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European Court of Justice
Rue du Fort Niedergrünewald
L – 2925 Luxembourg

6 December 2017

Re : Teva UK Ltd, Accord Healthcare Ltd, Lupin Ltd, Lupin (Europe) Ltd, Generics (UK) trading as "Mylan" v Gilead Sciences Inc. (Case C-121/17)

Your honors,

We are addressing this letter to you in regards with the forthcoming decision of the European Court of Justice related to the validity of Gilead Sciences' Supplementary Protection Certificate (SPC) covering TRUVADA®. As a French lead organisation working in the field of HIV and hepatitis, AIDES would like to share with the Court its concerns about the current situation and the impact of a SPC which should not have been granted in the first place.

Indeed, this SPC extends Gilead's exclusivity over the combination of tenofovir and emtricitabine until 21st February, 2020. The monopoly extension due to this SPC is currently maintaining the price at a high level, when generics are 60% cheaper than the original product in France.

Last July, during the International AIDS conference 2017 in Paris, Mylan announced its decision to launch a generic version of the combination in France. The box of generics will cost 179, 90 euros instead of 406, 87 euros, the current price of the original product. Likewise, the company Biogaran recently launched a generic version of the combination.

Nevertheless, Gilead's SPC is still in force and the company sued Mylan for infringement of its SPC and asked for a temporary ban of the generics. On September 5, the judge of the Paris High Court deemed such a ban was not justified given that Gilead's SPC is "in all likelihood invalid" (decision N°RG : 17/57112). Gilead was condemned to pay 100 000 euros for litigation costs. However, the decision of the Paris High Court is temporary and could be reconsidered in a year's time. The threat of a lawsuit against generic producers is real and can represent a strong legal barrier to the market entry of other generic competitors.

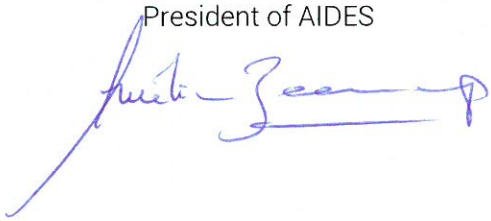
Thus, Gilead's SPC undermines both access for all and public health strategies. Indeed, besides its use for treatment, the combination of tenofovir and emtricitabine is also an effective tool of prevention against HIV. In France, 64% of HIV-positive people receiving Antiretroviral therapy (ART) take TRUVADA® for treatment which represent 73 440 people and more than 5 000 people take it for PrEP, for a preventive use against infection. The French healthcare system allows a 100% reimbursement for TRUVADA®, which ensures that prices are not a barrier for patients.

However, with the extension of the monopoly the price becomes a threat to the ability of the French healthcare system to implement and maintain this policy. In countries where such a policy has not been adopted yet, there is a serious risk that the high price of the treatment will postpone the adoption of a prevention policy or limit the coverage.

Given the negative impacts of Gilead's SPC, it is of paramount importance that the European Court of Justice proceeds with a decision regarding this SPC. We believe its validity does not stand because it is not compliant with the EU case law, as exposed in the appendix attached to this letter. Any delay in maintaining illegitimate monopolies and allowing the SPC granting system to be too lax and systematic have critical consequences on patients and health systems.

Aurélien Beaucamp

President of AIDES



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