TUPED537: The role of civil society in shaping the political environment for the incorporation of new technologies in Brazil: The cases of Dolutegravir and TDF/FTC

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Background

As Brazil has one of the oldest HIV patient cohorts in developing countries, it anticipates the need to access newer technologies as well as related challenges. However, since 2010, the internal political environment has been undermining the human rights perspective and the ability to confront monopoly powers over key technologies. As result, Brazil is unable to keep its protocols updated, in contradiction to its legacy of reducing the gap between rich and poor countries when it comes to access to the best treatment and prevention options.

From 2014 onwards, civil society intensified efforts to reverse this scenario by adopting multiple strategies that involved campaigns, protests, events, patent oppositions, consultations, publications and advocacy. Such efforts lead to the successful incorporation of Dolutegravir as first line treatment for over 100.000 people, despite strong opposition by the government initially. Civil society has also ensured the incorporation of TDF/FTC as a prevention tool, including though the public consultation with the highest number of submission in the history of the National Commission for the Incorporation of Technologies (CONITEC).

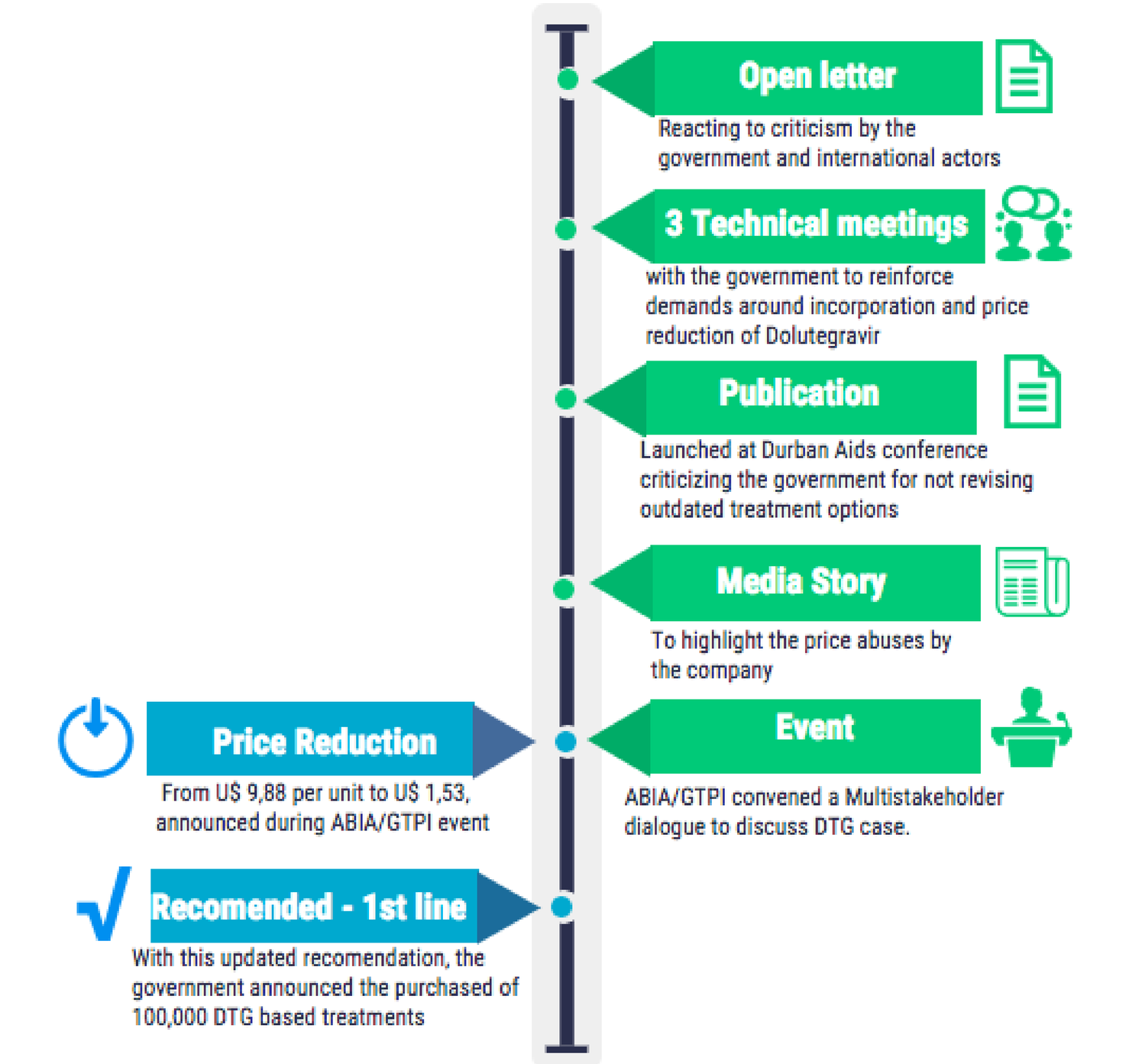
The Working Group on Intellectual Property (GTPI), a coalition of activists, NGOs, social movements and networks of people living with HIV/Aids, has organized numerous demonstrations aimed at increasing political pressure on decisions related to both Dolutegravir and TDF/FTC. Some of these demonstrations happened During major National and international events, such as the X and the X DST, HIV/AIDS and Viral Hepatitis National Congresses in 2015 and 2017, The National Health Conference in 201X (first picture), The 2016 International Aids Conference in Durban, The National Meeting of HIV/Aids NGOs (ENONG) in 2015, the World Aids Day Session at the Plenary of the House of Representatives in 2016 (Second picture). For the mobilization towards adoption of Prep, the Campaign #TruvadaLivre (Free Truvada) was an important tool used to unify civil society voices both to demand the government to initiate the Prep program at the public health system and to pressure Gilead to stop patent abuses and lower their price.

