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Medicines Patent Pool Reaches Licensing Deal for GSK Patents to Expand Access to Medicines for Children with HIV

118-Country Deal Shows a Path to More Affordable Treatment Options, But Companies Must Be Pushed to Take Further Action

WASHINGTON, D.C. –A patent licensing agreement announced Wednesday can help health programs in many countries improve their treatment response to the needs of children living with HIV, Public Citizen said. The agreement provides an improved framework for future industry licensing and could even stimulate the development of new pediatric combination therapies –but only if pharmaceutical companies follow the Medicines Patent Pool's lead.

The licensing agreement was made between ViiV Healthcare —a joint venture of GlaxoSmithKline (GSK), Pfizer and Shionogi —and the Medicines Patent Pool (MPP), a Swiss foundation funded by UNITAID. The agreement covers pediatric formulations of ViiV's existing and pipeline HIV drugs. Generics manufacturers may use the agreement's licenses to compete in the countries named. This generic competition with patented products leads to reduced prices and expanded medicines access.

"We congratulate the MPP and encourage all of Big Pharma to jump in the patent pool," said Peter Maybarduk, director of Public Citizen's Global Access to Medicines Program. "Where companies fail to negotiate, we will pursue compulsory measures. With civil society partners worldwide, we will challenge any patent barrier that impedes the goal of an AIDS-free generation."

Public Citizen has advised many governments around the world on their rights to issue compulsory licenses to overcome pharmaceutical monopolies.

ViiV has agreed to license pediatric formulations of its HIV/AIDS treatment abacavir (ABC) to the MPP, along with pediatric formulations of all drugs currently in the research pipeline as soon as they achieve regulatory approval.

"We encourage GSK, Pfizer and Shionogi to take the important next step of licensing adult formulations of pipeline drugs to the MPP while maintaining the pro-competitive terms of the pediatric license, and including all low-and middle-income countries," said Maybarduk.

Public Citizen also is urging AbbVie, formerly part of Abbott Laboratories, to enter license

negotiations for their patents on lopinavir and ritonavir, other important HIV medications. Licenses for these medicines would facilitate the development of new and needed multi-drug combinations.

“Abbott Labs’ patent and price abuses over many years earned it a negative reputation among many treatment advocates,” Maybarduk said. “But AbbVie could fashion itself a fresh start by immediately entering negotiations with the MPP.”

The MPP-abacavir agreement makes certain improvements on the terms of licenses negotiated by the MPP with Gilead Sciences in 2011. The MPP-Gilead licenses, while bettering the status quo at the time, placed limits on the manufacture of active pharmaceutical ingredient (API), while the ViiV agreement allows manufacture and API sourcing anywhere so long as quality standards are met. The deal allows licensees to sell outside the license territory in any country where there is no blocking patent (or under a compulsory license). Acknowledging that data exclusivity can be a barrier to access, the agreement waives any claims of data exclusivity for ABC and forbids claims of data exclusivity on the drug by sub-licensees. The licenses are royalty-free.

The agreement, in a Memorandum of Understanding between ViiV and the Medicines Patent Pool, also obligates ViiV to explore avenues for increasing access to future drugs outside of the license territory. ViiV and the MPP commit to seek out partnerships with others to encourage the development of fixed-dose combinations for which they do not hold all necessary patents.

“Recent studies demonstrating that HIV treatment is also effective as prevention have shown the world that an AIDS-free generation is possible —but only if we dramatically scale up access to treatment,” said Maybarduk. “The terms contained in the MPP-ViiV agreement, while far from perfect, provide an improved licensing blueprint. It is very important we see licenses for adult formulations with comparable terms. If pharmaceutical companies will heed the call to license on pro-competitive terms in all low-and middle-income countries, these agreements can support the dramatic increase in access to medicines we need.”

More information about Public Citizen’s Global Access to Medicines Program is available at: www.citizen.org/access.

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