



Mike FRICK
TB Project Co-director
Treatment Action Group (TAG)

Pauline LONDEIX
Observatoire de la transparence dans les politiques
du médicament

Paris, August the 4th, 2020

Dear Ms Londeix, Mr Frick,

We acknowledge receipt of your letter dated August 3, 2020 and would like to provide clarification about Sanofi's patent applications mentioned in your letter.

The two patent families filed by Sanofi in July 2013 are directed to very specific formulations (i.e. a particular film coated tablet and a particular dispersible formulation) and were historically filed to reward industrial capabilities of the inventors. The two patent families NEVER constituted a barrier for other formulations of rifapentine and isoniazid combinations or the use of the individual drugs to treat TB. Meaning, Sanofi does not have and never intended to have an exclusivity for any and all combinations of rifapentine and isoniazid. Quite the opposite, we believe that generic companies should enter the market if we – all stakeholders - want to reach the goals of the UN Declaration, which is to provide treatment for latent TB infection to at least 30 million people by 2022.

However, to avoid any wrong impression in regard to Sanofi's engagement in the fight against tuberculosis, a process of abandoning all the patent applications related to all national counterpart patents and applications of the two patent families were Sanofi was initiated in May 2019 and was completed by end of July 2020. This withdrawal is already effective in several countries. The process follows either withdrawal or abandonment requests or non-payment of maintenance fees depending on each country's regulations. The withdrawal has already been published by several patents' offices such as observed in Indonesia or Europe. However, other countries will take longer to reflect the abandonment in their public databases. Sanofi has no control over the processes of the national patent offices who are responsible for effecting the abandonments.

Consistent with the foregoing abandonment, Sanofi commits not to reinstate any of the patents/applications, and not to initiate any action against any party who would like to manufacture the specific formulations of the combinations once covered by Sanofi's two patent families, before the abandonments become effective under the relevant national patent regulations.

For decades, Sanofi has been in the forefront of the fight against tuberculosis. All stakeholders agreed to adopt a sustainable approach that will widen access. We are convinced that an approach that involve multi-partners from academics, public, private, governments such as what we currently observe with COVID19 is the only way to win against tuberculosis.

Remaining at your disposal for any further information or clarification, with our kindest regards.

A handwritten signature in blue ink, appearing to read "Isabelle Villadary", with a long horizontal flourish extending to the left.

Isabelle Villadary,
Malaria and Tuberculosis Programs Head, Corporate Affairs, Sanofi