Description

ABIA/GTPI championed and documented numerous efforts to promote policy change around treatment and prevention options. The documentation was organized to reveal the chronology of steps taken by civil society, relating them with policy milestones around the incorporation of Dolutegravir (2016) and TDF/FTC (2017).

Dolutegravir Timeline (2015)

Dolutegravir Timeline (2016)



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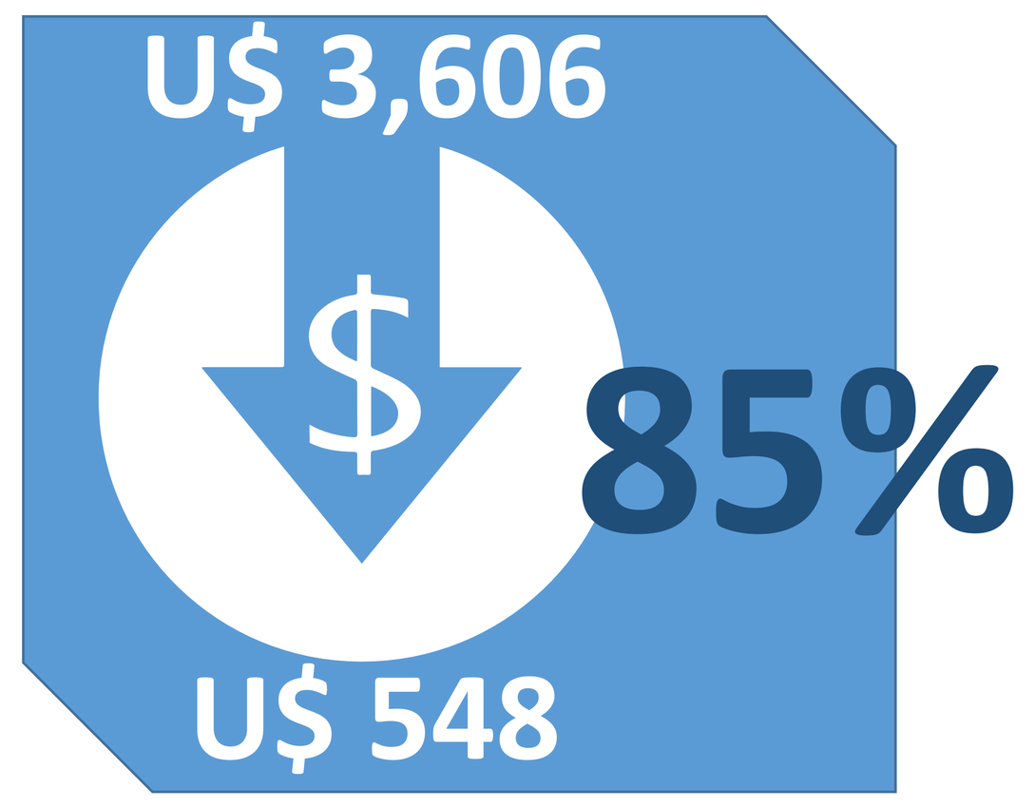
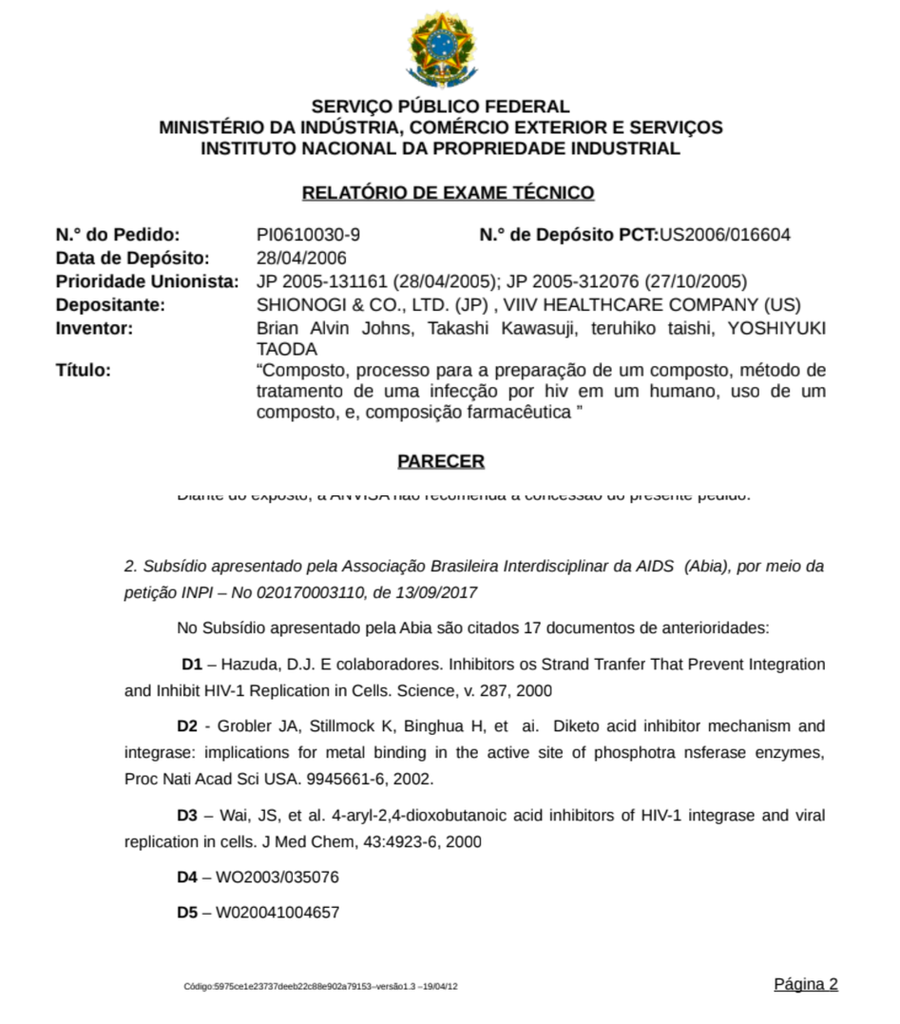


PATENT REJECTION

2017
Pre-grant patent opposition filed by ABIA/GTPI against the main patent application (PI0610030-9)

2018
Opinion for rejection issued by the patent officce based on ABIA/GTPI arguments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INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL

RELATÓRIO DE EXAME TÉCNICO

N.° do Pedido:	PI0610030-9 N.° de Depósito PCT:US2006/016604
Data de Depósito:	28/04/2006
Prioridade Unionista:	JP 2005-131161 (28/04/2005); JP 2005-312076 (27/10/2005)
Depositante:	SHIONOGI & CO., LTD. (JP) , VIIV HEALTHCARE COMPANY (US)
Inventor:	Brian Alvin Johns, Takashi Kawasuji, teruhiko taishi, YOSHIYUKI TAODA
Título:	"Composto, processo para a preparação de um composto, método de tratamento de uma infecção por hiv em um humano, uso de um composto, e, composição farmacêutica "

PARECER

2. Subsídio apresentado pela Associação Brasileira Interdisciplinar da AIDS (Abia), por meio da petição INPI – No 020170003110, de 13/09/2017

No Subsídio apresentado pela Abia são citados 17 documentos de anterioridades:

D1 – Hazuda, D.J. E colaboradores. Inhibitors os Strand Tranfer That Prevent Integration and Inhibit HIV-1 Replication in Cells. Science, v. 287, 2000

D2 - Grobler JA, Stillmock K, Binghua H, et ai. Diketo acid inhibitor mechanism and integrase: implications for metal binding in the active site of phosphotra nsferase enzymes, Proc Nati Acad Sci USA. 9945661-6, 2002.

