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Breaking Patents; Trading Long-Term Harm for Short-Term Benefits

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Meeting recently in Ottawa, health ministers from 30 countries pledged cooperation to curb any potential outbreak of Asian bird flu. While some conferees discussed distribution of vaccines and medicines, U.S. Health and Human Services Secretary Michael Leavitt defended the institutions that make the development of drugs and vaccines possible in the first place. “I would like to make clear that the United States will be respecting intellectual property rights,” he said.

Leavitt’s statement is welcome. The integrity of patents affects not only the financial health of some American and European pharmaceutical firms, but the future health of people the world over. Unfortunately, one of the world’s rising economic players is leading the charge against patents.

Brazil’s Bad Precedent. Last June, Brazil’s then-health minister, Humberto Costa, issued a 10-working-day deadline for the pharmaceutical firm Abbott Laboratories to drastically reduce the price of the key anti-retroviral drug Kaletra, under threat that it would break Abbott’s patent, issue a compulsory license and start producing a cheaper, generic version of the drug. Piracy of intellectual property? Yes, but through such threats, Brazil’s government has been extremely successful in obtaining continual reductions in the price of HIV/AIDS drugs for the country: New Jersey-based Merck & Co. Inc. reduced the price of Efavirenz by total 85 percent during 2001-2003¹; in 2003, U.S.-based Bristol-Myers Squibb reduced the price of Atazanavir by a whopping 76 percent²; and by 2004, Swiss-based Roche Holding AG had cut the price of Nelfinavir by a total of 72 percent.³

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With this kind of “negotiating” success, why should they stop? Because drug manufacturers are not the only losers. While Brazil may be able to pay lower prices for drugs in the short-term, this patent-busting activity could exert serious and detrimental effects on Brazilians and everyone else in the long term.

Brazil claims that its stealing of patents is justified because it cannot afford expensive “foreign” drugs to treat its crisis levels of HIV/AIDS infections. Yet even under the most basic scrutiny, this proposed *de facto* nationalization crumbles. Brazil’s problem is not unique, and other much poorer countries have infection rates far worse than Brazil’s—for example Swaziland’s HIV/AIDS infection rate stands at 38.6 percent of adults and Botswana’s at 37.5 percent of adults,⁴ compared with Brazil’s rate of 0.7 percent. And Brazil is clearly in a better position to buy drugs than most of sub-Saharan Africa. Its economy is expected have another solid year, following GDP growth of 5 per cent in 2004, booming exports, and falling unemployment.⁵

But Brazil’s healthy economic development is now threatened by its very actions on patents. By simply copying existing research, there is little hope of home-grown R&D, stifling the modernization of Brazil’s economy. Once the very short-term benefits of cheaper drugs for Brazilians have dried up, a lose-lose situation emerges for everyone. That’s because stealing ideas does not create new ideas; in fact, it does the very opposite and stifles the basis of innovation. Without protection for its intellectual investments, companies will naturally seek to keep secrets more closely guarded. The resulting loss of movement of innovation into the public domain is not just worrisome, it’s downright dangerous. It represents a serious threat, not merely to the profit margins of American pharmaceutical companies, but most importantly to future investment in cutting-edge research. And who benefits then?

The Brazilian government claims that it is suffering a public health crisis with 650,000 people HIV-positive.⁶ Under Article 31 of the World Trade Organization’s (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), a member state can issue under certain limited circumstances a compulsory license of key medicines while paying adequate remuneration.⁷ Since the pharmaceutical companies have already reduced their prices so dramatically—Abbott provides Kaletra to Brazil at the lowest cost outside Africa—the Brazilian government is justifying its behavior on the grounds of “national interest or other circumstances of extreme urgency.” But even under the worst case scenarios predicted for Brazil in the 1990s, rates of HIV/AIDS infections were never much above the one million mark, out of a current and growing population of 175 million. While the million mark is certainly tragic, these rates have never reached the genuinely crisis-level figures in sub-Saharan Africa.

