Actions to expand access to Kaletra in Brazil

In Brazil, more than 50,000 patients are currently taking lopinavir/ritonavir, the most used protease inhibitor in the country for the second line treatment regimen. Considering that universal access to ARVs has been part of the national response to the Aids epidemic since the 1990s, it is expected that the government will face a larger cost burden as more and more people under treatment will move to second line regimens that include lopinavir/ritonavir. This essential medicine accounts for 16% of the total expenditures of the Department of STD, Aids and Viral Hepatitis from the Brazilian Ministry of Health on ARVs. In 2005, it used to account for 30% of those expenses, but the price dropped over the last years, after several negotiations between Abbott and the government. Nonetheless, patents are likely to keep this drug as a burden for the Aids Program budget because Abbott continues to hold a monopoly due to a patent granted in 1997 due to expire in 2017 and further subsequent applications filed by Abbott, as part of a “patent evergreening” strategy. As discussed below, this strategy seeks to extend a drug monopoly.

In the past, the high prices of lopinavir/ritonavir forced the government to pursue different strategies, such as price negotiations and the threat to issue a compulsory license. In terms of civil society response, the Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/ Rebrip) and other groups have been putting into question the legitimacy of the monopoly and trying to avoid its extension. Currently, there are two actions at the judiciary level proposed by GTPI, one asking for a compulsory license for lopinavir/ritonavir and the other questioning the constitutionality of the mechanism through which the patent to lopinavir/ritonavir (and to hundreds of other drugs) was granted (the “pipeline” mechanism). Both actions, if judged favorably to GTPI’s requests, can open way for the purchasing of cheaper versions of the drug and also for local production. Also, in 2008, GTPI has filed a patent opposition for a divisional application made by Abbott. The patent was further denied.

However as previously mentioned, Abbott is using an abusive strategy called “evergreening” to ensure the extension of its monopoly. GTPI has identified 12 patent applications for lopinavir/ritonavir made by Abbott in Brazil. “We decided to file another patent opposition because the monopoly could be extended from 2017 to 2024, if this patent is granted”, said Renata Reis, coordinator of GTPI. The group is presenting an opposition today, as part of the global day of action, to contest one of the most recent applications made by Abbott, on the grounds of lack of novelty and inventive step. “The granting of undue patents must be avoided to signalize that market strategies seeking unlimited monopoly shall not undermine the sustainability of responses to public health needs”.