

## **Fact Sheet on Abbott Laboratories, HIV and Lopinavir/Ritonavir**

### *What is Abbott's track record on this drug?*

#### **Abbott and Pricing**

- Abbott Labs has engaged in egregious pricing for years. The *Wall Street Journal* in 2007 reported on how Abbott used its monopoly position to raise the price of Norvir (Ritonavir) in the U.S. by 400% – at the expense of the public's health. In 2009, Abbott settled this issue on a class action antitrust lawsuit for \$10 million.
- Abbott's track record on pricing this drug in the developing world is also troubling. A 2006 study for the World Health Organization (WHO) by Paul Farmer (Partners in Health) and others revealed that although Abbott charged some customers as little as \$550 for a one-year supply of Lopinavir/Ritonavir - (LPV/r), it “charged El Salvador and Peru between US \$4468 and US \$4511, respectively – over eight times (712-720%) more expensive than the benchmark, and double the GDP per capita of each of these countries.”
- Abbott continues to price this drug for developing countries much higher than the lowest available price. For example, in recent years, in countries such as Mexico, Colombia, Chile, Argentina, Brazil and South Africa, Abbott is reported to have charged between \$1000-\$5000 per patient per year. Due to consistent pressure by developing countries and civil society, as well as continuing generic competition, Abbott has brought its price down for countries like India to \$1000, per patient per year. For a drug that is now available for \$440<sup>1</sup> under the program sponsored by the Clinton Health Access Initiative and UNITAID, Abbott's pricing is absolutely unconscionable.
- Ongoing price reductions in the market are largely due to competition from multiple generic suppliers in India that are working to lower the price of the drug. In Brazil, Abbott reduced the price for Lopinavir/Ritonavir only after the government, in the interest of saving lives, threatened to override the patent by issuing a compulsory license that would allow generic competition.

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<sup>1</sup> Price per November 2010 CHAI price list

- In the first three months of 2010 alone, Abbott saw \$292 million in global sales from Lopinavir/Ritonavir, out of \$7.7 billion in total revenue for the period.<sup>2</sup>
- Public health groups around the world are engaging in legal and advocacy strategies to increase access to Lopinavir/Ritonavir and counter Abbott's pricing tactics.
- The Clinton Health Access Initiative has negotiated a price of \$440/per patient, per year for generic, heat-stable versions of this drug from four generic suppliers.

### **Abbott and Patents on Lopinavir/Ritonavir**

- Since 1992, **Abbott has tried to patent these drugs at least 75 times** – and is continuing to submit new applications.
- Every other pharmaceutical company holding patents on lifesaving HIV drugs has ensured that they are accessible and affordable to developing countries, including by offering licenses with low royalty rates to generic companies in India and elsewhere. Abbott has refused to partner with generics to supply the world's poor. *As former President Bill Clinton said in 2007, "Abbott has been almost alone in its hard-line position here over what I consider to be a life and death matter."*
- In 2007, the government of Thailand, after futile negotiations with Abbott on increasing access to Lopinavir/Ritonavir, issued a compulsory license in order to provide affordable versions of the drug to its HIV-positive patients. Abbott responded by withdrawing several of its drugs from the Thai market and pressuring the U.S. Trade Representative to take action against Thailand. Outcry from the global health community, including members of Congress and the Clinton Health Access Initiative, helped prevent this.

From a *New York Times* article on this issue: *"Standing next to Thailand's health minister, Mr. Clinton also forcefully endorsed recent decisions by Thailand and Brazil to break patents held by American pharmaceutical companies that are charging prices Mr. Clinton described as exorbitant, but that drug company officials said were reasonable.*

*"No company will live or die because of high price premiums for AIDS drugs in middle-income countries, but patients may," he said.*"

- Patents on Lopinavir/Ritonavir have implications for other lifesaving drugs as well. There is currently no co-formulated tablet of Atazanavir and Ritonavir, a clinically similar and cheaper HIV drug combination. Yet the companies holding the patents on these two drugs (BMS and Abbott, respectively) have not partnered to make this lifesaving combination available. Indian generics are reported to be

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<sup>2</sup> <http://www.thepharmaletter.com/file/94378/abbott-labs-first-quarter-2010-profits-plunge-but-forecasts-double-digit-ongoing-earnings-growth-in-2010-completes-facet-buy.html>

creating such a combination, but would not be able bring it to market if a patent on Ritonavir or Atazanavir is granted.

- I-MAK, a U.S.-based not-for-profit group, has challenged Abbott's patents in India and Europe. Multiple generic suppliers are also challenging Abbott's patents in India.
- According to Doctors without Borders, if one of the Lopinavir/Ritonavir patent "applications is granted, current generic competition, which is bringing prices substantially down as demand increases, will be under threat."<sup>3</sup>

***What is the state of the global HIV epidemic and how does this patent decision affect it?***

- Global HIV Scenario (2009):

Patients living with HIV/AIDS	33,300,000
Patients receiving ART	5,254,000
Patients needing ART	14,600,000
Percent coverage	36%
- Every person living with HIV deserves access to affordable HIV drugs (called antiretrovirals or ARVs), a position endorsed by the World Health Organization and other international organizations.
- Indian generic companies are the main suppliers of affordable, high quality ARVs to patients in developing countries around the world.
- According to the World Health Organisation (WHO), 3 percent of patients on first-line ARVs switch to second-line annually. Developing countries increasingly need a source of affordable second-line ARVs in order to control the costs of their treatment programs.
- Cost savings generated over a three-year period by introducing generic Lopinavir/Ritonavir to 43 low- and middle-income countries would be sufficient to start 130,000 new patients on HIV treatment who currently lack access. That is 130,000 lives that could be saved from opening up the market for this drug alone.
- If Abbott had won, it would have placed not just Indian patients at risk, but also the world's HIV patients. Competition led by the Indian generic companies has resulted in ARV prices coming down from \$10,000 per patient per year in 2000, to as little as \$79 today.

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<sup>3</sup> <http://apps.who.int/medicinedocs/documents/s17150e/s17150e.pdf>, p47.

***What is the HIV situation in India? How does this patent decision affect India?***

- There are 2.5 million HIV patients in India, of whom 199,000 are receiving treatment, according to the National AIDS Control Organization.
- Over the next five years, the need will grow enormously. Thousands of lives in India hang in the balance.
- Since Abbott's patent is now rejected, Indian generic companies will likely supply the cheapest version of Lopinavir/Ritonavir to the Indian government, as they have in the past with other drugs.
- If Abbott had been granted an (unlawful) patent, many patients would not have been able to access Lopinavir/Ritonavir because of its cost. This decision would have effectively sealed their fate.
- During the World Trade Organization negotiations, India led the developing country bloc to protect public health. When India passed its patent law, it included a strict provision against patent abuse. This case also signals that India will continue to be a leader among developing countries that sets an example of how to protect its citizens' lives while participating in international trade regimes.