Dubious Legality. The Brazilian government is grasping for even the most dubious legal basis to copy the drugs that are provided free of charge to all HIV positive patients who need them under its widespread anti-AIDS program (currently about 160,000 people).⁸ Regrettably, even without a sound legal basis for its actions, Brazil’s government continues to receive tacit international endorsement for its behavior.

Government development organizations and non-governmental organizations throughout the world praise the provision of Brazil's free-healthcare-on-demand. In April 2001 the United Nations passed an unofficial resolution encouraging other countries to follow Brazil's example and begin manufacturing their own drugs based on patented formulas. Although not an official resolution, and with strong objections from the United States, Brazil claimed a moral and ethical victory. The anti-AIDS initiative even received a medal from the U.N. AIDS Program in 2004 for "exerting leadership in improving the fight against HIV/AIDS." For Brazil, international support for patent-breaking has been a massive boost and justifies its recent calls on India and China to follow suit.

But what are the implications of making this high-stakes game the international standard?

Negative Consequences. For Brazil itself, it represents a step backward in terms of democratization and modernization. The development of new laws to combat piracy and intellectual property crimes were just a few years ago seen as essential to the construction of key democratic institutions in a developing country desperate to be seen as a serious international economic player and target for investment. Protecting intellectual property is a vital component of the necessary economic reforms Brazil needs, to comply with international standards,⁹ and ultimately to attract investment. It is questionable exactly how reliable the country's structures actually are; following widespread reporting of Abbott's deal over Kaletra, Brazilian officials are now questioning whether any formal agreement was actually reached and are continuing to use the threat of a compulsory license to hold out for yet more price reductions. With this kind of uncertainty, it is not surprising to see some major corporations rethink future capital investments in Brazil, the 11th largest economy in the world. For Brazil, the overall costs of losing R&D and other investments are much bigger than the savings the health program predicts from its ransom-holding negotiations.

In the wider scope of things, the negative implications for Brazil's domestic R&D, and indeed global R&D, are much bigger. When he signed the new industrial property law in 1996, then-Brazilian President Fernando Henrique Cardoso said, "No country grows based on plundering."¹⁰ With adequate protection for their intellectual pursuits, researchers are free to share the knowledge and databases which ultimately spur further development. In this vein, intellectual property rights encourage invention and exploitation and make it possible for others to pursue further scientific research. The free flow of ideas and information is vital for productive research and for the next batch of drugs to treat the next generation of diseases. Without the exclusivity of a reliable patent system, scientists and inventors are encouraged to keep their ideas, inventions, and technologies secret. Quite simply, a new drug that could cure cancer is no good to anyone as a trade secret.

The negatives of Brazil's behavior are twofold. Brazil's government is undermining not only the country's domestic development of cutting-edge research, which significantly hampers economic development, it is setting a very negative precedent for the future of global R&D. The level of time and financial investment involved in researching and

developing new drugs requires motivation and the loss of intellectual property rights is a colossal disincentive to innovate in this vital field.

The claim that intellectual property rights give pharmaceutical companies a “monopoly” over ideas is nonsense. The publishing requirements of patenting new drugs not only forces manufacturers to show how these drugs were developed in the first place, but provide other researchers with the possibility to improve upon them. As James E. Rogan, former Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, said, “A patent is not a monopoly, but rather a contract in which the public procures a great benefit in exchange for allowing the inventor to have exclusivity for a limited period of time.”¹¹ Simply stealing the formula while under patent is functionally the same as property theft. It damages the whole system that is necessary to encourage further development—and ultimately to keep getting new drugs to market, where they can treat new and challenging diseases. Improved public health is only sustainable in the long-term if innovation and research continues. Researchers who use their intellectual resources for the benefit of the globe’s citizens deserve worldwide protection for their work. Brazil’s moral posturing about high drug prices therefore inverts to tell a different story, where everyone suffers for short-term financial gain.

