figure below are countries ordered from bottom to top in terms of real GDP per capita. At the bottom are the poorest African countries. Moving up one would hit India at around \$500, China at around \$900, Thailand at around \$3,000. There is a ceiling for the policy, indicated here at a GDP per capita of \$5,000, which is about the income of Brazil.

Along the bottom axis are listed disease classes, with those concentrated in the poor countries towards the left, and those with worldwide incidence towards the right.

Consider one particular disease class, say cancer. Take the sales of *all* cancer drugs in the poorest country (that is, not just a particular product, but all sales including generics). This is shown as the thin white stripe at the bottom of the cancer column. Now add sales of cancer drugs in the next poorest country, and the next poorest country. Continue to move up, cumulating sales of cancer drugs, until reaching 2% of worldwide sales on



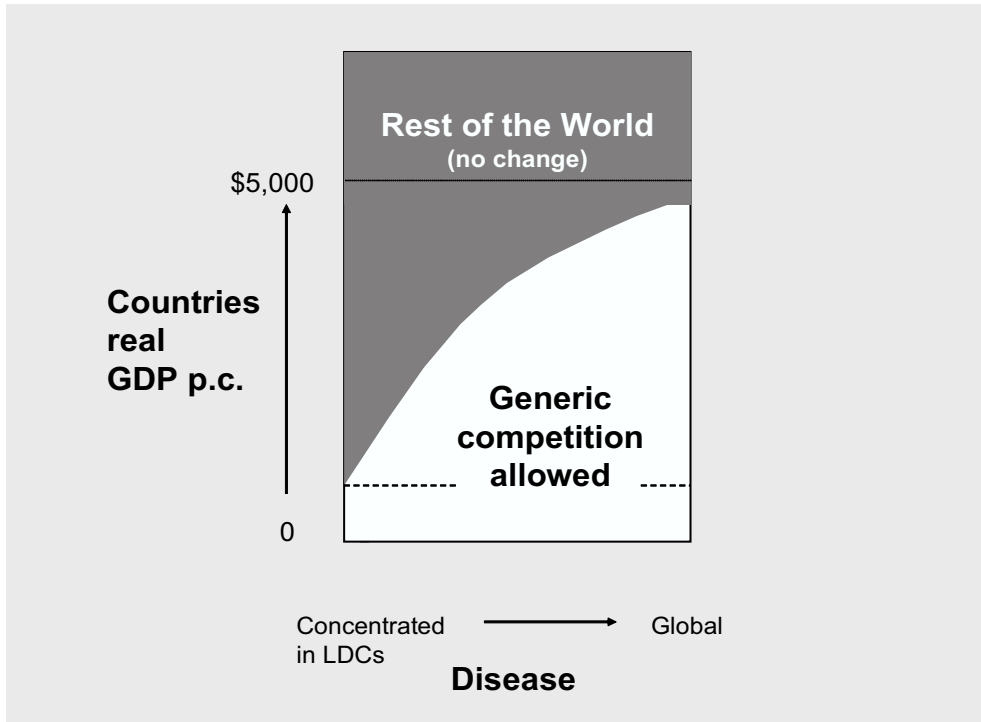
cancer drugs. All of the countries above this point stay in a TRIPS environment for cancer drugs – indicated by gray shading - and those below would be allowed generics. Repeating this calculation with each disease class in turn defines a generic region of countries and diseases where inventors will refrain from enforcing patent rights. Smoothed out, it is the white area in the second figure, below. Within this set of markets, firms would be able to manufacture and trade in generic products without the need to go through the procedural steps of compulsory licensing.

Because diseases to the left are more concentrated in the developing countries one hits the 2% cutoff there more quickly. It may seem counter-intuitive to propose differentiating in this way, but is precisely for these diseases that some incentive may need to come from sales in the developing world for products to be developed. These sales are likely to be financed, at least in part, by the international community.

For markets in the gray area above the curved line the policy as no effect. Nothing is taken away. In particular, the both the responsibilities and the flexibilities of TRIPS remain unchanged, as do any elements that are negotiated in the future.

The size of the generic region depends on two parameters: the ceiling income level (here \$5,000) and, more importantly, the percentage of global sales cutoff (here 2%). With a 1% cutoff the generic region would, of course, be smaller and the policy would have less effect and vice versa with 3%.

As indicated by the dashed line, the poorest countries would be allowed generics on all pharmaceuticals. Countries higher up, such as India, would have a mixed situation. They would be in the TRIPS environment for diseases to the left that are concentrated in the



developing world, while in the generic region for more global diseases. Countries always remain ranked by income, so no country is allowed generics when a poorer country is not.

The policy is dynamic. The generic region is recalculated each year as country markets evolve. Thus it *only ever* knocks off the bottom, say, 2% of the market by sales. Given the small margins in poor countries this is an extremely small part of potential profit for firms, but at the same time, given the asymmetries in markets it represents countries with very many people.

The Mechanism

The developing countries are not required to take action to implement this policy. They continue to take steps necessary to comply with TRIPS and any bilateral treaty obligations in accordance with their current plans. They implement new laws allowing for product patents, issue patents as requested, enforce them in the courts, and so on.

The policy is implemented in the developed countries. It works as follows. By law, if someone invents something in the U.S. he is required to get permission from the U.S. government to make overseas patent filings. This is called the foreign filing license (FFL) and it was created for national security reasons to protect sensitive technologies. The policy is very simply to add a declaration to the request for this license that is along the following lines:

I, the undersigned, request a license to make foreign 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'

where 'Cancer' and 'India' would be a description of the generic region.

Thus it is an undertaking by the inventor, to his own government, not to enforce any rights he may have in certain markets. If the patent holder were later to begin an infringement suit in one of the proscribed markets, he would have falsified the declaration. Doing this would render his patent in the domestic market unenforceable with respect to the same product.

Nothing in the policy prevents a firm from obtaining patents wherever it likes. Thus there are no decisions related to the policy that need to be made at the time of patent application. This is important because it is not always clear in the early stages what a particular pharmaceutical innovation might turn out to be useful for. Instead, the decisions that relate to the policy – decisions about where to enforce patent rights – need to be addressed only once products have reached the market with approval to treat defined conditions.

Comments on Implementation

Implementation of the policy would need to be coordinated across the developed countries that have pharmaceutical research activity, including, at least, the United States, Canada, Europe and Japan.

The policy requires legislation in each country to amend its patent code. In the U.S. this would include adding the declaration to the FFL along with procedures for calculating the generic region; and making some other small changes to existing law. The U.K. has a very similar FFL provision to that found in the United States. For other countries, the implementing the policy would require them to add the FFL provision to their patent codes.¹

Success is most likely if those involved see the policy as an opportunity for agreement and are willing to treat it as an initiative separate from other issues under negotiation or causing conflict. For the industry, keeping it separate would mean not linking support for the required legislation to other conditions, particularly involving countries that would *not* be beneficiaries of the policy. For the development community it would mean being enthusiastic about the legislation without, in a similar way, linking support to remaining areas of discontent. Having discussions outside of the WTO would help to make clear the separation between this initiative and both past controversies and current negotiations.

¹ For legal details see "A New Global Patent Regime for Diseases: U.S. and International Legal Issues," *Harvard Journal of Law & Technology*, Vol. 16, Number 1 Fall 2002, available at <http://www.are.berkeley.org/~lanjouw>.