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I-MAK Challenges Patents on Lifesaving HIV Drug Combination in Europe, India

August 16, 2007

New York – Today, a U.S.-based non-profit organization, the Initiative for Medicines, Access & Knowledge (I-MAK) announced its filings of critical patent challenges on the HIV drug combination Lopinavir/Ritonavir. This drug combination is manufactured and sold by U.S. drug company Abbott Laboratories under the brand name Aluvia®. I-MAK's patent submissions were filed at the European Patent Office and the Indian Patent Office.

The tablet form of Lopinavir/Ritonavir is considered to be important for patients compared to the older soft-gel capsule form. The tablet does not require refrigeration, does not have dietary restrictions, and lowers the number of pills a patient must take per day. However, Lopinavir/Ritonavir is an old drug, and has been known and formulated for several years. Merely reformulating old drugs in a different way, without showing inventiveness, is not patentable under either European or Indian law.

Today, I-MAK challenged the validity of Abbott's patent applications and Abbott's attempts to prolong its exclusivity over the drug. To date, no patent has been granted on the Lopinavir/Ritonavir tablet in Europe, India or the U.S. It is believed that the patent is also not granted in Brazil, South Africa or China.

Access Issues for Lopinavir/Ritonavir Tablet

The World Health Organisation recommends Lopinavir/Ritonavir as a leading second-line antiretroviral (ARV) therapy. The present cost structure by Abbott Laboratories - \$2200 per patient, per year as its middle-tier price and \$500 per patient, per year as its lowest price – remains a serious barrier to scaling up access to HIV treatment worldwide. Further, the price of \$500 is only offered to a small number of countries, and developing countries with large numbers of People Living with HIV must purchase the drug at significantly higher prices.

The Clinton Foundation HIV/AIDS Initiative has been among the organizations pursuing cost and price reductions for Lopinavir/Ritonavir by encouraging the entry of generic competition. President Clinton announced a reduced generic price for Lopinavir/Ritonavir in May 2007, and urged Abbott to do more to enable generic production and lower its own pricing in the developing world. To date, there is no change in Abbott's refusal to license the Lopinavir/Ritonavir tablet to generic companies or to reduce its prices in developing countries.

Currently, very few generic versions of the drug are available. Cipla, an Indian generic company who pioneered the lowering of prices on first-line HIV drugs in 2001, is currently offering a generic version of the Lopinavir/Ritonavir tablet.

I-MAK's submissions raise serious questions on the validity of Abbott's claimed exclusivity, which, if successful, should open the door for suppliers to provide (or continue to provide) the drug at lower cost.

Basis of Patent Challenge

I-MAK's patent submissions are based on legal and scientific grounds. The crux of the argument is that the tablet is not inventive: under the law, a drug must be an invention to obtain a patent. The I-MAK submissions argue that Abbott is claiming inventiveness by merely adding known substances, like the polymer PVP to the old drug combination Lopinavir/Ritonavir, using a previously patented technology, Meltrex® (or melt-extrusion).

“Abbott's application on the Lopinavir/Ritonavir tablet is not inventive and, if granted, would prevent others from supplying low-cost versions of the drug,” stated Tahir Amin, Director of I-MAK. “It is an egregious example of how the public is harmed by improper extension of patent life by Abbott Laboratories.”

Background on Lopinavir/Ritonavir Tablet

Lopinavir and Ritonavir are HIV medications classified as protease inhibitors. Entities including international organizations Clinton Foundation HIV/AIDS Initiative, Medecins Sans Frontieres, The Global Fund to Fight AIDS, Tuberculosis and Malaria and UNITAID have highly prioritized the Lopinavir/Ritonavir combination to save the lives of patients across the world.

Abbott Laboratories has come under scrutiny in the past for its unconscionable pricing practices on Lopinavir/Ritonavir, such as the 2004 Ritonavir price hike and the more recent controversy against the Government of Thailand for issuing a compulsory license on Lopinavir/Ritonavir.

About the Initiative for Medicines, Access & Knowledge (I-MAK)

I-MAK is an independent not-for-profit public service organization consisting of lawyers and scientists working to protect the public domain against undeserved patents. I-MAK works globally to ensure that patents do not act as a barrier to research and restrict the public's access to affordable medicines. Previously, I-MAK has supported patient's groups in filing against the Lopinavir and Ritonavir patents individually, as well as against the previously known soft-gel capsule of Lopinavir/Ritonavir.

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