SECONDARY PATENTING: A Threat to Affordable, Generic ARVs

ACCESS to HIV/AIDS MEDICINE KALETRA
Abbott Laboratories currently holds the patents on Kaletra (Aluvia), a lifesaving HIV/AIDS drug combination. The World Health Organization recommends Kaletra as a critical second-line treatment for people living with HIV.

In many countries where Kaletra is not under patent protection, branded and generic versions are available at prices as low as $368 per patient, per year. Yet Abbott prices the drug at much higher prices in middle-income countries where it holds patents, such as $1000 in Vietnam and $4000 in Argentina. Such exorbitant pricing limits the number of patients a country can afford to treat with their limited public health budgets, which are often donor funded. In some countries like Malaysia, many patients must pay for second-line medicines out of pocket.

Patients and advocates around the world are challenging Abbott to ask: why is this drug combination not affordable and accessible for all people living with HIV?

The PATENTS, the PROBLEM
Kaletra is a combination of two antiretroviral agents: ritonavir and lopinavir. The patents for these two underlying compounds are set to expire in 2014 and 2016, respectively. Theoretically, generic suppliers ought to be able to sell to all countries starting in 2016.

However, in order to prolong market exclusivity, Abbott has filed follow-on patents which threaten to prevent that competition until at least 2028. Follow-on patents are an example of a “life cycle management” strategy that can manipulate the system for the benefit of the patent holder. When an abundance of follow-on patents are filed, a patent “cluster” is formed which may have no other purpose than to delay generics from entering the market.

Ownership of patents is not unjust or undesirable in and of itself, but the strategies used by Abbott and other pharmaceutical companies to manipulate the patent system should be curbed.

TOO MANY PATENTS: 108 and Counting
Harvard researchers identified 108 United States patents and patent applications belonging to Abbott, which could be used to protect Kaletra’s market exclusivity. Many of these patents exist in other countries as well. These researchers found several clusters of patents that were problematic for two reasons: they had overlapping claims (patenting the same subject matter) or the claims were not inventive. Both raise serious questions of whether these patents should be granted under the law.

One such problematic cluster of patents is for the heat-stable tablet version of Kaletra, which includes nine pending applications covering variations of the heat-stable formulation technique. In addition to the problem of overlapping claims, the patents in this cluster were found not to be inventive, as the heat-stabilizing process has long been known to the scientific community.

Additionally, the researchers discovered four patents which covered polymorphic forms of ritonavir and lopinavir. A polymorph, which is an alternate crystalline form of a compound, is not an invention but rather exists inherently in the base chemical compound.

Why BAD PATENTS MATTER
Non-inventive patents could be used by Abbott to shut out competition, or at minimum to increase transaction costs and delay generic entry. Granting low-quality patents could also impact innovation as patent clusters may prevent useful research, including for fixed dose combinations. This strategy of ‘scorching the earth’ through numerous patents has negative effects on both competition and innovation.
Artificially Extended Patents = Higher Prices:
The patent clusters analyzed provide Abbott with potential exclusivity in certain markets for Kaletra until at least 2028 – twelve years after the patents on the underlying compounds should expire, and 39 years after the first patent for ritonavir was filed.

During that extended patent term, Abbott would be able to maintain monopoly pricing in any country that grants these patents – pricing that is paid by public health systems, international donors, and patients.

Blocking Competition: If generics wish to enter a country’s market, they will have to perform complex patent searches specific to each country. In the case of Kaletra, generic entrants will likely have to work around many of the 108 patents identified. This obfuscation prevents competition by hindering competitor entry, and allows Abbott to initiate protracted litigation when a competitor does try to enter.

WHAT CAN BE DONE?
One effective remedy is to make it more difficult for pharmaceutical companies to abuse the patent system by raising the threshold for inventiveness in patent laws. The effect is to reduce the likelihood that companies will flood the patent system with low-quality follow-on patents. This safeguard has already been implemented by several countries, including India, Argentina and the Philippines.

As a direct response to the intentional manipulation of the patent system and protecting public health needs, governments who are paying exorbitant prices for this drug should also be prepared to issue compulsory licenses for Kaletra.

Please support patient health and a well-functioning patent system by curbing Abbott’s manipulative patent practices. Learn more at www.i-mak.org/lopinavirritonavir and www.citizen.org/Kaletra-campaign

Duration Of Patents Covering Ritonavir And Lopinavir/Ritonavir

Source: Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades, Tahir Amin and Aaron Kesselheim, Health Affairs, October 2012. Notes: Timeline represents patents and patent clusters held by Abbott Laboratories. Dates shown are subject to future patent extensions and reexamination of patents at the request of parties who may have evidence of lack of inventiveness. The blue bar represents potential delay in generic entry as a results of life-cycle management, and not a patent duration. Polymorphs are defined in the text.