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An incomplete picture of public health issues and intellectual property rights in Brazil

Editor:

In recent months the debate over public health issues has increasingly focused on intellectual property rights. Attention that initially centered on South Africa has expanded to include Brazil. From the perspective of the research-based pharmaceutical industry, the situation in Brazil is very different from that portrayed in most recent media coverage and other commentaries, particularly the May 2001 Oxfam report entitled "Drug Companies vs. Brazil: the Threat to Public Health" (1, 2). Far from being a threat, we in the research-based pharmaceutical industry are proud of the role we play in Brazil and elsewhere to promote access to innovative therapies. In addition to providing high-quality medicines, we employ 36 000 people in Latin America, foster the transfer of technology through clinical trials and manufacturing, invest in manufacturing facilities, and also invest over US\$ 50 million there each year in research and development. We support the regulatory harmonization efforts of the Pan American Health Organization (PAHO), and we

welcome the opportunity to work in partnership with other stakeholders throughout the Western Hemisphere.

In its report Oxfam condemns pharmaceutical companies and the Government of the United States of America for supporting the "local working" case against Brazil that is now being considered by the World Trade Organization (WTO). Oxfam advocates price controls and compulsory licensing as the key to improved access to all essential medicines, not just HIV/AIDS treatments. We regard these matters very differently. Oxfam basically blames research-based pharmaceutical companies for their greatest achievement: developing medicines that have transformed patients' lives. Never before in human history has the death rate for a fatal disease been cut so deeply and so quickly. In countries where antiretrovirals are widely available, such as Brazil and the United States, the death rate has fallen by half or more. While they are among the most philanthropic businesses in the world, pharmaceutical companies should not bear sole responsibility for solving global public health crises that have deep and complicated roots.

Protecting intellectual property expands patients' access to innovative medicines and, contrary to

Oxfam's assertion, does not impede the development of a true generic market. Just look at the United States, with its strong intellectual property laws and one of the strongest generic markets in the world. Mexico's Health Minister recently affirmed that his country's decision to implement stronger intellectual property protection before joining the North American Free Trade Agreement (NAFTA) has benefited Mexican patients. The Oxfam report laments that "competitors have to replicate trials, at great expense, or wait until [intellectual property] exclusivity expires." Ironically, Oxfam objects when others have to pay for research and development (R&D), but the group fails to recognize innovators' massive R&D expenditures. Those expenditures average US\$ 500 million for a new drug; in the case of one leading antiretroviral they were US\$ 1 billion.

Oxfam accuses companies of "bullying" and "pressuring" Brazil. This pity for Brazil is patronizing and inaccurate. Brazilian health authorities are tenacious advocates of their country's interests and skillfully use the many tools at their disposal.

The research-based pharmaceutical industry has an important role in Brazil. In addition to supplying high-quality medicines, we provide Brazil with high-tech jobs, tax revenue, and an increase in gross domestic product due to exports. Contrary to Oxfam's contention that technology transfer is harmed by intellectual property protection, Brazil's 1996 passage of a strong intellectual property law resulted in massive investment in the country by the United States pharmaceutical industry (roughly US\$ 2 billion). A recent study that we commissioned the KPMG consulting firm to carry out found in the 1996–2000 period that the pharmaceutical sector in Brazil saw significant increases in fixed assets (351%), R&D investments (474%), employment (35%, or 6 131 new jobs), taxes (152%), and revenues from exports (1 359%). For some research-based pharmaceutical companies, Brazil is home to their largest factories in the world.

We applaud Brazil for demonstrating the political will and committing the necessary resources to fighting the AIDS epidemic. We are proud of our major role in that success, safely and reliably supplying 80% of Brazil's HIV/AIDS medicine needs. Nevertheless, the United States' case before the WTO has nothing to do with Brazil's AIDS program—or with the country's price controls, as Oxfam claims. The case is about a narrow and technical, but nonetheless important, trade issue. Brazil requires that patent holders manufacture their products in Brazil, or they will be forced to sell their rights to a copier there. We believe this requirement is inconsistent with the WTO's Agreement on

Trade-Related Aspects of International Property Rights (TRIPS). Brazil had such a protectionist provision before joining the WTO, and invoked it over 400 times, affecting the rights of patent holders in many industries. The WTO's TRIPS Agreement says that companies can import their patented product instead, but Brazil has chosen to interpret its TRIPS obligations in a radically different and ultimately untenable way. If every WTO member were to insist on this "local working" requirement, it would mean in effect that, for example, Ford would have to manufacture cars in all 140-plus countries belonging to the WTO, no matter how unfeasible that might be. The requirement would also mean that companies would no longer be free to make rational, economically sound manufacturing and distributing decisions. For industries such as pharmaceuticals that have very strong economies of scale, local working provisions will actually make their products more expensive rather than less so. Brazil's local working provision is not limited to pharmaceuticals or health care, but is applicable to all industry sectors. Therefore, it is not a health policy but rather an industrial policy designed to promote local producers at the expense of multinational originators.

