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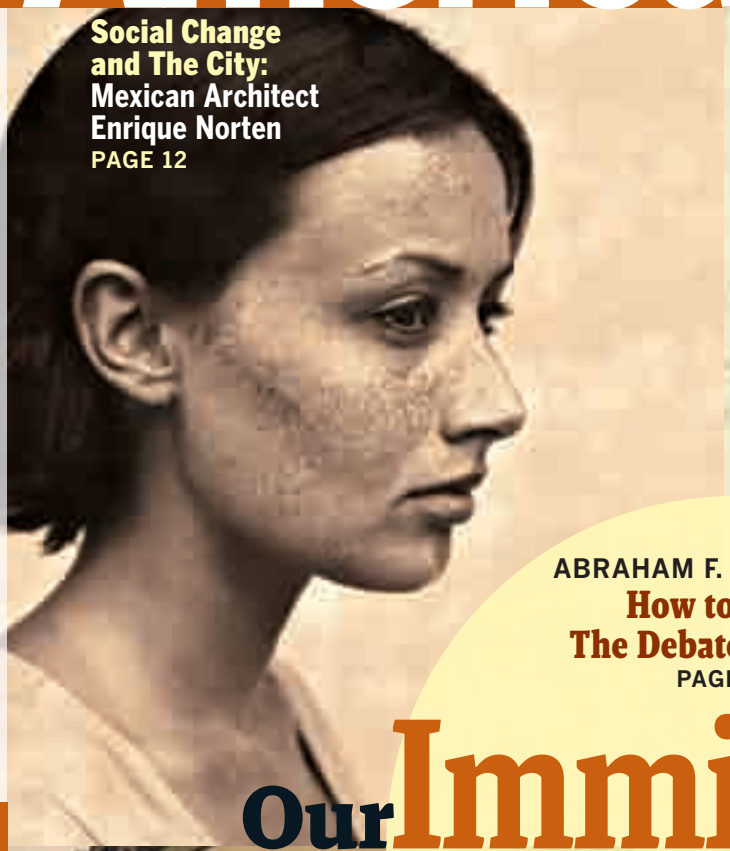
Immigration



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BOB SACHA/CORBIS

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WINDA BERKOWITZ (LEFT); ITSUO INOUYE/AP

hard talk forum

Does patent protection prevent

yes

André de Mello e Souza

Patents Price Medicines Out of Reach of the Poor

Globalization of IPR has reduced availability of generics as well.

Both logic and empirical evidence suggest that patent protection prevents access to medicines in developing countries. Patents are by definition monopolies and, as such, increase prices, other things being equal. Abundant data demonstrate that generic producers dramatically lower the cost of drugs, because they operate with lower profit margins and promote competition.

Accordingly, in Brazil the substitution of patented imported antiretrovirals (ARVs) used to treat AIDS with locally produced generic equivalents caused their price to fall 80.9 percent on average. This was possible only before the country began to grant patent protection for pharmaceutical products. However, after such protection began to be offered in 1997, the cost of ARV therapies in Brazil escalated, threatening the sustainability of the government's AIDS treatment program and the survival of over 160,000 patients. Since then, the affordability of these therapies has depended on the capacity of the health ministry to make credible threats of issuing compulsory licenses for ARVs, thereby forcing the patent holders to considerably discount these drugs. In addition, local generic ARV production has relied on the importation of active ingredients from India and China. As both countries concede patent protection for new ARVs in compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), these ingredients may no longer be available.

The globalization of intellectual property rights promoted by TRIPS has also undermined efforts by other developing countries to gain access to cheap, generic ARVs. Research conducted by Oxfam tracking the price of patented ARVs in Uganda from May 2000 to April 2002 showed that such prices fell as much as 97 percent after the country started to import generics from India. As a result, at one treatment center alone, the number of patients taking these medicines increased by 200 percent within a year.[1] Unfortunately, like Brazil, Uganda will face difficulties in financing anti-AIDS therapies after changes in the Indian Patents Act begin to take effect.

Some interested parties claim that the lack of access to medicines in the developing world is caused by poverty and insufficient health care spending rather than the high cost of medicine. Studies conducted by Amir Attaran and Lee Gillespie-White, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the pharmaceutical multinational Merck, show that many of the anti-AIDS cocktails are not subject to patents in most African countries—with the notable exception of South Africa—and could thus be readily used by these countries. The studies also point out that lower prices in ARV

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ILLUSTRATIONS BY WESLEY BEDROSIAN

access to medicines in developing countries?

no

Harvey E. Bale

Patents Protect Research Needed to Treat Diseases

Poor health systems and infrastructure are what impede access.

Patents are not a barrier to equitable health care. New medicines are needed to meet global disease challenges. More than $60 billion is spent annually by pharmaceutical, vaccine and biotechnology companies in pursuit of that goal. The emerging global system of intellectual property protection will guarantee and generate much of the product research and nearly all of the product development necessary to cope with the diseases that threaten developing countries.[1] The 2003 agreement on TRIPS, as well as other bilateral and multilateral agreements, sustain the research and development we need to confront those threats.

