

## focus 7 on *drug access*

### *Balancing access to medicines for the world's poor with incentives for pharmaceutical innovation*

*What's the best way to expand access to drugs in developing countries, while preserving incentives for pharmaceutical research? A possible solution entails recognizing that medicine markets are far from uniform and that both the nature of diseases and the income of countries matter for access and incentives.*

Some diseases, such as malaria, mainly affect poor countries, but they have received little R&D investment, and few treatments are available. Much attention has been devoted in recent years to creating the right incentives and structuring financing to increase R&D investment in drugs for diseases that affect poor countries, for which commercial potential does not provide enough stimulus.<sup>1</sup> Policy initiatives include the following:

- Increasing research through public sector institutions—for example, programs coordinated by the U.S. National Institute of Allergy and Infectious Diseases, the World Health Organization's Special Programme for Research and Training in Tropical Diseases, and the nonprofit Drugs for Neglected Diseases Initiative founded by *Medécins Sans Frontières*.
- Establishing public-private partnerships, such as the Medicines for Malaria Venture and the Malaria Vaccine Initiative, the International AIDS Vaccine Initiative, and the Global Alliance for Tuberculosis Drug Development.
- Designing a purchase commitment for new vaccines ("AdvancedMarkets"). Sponsored by the Bill and Melinda Gates Foundation, the groundwork has been laid to create markets by having donors commit, in advance, to paying part of the cost at a guaranteed price for a new, as yet undiscovered, vaccine. This would give firms an incentive to invest in this area.<sup>2</sup> (A similar initiative has been proposed for agricultural research relevant to developing countries.<sup>3</sup>)
- Developing an open-source approach to early-stage tropical diseases research. The idea is to harness the expertise and resources of academic scientists, students, public sector researchers, and others who may be happy to spend some of their time doing research on tropical diseases either for altruism or scientific

curiosity (similar to what happens with open-source software). Leads that emerge could then feed into any of the other schemes for the next stages of development and clinical testing.<sup>4</sup>

Providing patent protection in poor countries for drugs primarily for their markets would not by itself provide sufficient incentives, because their purchasing power is very low. But, even a small increase in market-based research incentives could be a useful part of a larger strategy to address the treatment of diseases specific to the developing world.

Other diseases have global incidence and worldwide markets, and they are an important cause of death and disability among the poor. In the high-mortality regions of the world, cardiovascular disease is estimated to cause a greater share of the total disease burden than malaria and other tropical diseases combined.<sup>5</sup>

Although many people in poor countries suffer from global diseases, they are an insignificant part of the commercial market. Estimates suggest that currently almost half of the world's people live in countries that together represent less than 2 percent of global spending on drugs for cardiovascular disease.<sup>6</sup> Because of the great asymmetries in markets, many of the poor could be allowed generic access to important classes of drugs without damaging research incentives. The foreign filing license approach described below is a feasible way to attain this outcome.

#### **Legally binding commitments not to enforce patent rights**

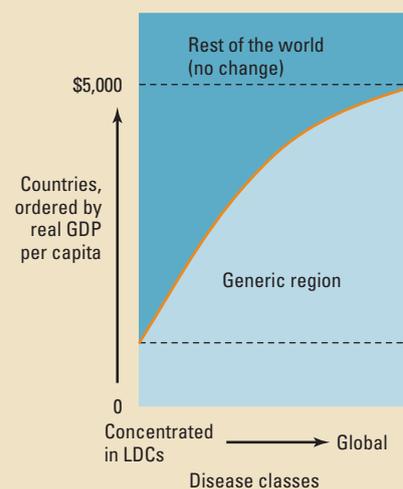
The proposal considered here<sup>7</sup> would have inventors in developed countries make legally binding commitments to their own governments not to enforce patent rights in certain pharmaceutical markets. These markets would be defined as those together representing the bottom, say, 2 percent of

global drug sales in each disease class (see figure below).

Along the horizontal axis of the figure are disease classes, listed with those concentrated in poor countries toward the left, and those with worldwide incidence toward the right. Along the vertical axis are countries ordered by per capita income. The white area shows the "generic region" that would be created by the policy. Within the generic region, firms would be able to manufacture and trade in generic products without any political or procedural complexity arising from the patent system. The generic region would be recalculated each year to accommodate changes in income and the evolution of markets.

Because diseases to the left are more concentrated in developing countries, the 2 percent of global markets cutoff is reached at lower levels of real GDP per capita. It may seem counterintuitive to propose differentiating in this way, but it is precisely for diseases that are concentrated in developing countries that some incentive for product development may need to come from sales in the developing world.

#### **The proposed generic region**



Source: Lanjouw (2004).

The poorest countries falling below the dashed line 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 concentrated in the developing world, while in the generic region for more global diseases. For markets in the gray area above the curved line, the policy as no effect. Both the responsibilities and the flexibilities of TRIPS remain unchanged.

The size of the generic region depends on two parameters: the ceiling income level (here \$5,000) and, more important, the global sales cutoff (here 2 percent).

The proposal would be implemented by having inventors in developed countries make a legally binding commitment to their own governments not to enforce patent rights in the generic region, as part of obtaining a license to make foreign patent filings (the foreign filing license). Firms would continue to obtain patents wherever they like, and no decisions related to the policy would be needed at the time of applying for a patent. Instead, decisions

that relate to the policy—about where to enforce patent rights—would arise only after products have reached the market. To ensure compliance, the patent holder would lose the right to enforce the domestic patent on the same product if the holder were to break the commitment and begin an enforcement action in one of the proscribed markets.

Implementation would need to be coordinated across the developed countries that have pharmaceutical research activity, including, at least, Canada, Europe, Japan, and the United States. The policy would require legislation to amend the patent code in each country. In the United States and the United Kingdom this would include adding an inventor declaration to an existing foreign filing license process; other countries would need to put a foreign filing license provision into their codes.<sup>8</sup> The classification of countries and disease classes could be carried out by an international organization and reviewed annually.

Developing countries would not be required to take any action to implement

this policy. They would continue to take steps to comply with TRIPS and any bilateral treaty obligations in accord with their current plans. The countries in the generic region could be treated as one country from the viewpoint of patents. Production could be based in any one country and drugs could be exported to all other countries in that group, without any costs associated with patents and compulsory licensing.

So, if any country in the generic region had the ability to produce a given drug, then all other countries in the region could take advantage of its production capacity. This would help get around the problem that most small countries do not have the capacity or market size to make domestic production of generic drugs a viable activity.

Firms have been willing to make a voluntarily commitment not to exercise patent rights in the poorest countries. The foreign filing license proposal discussed here would take that commitment and convert it into a reliable part of the global rules-based system.

Source: Lanjouw (2002, 2004).