



AIDS & Trade: Myths & Realities

U.S. Pressure on Southern Africa & Thailand Will Impede Access to Medicines

With thanks to HealthGAP (www.healthgap.org)

Although the U.S. initially won significant intellectual property concessions in a multilateral negotiations that resulted in the formation of the World Trade Organization and the passage of the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), the U.S. has now turned to bilateral and regional agreements in Latin America (CAFTA, Chile, and Peru), in Southeast Asia (Singapore and now it hopes Thailand and then Malaysia), and in Africa (on-going negotiations with the Southern Africa Customs Union) to secure increased market exclusivity/monopoly rights for its research and development pharmaceutical industry.

Reeling from the negative publicity and pro-access to medicines messaging in Thailand and internationally, the Office of the U.S. Trade Representative (USTR) has mounted a public relations campaign full of distortions and omissions. The U.S.'s myths must be refuted with the truth: Southern Africa, Thailand and other developing countries have a right, indeed an obligation, to guarantee access to more affordable generic medicines in order to address its multiple public health needs.

Myth 1: The FTA will not raise the price of generic medicines in Thailand or South Africa; those medicines will continue to be available at price generic companies choose; most HIV/AIDS drugs are generic.

Reality: These reassurances contain a small truth within a big lie. It's true that an FTA will not affect pricing on drugs that are already being produced generically – that is older, first-line medicines. However, the new rules will increasingly affect the price of newer medicines, especially as drug companies increase their patent filings in Thailand and South Africa, as they seek extensions of patent terms, and as they enforce data rights for their newer medicines. Consumers in Thailand and South Africa will need and are entitled to affordable access to newer medicines at less than monopoly prices. By gaining longer patents and additional data exclusivity rights, big drug companies can continue to exclude or at the very least delay entry by generic competitors, thereby keeping the prices of medicines artificially high.

Myth 2: The U.S. is not proposing extensions of patents beyond the 20 years that is already the law in Thailand and South Africa; data exclusivity does not extend patents.

Reality: The U.S. has sought extensions of patent terms for regulatory delay (both in issuing a patent and in granting marketing approval) in all of its recent FTAs. Inside sources have confirmed that the U.S. is seeking such extensions in the Thai agreement as well and is likely to do so with SACU. The U.S. argument that data exclusivity does not extend patents is true as a matter of patent law, but in economic terms data exclusivity creates a practical right of marketing exclusivity that can delay introduction of generic products even if a patent has expired or even if there is no patent whatsoever.

Myth 3: Data exclusivity does not bar entry of generic equivalents; generic producers are free to submit their own test data and gain marketing approval.

Reality: The U.S. administration argues that it is incredibly expensive for originator drug companies to discover and prove the safety and efficacy of new drugs, but then it argues illogically that those same costs would not bar entry of a generic competitor. To the contrary, not only would it be too expensive and time-consuming for generic companies to repeat clinical trials to gain access to relatively small and poor markets like Thailand and Southern Africa, it would also be ethically improper since the safety and efficacy of the underlying product (and its equivalents) have already been established.

Myth 4: Big pharmaceutical companies must get higher profits from even small, poor countries like Thailand and those in Southern Africa in order to have incentives to invest in research and development.

Reality: Profits from sales in developing countries are insignificant in creating incentives for future research and development. The U.S. drug industry is already the most profitable industry in the world. Pharmaceutical sales in Thailand and Southern Africa are an infinitesimal portion of global sales (totaling \$518 billion in 2004) and all developing country markets combined (Africa, Asia, and Latin America) comprise less than 11.5% of global drug sales with Africa making up just .4%. U.S. drug companies make most of their sales (88.5%) and an even higher portion of their profits from the rich markets of North America, Europe, and Japan. They don't need to squeeze blood from poor consumers in Thailand and Southern Africa in order to bring a new medicine to the market.

Myth 5: Because high profits are necessary for research and development, U.S. IPR-enhancement goals represent a careful balance between current access and future innovation.

Reality: As an industry, major pharmaceutical companies spend nearly three times as much on marketing and administration as they do on research and development. Even after investing in tax-deductible R&D, drug companies typically earn 1 _ as much in profit as they spend on R&D. Moreover, much of the research conducted by industry is in pursuit of me-too drugs, marketing studies, and patent extensions. 53% of "new drugs" 1981-91 were rated by the FDA as providing little or no therapeutic gain and only 16% offered important therapeutic gains. From 1992-99, under a new review system, only 22% (170/730) of "new" drugs merited priority review at the FDA.

Rather than representing a true balance between innovation and access, U.S. trade policy represents a continuous assault on consumer interests and the human right to health, all in pursuit of super-profits for the decade's most profitable industry. Squandering precious research dollars in pursuit of block-buster drugs, trivial product changes (to gain patent extensions), and market-share for copy-cat drugs, the pharmaceutical industry is intent on maximizing its right to sell high priced produced to rich countries and rich elites in developing countries, even if that means hundreds of millions of poor people must wait decades for pharmaceutical patents to lapse and for prices finally to fall.

