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PATENTS AND HIV MEDICATIONS: AN OVERVIEW

A key challenge to expanding access to treatment for HIV in developing countries is the high prices of medicines. Prices often far exceed the cost of production and preserve excessive profit margins for pharmaceutical companies.

The pharmaceutical industry has a powerful lever to protect these profits: the patent system. When a drug company invents a new medicine, it is rewarded with a patent that grants it the exclusive right to sell this medicine for 20 years.

This is both fair and necessary: genuine research and development are expensive, and innovation would wither absent patent protection.

But the pharmaceutical industry often games the rules, using the patent system to illegitimately monopolize the market in countries around the world. Here's how it works: As a drug's patent approaches expiry and is exposed to generic competition, drug companies often make very slight modifications to the drug and submit new patent applications claiming that they cover an entirely new innovation. These alterations, however, rarely change the drug's therapeutic impact – in other words, they do not generate additional clinical benefits but rather simply represent a new method of manufacture, delivery, or storage. Many of these additional patents are used as a smokescreen, forcing generic competitors to undertake costly legal challenges or avoid the market altogether because of the legal uncertainty.

As a result, lower-cost generic versions of the medication that are of equal quality and efficacy are not available in that market. In developing countries this means millions of poor people go without the treatment because they cannot afford the branded, high-margin product. India plays a critical role in this bleak picture: Indian manufacturers export generic versions of drugs (including HIV drugs) to developing countries at prices that are frequently the lowest in the world. Illegitimate patent protection on drugs in India would have a tremendous negative impact on the supply to lower-income countries.

This dynamic is playing out in India right now, with a critically important antiretroviral medication for the treatment of HIV: Lopinavir/Ritonavir. This week, Abbott Laboratories was denied its frivolous patent application for Lopinavir/Ritonavir (heat stable tablet)¹, opening the door to access for many more patients. This drug, which is in the protease inhibitor class, is among the most powerful and important tools for

¹ Branded as Kaletra in developed countries and as Aluvia in developing countries

preventing the onset of AIDS in HIV-positive patients that exist today. Indeed, Lopinavir/Ritonavir is one of the medications recommended by the World Health Organization for second-line treatment in HIV-positive patients whose first set of medications can no longer keep them healthy.

Lopinavir/Ritonavir is the subject of the greatest abuse of the patent system around the globe. **Since 1992, when Abbott was awarded its first patent related to Ritonavir in the U.S., the company has sought at least 75 new patents on essentially the same set of drugs in Lopinavir/Ritonavir.** Abbott has continued to make minor modifications over the last two decades and cement its monopoly on these products. In a continuation of that strategy, Abbott tried to seek a new patent in India on the basis of a modification that adds no clinical benefit.

A generic version of Lopinavir/Ritonavir is currently being produced in India for domestic consumption and export to many developing countries that have been hardest hit by the HIV epidemic. Only because Abbott's patent application has been denied will these and other generic manufacturers be able to continue to produce the quantities of the medication that patients in India and around the world need to survive.

And the need is tremendous. 14.6 million people around the world need ARVs to survive. Today, India's rejection of Abbott's patent application can help save many of them.

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