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Background

Patents are intellectual property titles that grant temporary and exclusive monopolies over technologies, including medicines. In the health sector, this exclusivity transforms essential goods into high-priced commodities, limiting competition and restricting access — especially in low- and middle-income countries. Although patents are territorial, the TRIPS Agreement, in 1995, imposed a global standard that made product patents for pharmaceuticals mandatory for all World Trade Organization (WTO) members. It shifted power toward transnational pharmaceutical corporations and reduced countries' ability to respond to public health needs.

Compulsory License (CL) is a legal mechanism under TRIPS that allows governments to compulsorily license a patent without the consent of its holder, in the public interest. Voluntary Licenses (VLs) are agreements negotiated with patent-holding companies to select third parties, under terms defined unilaterally by the company. These licenses often include geographic, commercial, and production restrictions, limiting their potential impact on broad public health goals. Internationally, VL have gained recognition as part of the access to medicines agenda, especially with the creation of the Medicines Patent Pool (MPP) in 2010.

In Brazil, this contradiction became evident: the country guaranteed universal access to HIV/AIDS treatment in 1996, the same year it began recognizing pharmaceutical patents for products. Under this tension, Brazil initially relied on public production and threatened the use of compulsory license (CL) to reduce prices. From 2008 onward, however, Brazil shifted its strategy. It began prioritizing public-private partnerships (PPP), frequently based on voluntary licenses (VL). This study examines how these different strategies — CL and VL — shaped access to key antiretrovirals in Brazil, focusing on the cases of efavirenz (EFV) and dolutegravir (DTG).

Description

This study compares two key licensing experiences for HIV treatment access in Brazil: CL for EFV in 2007 and the VL for DTG in 2020.

EFV, at the time part of Brazil's first-line HIV treatment, became a landmark case in the fight against pharmaceutical monopolies. After two years of failed price negotiations with the patent holder Merck and amid strong social mobilization, the Brazilian government declared the public interest and issued the country's first-ever CL in 2007. The CL enabled the importation and later local production of generics by the public laboratory Farmanguinhos/Fiocruz, resulting in a 58% price reduction and estimated savings of USD 104 million between 2007 and 2012.

This experience consolidated what became known as the "Brazilian model" for access to medicines — combining price negotiations, threats of CL, public production, and strong social participation. However, in the following decade, this approach was gradually replaced by PPP, which deprioritized TRIPS safeguards and shifted the focus toward voluntary agreements with transnational pharmaceutical corporations.

In contrast, DTG — currently used by over 600,000 people living with HIV in Brazil and recommended by the World Health Organization (WHO) since 2019 as a first- and second-line treatment — was incorporated without any consideration of TRIPS safeguards. Its adoption in Brazil's Unified Health System (SUS) came only after sustained advocacy by civil society organizations, particularly the Working Group on Intellectual Property (GTPI) and Brazilian Interdisciplinary AIDS Association (ABIA). Civil society mobilization and technical engagement helped push for its adoption in 2016, achieving some price reductions but still at unsustainable levels.

In 2020, Fiocruz's pharmaceutical unit Farmanguinhos signed a confidential bilateral VL with ViiV Healthcare (a joint venture of GSK, Pfizer, and Shionogi), framed as a "strategic alliance" for technology transfer and local production of DTG and the coformulation with lamivudine (DTG/3TC). While marketed as a step toward national production, the deal extended ViiV's monopoly beyond its original patent term (from April 2026 to December 2029) and locked in prices roughly 20 times higher than international benchmarks. By 2025, all DTG used in Brazil is not produced nationally, it is still imported.

Conclusions

Pharmaceutical monopolies continue to undermine Brazil's autonomy, binding the country to opaque agreements that prioritize corporate profits over public health needs. However, despite being framed as tools for public interest, VL remain fundamentally commercial instruments, shaped by corporate priorities rather than democratic or health-driven decision-making. The case of DTG demonstrates how VL, although often promoted as access strategies, can in fact entrench monopolies, restrict transparency, inflate prices, and delay local production.

For emerging health technologies, such as lenacapavir, CL remains a legitimate and essential tool to overcome patent barriers, enable local manufacturing, and ensure timely and equitable access. To uphold the constitutional right to health, Brazil must reclaim and reinforce its public health safeguards. Transparency, technological sovereignty, and meaningful multisectoral participation are not optional — they are fundamental to protecting and sustaining universal access.

References

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