Myth 3: Data exclusivity does not bar entry of generic equivalents; generic producers are free to submit their own test data and gain marketing approval.

Reality: The success or failure of a pharmaceutical sector in any country depends very little on the patent law in small and poor countries – success depends on a technological infrastructure and access to patent protections and marketing opportunities in rich countries. Indian pharmaceutical companies have become increasingly innovative even before the new Indian Act and most of their prospective innovation is oriented towards penetration of the First World market. Moreover, after passage of the TRIPS Agreement, which set new standards for intellectual property rights, diminished local working requirements (requirements of local production of patent products), and enhanced

Big Pharma's importation rights, many countries including Peru, Chile, and South Africa experienced a significant disinvestment in their local pharmaceutical industries.

Myth 7: Big drug companies won't bother to register their new products in countries like those in Southern Africa or Thailand unless they are given data exclusivity (U.S.T.R. cites Jordan in this regard).

Reality: Even with small quantity sales, major drug companies still have incentive to sell drugs at a profit to middle-class and rich elites in smaller markets. Moreover, Big Pharma has been registering and selling its brand-name drugs in dozens of countries without data-exclusivity for the past 25 years. In addition to seeking data exclusivity monopolies, drug companies typically have underlying patent-based monopoly rights to their newest medicines, which already erect strong barriers against generic competition.

Of course, the larger problem is that Big Pharma often neglects to register its newest products in poor country markets because the volume of sales is not worth the effort. This is a major problem in drug companies' so-called AIDS-drugs access programs where companies make proud announcements of price reductions in low-income (not middle-income) countries and then neglect to register their products (or even to seek temporary import permissions from drug regulatory agencies). For example, Gilead has registered Tenofovir and Truvada in only a handful of access countries (6/97 and 3/97 respectively). Likewise, Abbott has not sought registration of its new single-dose, non-refrigeration Kaletra formulation in any of its 68 access countries.

Myth 8: Only a few drugs are affected so people should not be worried.

Reality: Although it is true that data exclusivity will not apply to all drugs, it does apply to the newest medicines, many of which represent therapeutic breakthroughs, and, if implemented in the manner wanted by the U.S., will apply to most new medicines brought to market in Southern Africa and Thailand in the future. There's no reason that people should not have access to affordable versions of the newest and most effective medicines even if those drugs are relatively few in number.

Myth 9: The World Trade Organization's TRIPS Agreement requires Southern African nations and Thailand to adopt data exclusivity provisions.

Reality: The U.S. administration is misrepresenting the standards required by the TRIPS Agreement. The relevant portion of the TRIPS Agreement, Art. 39.3, only requires protection of undisclosed data against "unfair commercial use" – basically theft or commercial espionage. Nowhere does it state that exclusive rights must be provided for a given period. In fact, TRIPS makes clear that countries may decide for themselves what constitutes "unfair commercial use" and that there are many possible approaches to satisfy this requirement. Permitting a drug regulatory authority to do its job – assuring the quality, safety, and efficacy of medicines – is not unfair commercial use; it is a mandated public service. Prior to 1994, the U.S. tried to get its strict interpretation of data exclusivity into the TRIPS Agreement and failed – negotiators simply rejected its proposal. The TRIPS Agreement, as clarified by the Doha Declaration, ensures the primacy of public health and further ensures that intellectual property rules do not interfere with promoting "access to medicines for all." Furthermore, the Trade Promotion Authority Act of 2002, §2102(b)(4)(C) requires the U.S. to uphold the Doha Declaration. The USTR is defying this requirement.

Myth 10: The proposed FTA would permit Southern African nations and Thailand to take measures it considers necessary to protect public health, particularly with regard to the epidemics of HIV/AIDS, TB, and malaria.

Reality: The exact language of the U.S. proposal creates ironclad protection for pharmaceutical test data with no textual exceptions for registering medicines produced domestically or imported pursuant to compulsory licenses or government use orders. While patents that block access to medicines can be remedied through compulsory licenses

and other TRIPS-compliant safeguards, there is no such explicit recourse for data exclusivity. The U.S. is using vague assurances about rights to protect public health for “epidemics such as HIV/AIDS, tuberculosis and malaria to offset explicit language that takes away such rights. “Sign this contract, but rely on my good intentions in an unsigned postcard” doesn’t work when you buy a used car and it shouldn’t work in trade agreements either.

Myth 11: U.S. is willing to meet with civil society opponents to “clear up misunderstandings.”

Reality: The U.S. insists that its FTA negotiations and all negotiating positions and documents be kept secret. It did not even distribute its proposed IPR provisions to Thai negotiators until the very last moment. Moreover, civil society groups in the U.S. have met with the USTR on many occasions to raise objections to its TRIPS-plus provisions in free trade negotiations as have some members of Congress. Contrary to clearing up misunderstandings, these meetings have consistently confirmed that the USTR is more interested in imposing an ever higher standard of intellectual property protections on developing countries. Each successful negotiation becomes a new step toward even stronger IPRs.