

Advocacy for access to Truvada in Argentina – International Treatment Preparedness Coalition (ITPC)

Case Studies in Health and Human Rights Advocacy



Background and Context

The International Treatment Preparedness Coalition (ITPC Global) leads with the ***Make Medicines Affordable*** Campaign a project aimed to promote access to affordable medicines in middle-income countries. This case study focuses on the work and victories achieved in Argentina by ITPC's partner, Fundación Grupo Efecto Positivo (FGEP), for access to generic antiretrovirals (ARVs) between 2014 and 2018.

The Health and Human Rights Issue

The issue addressed was the **unaffordability of the ARVs emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF)**, commercialized under the name Truvada by pharma company Gilead, in Argentina. Truvada was used for people living with HIV and **cost US\$ 2,700 per person per year**, representing US\$ 12 million per year in 2015 and a substantial burden for the Argentinian Ministry of Health. Truvada was also approved in 2012 by the Food and Drug Administration for preventive use to reduce the risk of contracting HIV, yet the exorbitant price of the medicine in Argentina made scale-up challenging, **depriving many people exposed to HIV from an efficient complementary preventive treatment.**

How did the advocacy happen?

- In April 2015, Fundación Grupo Efecto Positivo (FGEP) decided to analyze Gilead's patent application and found that it did not meet patentability criteria (a medicine cannot be patented if it doesn't meet the criteria of novelty, inventive step and industrial application).
- FGEP subsequently submitted evidence of those shortcomings through a pre-grant patent opposition to the Argentinean patent office.
- The evidence filed by FGEP was reflected in the patent examiners' report which stated that the application "did not meet legal and regulatory requirements."
- As a consequence, in November 2016, Gilead decided to withdraw the application, giving possibility for generics to produce and commercialize FTC/TDF at lower prices.

- Argentinean generic companies registered their products, followed by Indian generic company Cipla, enabling a significant drop in prices.
- The success of FGEP's advocacy **resulted in cost savings of US\$ 128 million in Truvada and 159 US\$ million in Atripla (TDF/FTC, Efavirenz) over the past 5 years**. According to the Access to Medicines Observatory, **US\$ 312 million were saved** in purchase of medicines thanks to the successful patent opposition.

Who made it happen?

Argentinean civil society was a key actor in enabling access to TDF/FTC. FGEP 1) shed light on the issue of unaffordability of prices and alerted the media, public opinion and public stakeholders; 2) undertook the technical work of patent analysis and submission of patent opposition; 3) coordinated with national stakeholders including local pharmaceutical companies and the Ministry of Health, to strategize, mobilize and share information for access.

Local generic companies were instrumental in making the case a success as they also submitted a patent opposition and registered their products as soon as the patent application was withdrawn.

The **Argentina patent office** and its careful examination of the patent opposition cases was also determinant in the rejection of the patent.

Finally, **public authorities** such as the Ministry of Health, the **media** and the **general public**, were also mobilized for the success of this patent rejection and access to affordable TDF/FTC.

What were the key takeaways?

Communities and civil society organizations played an instrumental role in treatment advocacy successes:

- **Public health and technical expertise:** civil society and community treatment activists have unique public health expertise and legitimacy, which comes both from personal understanding and need for urgent solutions to issues of unaffordability of medicines, but also from the tremendous technical expertise acquired over the decades on technical issues such as treatment literacy and intellectual property. In the Truvada patent opposition case, lawyer Lorena di Giano, executive director of FGEP and a woman living with HIV, was instrumental in making this case a success, developing arguments for the patent opposition and shedding light on the case as a public health issue.
- **Advocacy and mobilization:** civil society is uniquely positioned in enabling the right conditions for access through the development of arguments, mobilization of the media and general public, and design of advocacy strategies to create favorable dynamics. In the Argentinean case, the success was also enabled by the development of an advocacy strategy by FGEP that adapted to the national context and was capable of fast adaptation to rapidly changing environments.
- **Collaboration between stakeholders:** civil society was central in mobilizing other stakeholders to support patent oppositions and treatment advocacy. This mobilization included sharing information and expertise with public authorities, mobilizing patent attorneys and discussing with national patent offices ahead of filing an opposition, as well as coordinating strategies with local generic manufacturers.

For more information, please see relevant articles from [FGEP's website](#) and [IP Watch](#).