When Brazil talks of saving \$18 million this year through Kaletra’s price reduction, it conveniently forgets that even expensive drugs help keep health care costs down by lessening the need for hospitalization and increasing the health and productivity of the workforce. Indeed, the entire cost of the Brazilian HIV/AIDS program is just 1.8 percent of the Ministry of Health’s budget, much less than the 3 percent of the budget it represented three years ago. It seems that for the Brazilian Government, their bottom line is one that stands in isolation to most other financial facts. And Brazil’s obsession with cutting drug prices only tells half the story anyway. Increased public awareness about sexual health and intravenous drug use has proven hugely successful in targeting those most at risk from contracting HIV in Brazil. Patent-breaking and the threat of it, is not only misguided, but dangerous. For drug treatment to continue to be effective, continuous development of new drugs is necessary.

Conclusion. The Bush Administration must apply itself to resolving this situation as soon as possible, preferably through a multilateral forum. In January 2001, the Administration initiated a Generalized System of Preferences (GSP) review for Brazil based on a petition from the International Intellectual Property Alliance. The petition evidenced hundreds of millions of dollars in losses due to piracy of copyrighted materials—and that’s not even counting the millions more at risk through patent-breaking in the pharmaceuticals industry.¹² The Pharmaceutical Research and Manufacturers of America, in a submission to the Office of the U.S. Trade Representative (USTR), estimated that the U.S. industry losses in Brazil due to patent piracy exceeded \$720 million in 1995 alone.¹³ Under the GSP, Brazil benefited from \$2.5 billion of duty-free GSP imports to the U.S. in 2003¹⁴, designed to promote economic growth. Brazil is getting significant economic benefits from playing in the international arena; it is time for

it to act as a responsible player and comply with the WTO's multilateral agreements on intellectual property which the country has signed.

With the knowledge-intensification of industry and commerce, this question of what constitutes property has become ever more complex. Big pharmaceutical companies have become an easy media target for bad press, but no one is more aware of the need to address the issue of affordability and access to medicines. Publicity stunts such as Live 8 have provoked greater public debate about global poverty, and sensible companies do not ignore mass protest. But equally, companies are private sector operators that either run for profit, or don't run at all. The collectivist notion of health care as a basic human right to which people are entitled regardless of cost or ownership threatens to undermine the development of new medicines upon which so many peoples' health depends. Someone has to pay to develop these new medicines, and a handful of American and European pharmaceutical companies cannot reasonably be expected to fund the world's health care.

Patents provide valuable protection for inventions and encourage further invention and innovation. Without sufficient incentive to encourage research and development by potential right holders, we lose the very basis that has inspired cutting-edge drug research to date. What about Brazil looking to its own responsibilities? At the moment, its actions are merely threatening the advancement of the world's access to future medicines.

¹ <http://www.accessmed-msf.org/prod/publications.asp?scntid=5920031122422&contenttype=PARA&>

² <http://www.aegis.com/news/ads/2003/AD032415.html>

³ http://www.kaisernetwerk.org/daily_reports/rep_index.cfm?hint=1&DR_ID=21751

⁴ <http://www.globalpolicy.org/socecon/develop/aids/2004/0319swaz.htm>

⁵ <http://www.state.gov/r/pa/ei/bgn/35640.htm>

⁶ United Nations Programme on HIV/AIDS:

<http://www.unaids.org/en/geographical+area/by+country/brazil.asp>

⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights:

http://www.wto.org/english/docs_e/legal_e/27-trips.pdf

⁸ http://internacional.radiobras.gov.br/ingles/materia_i_2004.php?materia=233557&q=1&editoria=

⁹ The World Trade Organization (WTO) agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) mandated that all WTO member countries have adequate patent protection in place by the year 2006.

¹⁰ <http://usinfo.state.gov/products/pubs/intelprp/brazil.htm>

¹¹ <http://www.acton.org/publicat/randl/interview.php?id=448>

¹² http://www.ustr.gov/Document_Library/Press_Releases/2004/December/Brazil_Generalized_System_of_Preferences_Intellectual_Property_Rights_Review_Extended.html

¹³ <http://usinfo.state.gov/products/pubs/intelprp/brazil.htm>

¹⁴ Ibid.