The United States is not "beating up" on Brazil to somehow "punish" it for its successful campaign against AIDS, as Oxfam alleges. Rather, the goal that the United States has is simply to change the law. The United States is asking the appropriate multilateral body, the WTO, to resolve a commercial dispute with a trading partner, just as Brazil has done on numerous occasions in recent years. Indeed, Brazilian officials encouraged the United States to bring the matter to the WTO to decide this difference in interpretation over whether the Brazilian requirement is consistent with the TRIPS Agreement.

Oxfam believes that Brazil's local working provision will somehow encourage drug companies to operate inside the country, apparently not realizing that the research-based industry is already very active there, as we have noted above.

Oxfam echoes the contention that Brazil would never actually implement this local working provision—a tacit admission that the provision is in fact problematic. However, this law is not discretionary, and as long as it remains on the books, any Brazilian citizen has the right to petition a judge to issue a compulsory license, no matter what Brazil's executive branch says. For that reason, the United States ultimately decided it had to seek a WTO dispute settlement panel to resolve this matter. Moreover, there are already applications pending in Brazil for compulsory licenses for products in a variety of in-

dustrial areas. In the past in other countries, compulsory licensing led to inappropriate, coercive “voluntary” licensing, and we have reason to believe Brazil would adopt similar tactics.

With respect to compulsory licensing, contrary to numerous media reports, Brazil has never resorted to such a measure since adopting its patent law in 1996. The Brazilian Government has tenaciously negotiated with manufacturers to obtain the best medicine available at a mutually satisfactory price. That is the true “Brazil model.” It is unfortunate that Oxfam and others regard compulsory licensing as a panacea, since it will do little to help the sick and the needy. Forcing an inventor to turn over a patent to a third party does not reward investment or provide an incentive for further research. Compulsory licensing does not encourage partnerships and investment, does not foster technology transfer, and does not promote greater access to medicines.

We are also concerned about price controls in Brazil. The Brazilian Government imposed a “voluntary” price freeze in July 2000, followed by a decree freezing prices throughout 2001. This measure is completely contrary to the free market principles to which Brazil has committed itself in recent years. It sends an extremely negative message to international investors and bodes ill for other industries as well. This measure will do nothing to improve Brazilian citizens’ access to medicines, which is the Government’s purported goal in imposing these controls. Pharmaceutical research is enormously expensive and risky; very few products make it from the laboratory bench to the market. Price controls threaten biomedical innovation by undercutting the profits needed to finance research and development.

The Brazilian Government is saving at least as much in hospital costs as it spends on antiretrovirals, without even taking into account the social and economic benefit in terms of lives saved, productivity restored, and hope rekindled. Moreover, Brazil has received steep discounts on antiretrovirals from research-based pharmaceutical companies.

Contrary to Oxfam’s assertion, there is no link between the imposition of the price freeze in December 2000 and the United States’ request in February 2001 for a WTO dispute settlement panel. The WTO case was initiated in May 2000, months before the price controls were instituted.

Brazil has set an excellent example for other countries afflicted by the AIDS epidemic. The nation has halved the death rate, raised public awareness, promoted education and prevention, applied World Bank funds to strengthen its public health infrastructure, and provided medicine to patients. Unfortunately, many aspects of Brazil’s success are not easily replicable elsewhere. In addition to being relatively richer than some of the worst-affected coun-

tries in sub-Saharan Africa, Brazil differs in terms of cultural factors, the number of people infected, and the relative transparency and efficiency of its Government. This disparity was apparent during the May 2001 World Health Assembly meeting in Geneva, when African countries respectfully differed with Brazil on the relative importance of prevention and education versus treatment, given their particular circumstances. While it is commendable that Brazil has offered to help other countries, in reality it cannot even supply its own needs for antiretrovirals domestically. Brazilian Government labs and domestic copiers simply cannot supply the market reliably and on a sufficiently large scale. The Government labs are heavily subsidized by the Government and have limited production capacity. Local producers have been unable to fulfill Government tenders they have won, forcing Brazilian officials to ask multinational companies to fill the gap. As the Oxfam report itself notes, an antiretroviral developed by one international pharmaceutical firm is off patent, but Brazil needs to purchase it from that company in order to cover shortfalls in local manufacturing. In addition, local production has not always led to significantly lower prices. Indeed, those prices have at times been higher than the ones proposed by the drug’s original developer.

Despite impressive medical advances in recent years, too many patients in Latin America lack access to health care. The pharmaceutical industry wants to be a partner in the multifaceted process of making that goal of access a reality. We also believe that the Free Trade Area of the Americas will promote greater access to health care by enhancing transparency, harmonizing standards, and lowering trade barriers. Ideally, medicines should be free from taxes and tariffs. Enhanced intellectual property protection will also benefit patients throughout the Region of the Americas as well as stimulate domestic research and development. After all, developed countries do not have a monopoly on good ideas.

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References

1. Oxfam GB. Drug companies vs. Brazil: the threat to public health. Oxford, United Kingdom: Oxfam GB; 2001. Available from: <http://www.oxfam.org.uk> [Internet site].
2. Brazil fights for affordable drugs against HIV/AIDS. Rev Panam Salud Publica 2001;9(5):331–337.