DEVELOPMENT, TRADE, AND THE WTO

A Handbook

Bernard Hoekman, Aaditya Mattoo, and Philip English, editors

THE WORLD BANK
Washington, D.C.

BOX 35.2 COMBATING DISEASE WORLDWIDE: FOSTERING THE REQUIRED R&D

A critical task facing the global economy is to develop mechanisms that encourage research aimed at developing treatments for diseases which are common in poor countries and, at the same time, achieve widespread distribution of those treatments at affordable prices. The issue has become prominent because of the severe epidemic of HIV/AIDS, in particular in Sub-Saharan Africa, South Asia, and Southeast Asia. But HIV/AIDS is not the only disease plaguing poor nations; malaria, tuberculosis, and other maladies are equally debilitating. In fact, HIV/AIDS is unusual in that it affects both rich and poor countries. Pharmaceutical firms therefore have incentives to develop HIV/AIDS medicines for sufferers in high-income economies, and what is being debated is how to transfer these medicines to poor countries. In contrast, malaria and other diseases endemic to impoverished nations are "neglected" in that they attract little research and development (R&D). For example, the World Health Organization (WHO 1996) has estimated that of the US$56 billion spent globally on medical R&D in 1994, less than 0.2 percent was spent on tuberculosis, diarrheal maladies, and pneumonia, and virtually all of this research was carried out by public agencies and military authorities. R&D on antimalarial vaccines and drugs is meager. Some research is going on under the auspices of the Multilateral Initiative on Malaria, involving the United Nations Development Programme (UNDP), the World Bank, and WHO, and by the Medicines for Malaria Venture, a public–private sector cooperative initiative. Funding for the Multilateral Initiative comes to perhaps US$3 million per year, and Medicines for Malaria is soliciting support from foundations in the hope of raising US$30 million per year. These amounts are inadequate for the job, given the costs of developing and testing new drugs.

There are two main reasons for this low rate of R&D. Most important, the low purchasing power in poor companies gives pharmaceutical companies insufficient incentives to introduce new drugs into those markets. A second reason is that in the past many developing countries did not recognize or enforce patent protection for pharmaceutical products. Regarding the latter problem, the TRIPS agreement requires that developing WTO member countries provide patents for new pharmaceutical products by 2005 at the latest (by 2016, for least-developed countries). There is concern, however, that the provision of product patents in pharmaceutical products could confer considerably greater market power on rightsholders by delaying the entry of generic competitors for new products. Then such firms might reduce sales or output in particular markets, supporting higher monopolistic prices in key medical therapies.

Considerable pressure has been exerted on pharmaceutical companies to provide drugs to poor countries at marginal production cost (or less). For example, Merck & Co. recently announced that it would cut the prices of two AIDS-controlling drugs in Africa by 40 to 55 percent, adding to sharp price cuts announced a year earlier. Abbott Laboratories offered to sell its two AIDS drugs, Norvir and Kaletra, at prices that would earn the company no profit. Many other firms, including the Bristol-Myers Squibb Co. and GlaxoSmithKline PLC, have announced similar price cuts. These research-intensive firms have three concerns about low-cost distribution programs. First, provision at marginal cost adds nothing to their ability to cover the costs of R&D. Second, while they may be willing to supply their medicines cheaply, they wish to retain the exclusive distribution rights inherent in patents. Indeed, this preference underlay the recent lawsuit by several firms against the South African government, challenging the constitutionality of its 1997 Medicine and Related Substances Control Act. Third, drug manufacturers are concerned that the availability of far cheaper medicines in poor countries could erode their ability to sustain higher prices in rich countries.

Under Article 68 of Brazil's Industrial Property Law (Law 9.279/96), foreign firms must manufacture patented drugs within Brazil before three years have elapsed from the grant of the patent. Failure to meet these "working requirements"

BOX 35.2 (CONTINUED)

could result in an order by the Brazilian authorities to local firms to manufacture generic substitutes under compulsory license—a threat that recently faced the makers of the AIDS drugs Efavirenz (Merck & Co.) and Nelfinavir (Roche). This issue was raised by the United States at the WTO, but a bilateral settlement was arrived at, and the case was withdrawn.

In economic terms, to address effectively the diseases endemic to poor countries through development of and access to new treatments requires separation of the dynamic incentives for R&D from the need for widespread distribution at low cost. Because paying for the required R&D is beyond the means of poor countries, any comprehensive solution to the problem requires significant increases in assistance from industrial countries and financial support from multilateral organizations and private donors. These monies would be used for two purposes. An immediate task would be to build effective health care delivery systems in poor countries, where health infrastructures are weak. The second task would be to provide incentives for firms to engage in R&D in new and effective vaccines and medicines. Most likely, these incentives would involve purchase by governments or international public agencies of bulk amounts of targeted drugs from manufacturers at negotiated prices and the distribution of the drugs to designated countries at low cost, while preventing backflow of cheap medicines to higher-income nations. If such negotiations are unfeasible or ineffective, it may be advisable to establish a system of royalties under which countries could acquire licenses to produce and distribute the drugs. For this system to be effective, small countries without production facilities may need to be given the right to import drugs from generic producers in third countries.

Ganslandt, Maskus, and Wong (2001) estimate the annual cost of such an international strategy at between US$8.2 billion and US$12.1 billion. While this commitment would represent a substantial portion of current aid funding (which amounted to US$84.9 billion in 1999), it would correspond to only 0.03 to 0.05 percent of the OECD's 1998 GDP. Indeed, if the US$12.1 billion were paid by the United States, the European Union, and Japan it would come to only US$13.50 per person per year. For a final perspective, the US$12.1 billion may be compared with the anticipated loss in South African GDP, if the current epidemic continues unchecked, of US$22 billion in 2010.

Source: Prepared by the volume editors, based on Ganslandt, Maskus, and Wong (2001).