Of course, making health care, including medicines, more accessible is important. Over the past 30 years, according to the World Health Organization (WHO), one-third of the world's population has lacked access to essential medicines and drugs. Most of those cut off from access live in developing countries. But they also deserve to have medicines and drugs that are reliable. These products should be free of impurities, stored properly, not counterfeited—and, in the case of generic drugs, be "bioequivalent" to the innovative ones.

Most of the medicines sold in developing countries are supplied generically, either branded or unbranded. But counterfeits crowd higher-quality medicines out of the market, reducing the availability of better and safer alternatives.[2]

Even where good-quality medicines (patented and generic copies) are available, the reasons patients in many developing countries can't get them usually have nothing to do with price. For example, in regions like Africa, where the AIDS crisis has spread to major proportions, less than half of those needing ARV treatment get it. The WHO's HIV/AIDS chief, Kevin De Cock, has noted that Africa is short 1 million health care workers, while health infrastructure is in poor condition.

Many other diseases prevalent in developing countries are treatable with off-patent drugs. Yet, these presumably inexpensive medicines still do not reach the billions of people who need them. India is a relative latecomer to the adoption of pharmaceutical patent protection (and its legislation still cannot be described as adequate). Even though relatively few pharmaceutical products are under protection in India, approximately two-thirds of the population lacks access to them.

In May 2000, five major developers of HIV antiretroviral drugs and five international agencies (WHO, World Bank, UNAIDS, UN Children's Fund, and UN Population Fund) agreed that the major barrier wasn't patents. As part of the launch

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yes

André de Mello e Souza

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medicines have not by themselves led to substantial increases in treatment opportunities in Africa.[2]

There are at least two major fallacies in these studies. First, as several NGOs have countered, patents for anti-AIDS medicines are correlated with purchasing power and the size of HIV-infected populations.[3] In order to correctly assess the impact of patents on access to medicines, the market sizes of different countries must be taken into account. Lumping South Africa in with other less populous and poorer countries, plus the greater demand for ARVs in South Africa, obscures the adverse effects of patents on access to medicines under conditions of less affluent countries. Therefore, these effects have been considerably underestimated by the above-mentioned studies.

Second, evidence shows even medicines not protected by patents remain unavailable in African countries; patents cannot be considered a major barrier to treatment. But the effects of patent protection on the costs of (and access to) medicines often-times transcend national borders. South Africa, which exports patented ARVs to the rest of the continent, is a case in point.

Patents also indirectly lead to higher prices by allowing the formation of pharmaceutical cartels, usually concealed behind a plethora of licensing arrangements between companies. The market is thereby partitioned in ways that would have been illegal in the absence of patent protection. Most notably, during the 1960s the price of the antibiotic tetracycline was identical in 13 countries for which price data were available.[4]

The lack of accessibility to medicines in the developing world may also be compounded by the indirect effects of patent protection in high-income countries. The Commission on Intellectual Property Rights warned in 2002 that such protection "may provide powerful incentives to do research of particular kinds which mainly benefit people in developed countries, diverting intellectual resources from work on problems of global significance."[5] The pharmaceutical industry has failed to develop the medicines needed to treat many ravaging infections endemic to the developing world, such as tuberculosis, malaria, leishmaniasis, African trypanosomiasis, Chagas disease, and dengue fever.

André de Mello e Souza *is assistant professor of international relations at the* Universidade Católica *in Rio de Janeiro.*

FOR SOURCE CITATIONS SEE: americasquarterly.org/melloesouza.html

no

Harvey E. Bale

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of an initiative aimed at improving worldwide access to ARV treatments, they acknowledged that the protection of intellectual property rights in compliance with international agreements was necessary to stimulate innovation.[3]

Medicines for malaria, tuberculosis and diarrheal diseases, ailments that particularly affect developing countries, will similarly benefit from intellectual property protection. With responsible government policies, pharmaceutical companies can safely sell and offer differential pricing to poor countries that will effectively deliver essential medicines. Programs to combat other major diseases, such as river blindness, trachoma, leprosy, lymphatic filariasis, and intestinal helminthes, can also be reinforced with a combination of patent protection and government and private-sector partnerships designed to strengthen health care infrastructure, ensure adequate financing for health and build local health care capacity through training and support.[4]

Indiscriminate use of compulsory licensing provided for under TRIPS[5] that allows countries to force companies to relinquish patents in cases of medical emergency may save "costs" temporarily. But the real cost to those countries, in terms of quality and access to newer technology and products, is greater than any short-term savings.

In the past, debate over intellectual property protection reflected a "North-South" divide. Today there is a growing division within the South itself. Countries like Korea, China, Singapore, and Mexico consider the preservation of patent rights for medicines crucial for wealth creation and the establishment of a sound health care infrastructure. In contrast, countries like Thailand (at least under the recent military rule) and Brazil (with locally dominant, government-owned drug factories) ignore intellectual property rights and have failed to invest sufficiently in long-term health system improvements. In this developing-country divide, the former group understands that patents are complementary to sound public health, not a threat.

Harvey Bale *is a former director general of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).*

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