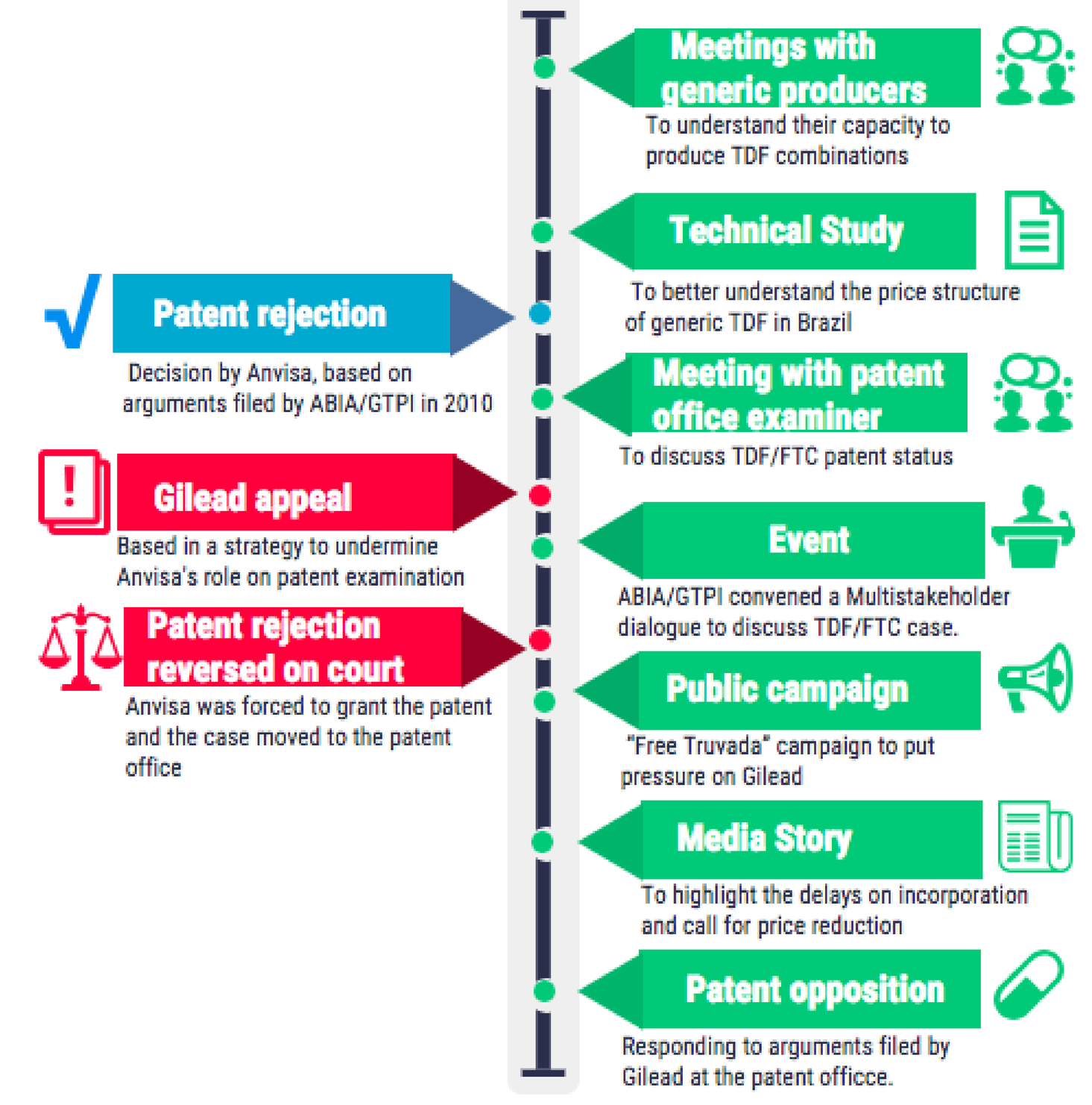
D3 – Wai, JS, et al. 4-aryl-2,4-dioxobutanoic acid inhibitors of HIV-1 integrase and viral replication in cells. J Med Chem, 43:4923-6, 2000

D4 – WO2003/035076

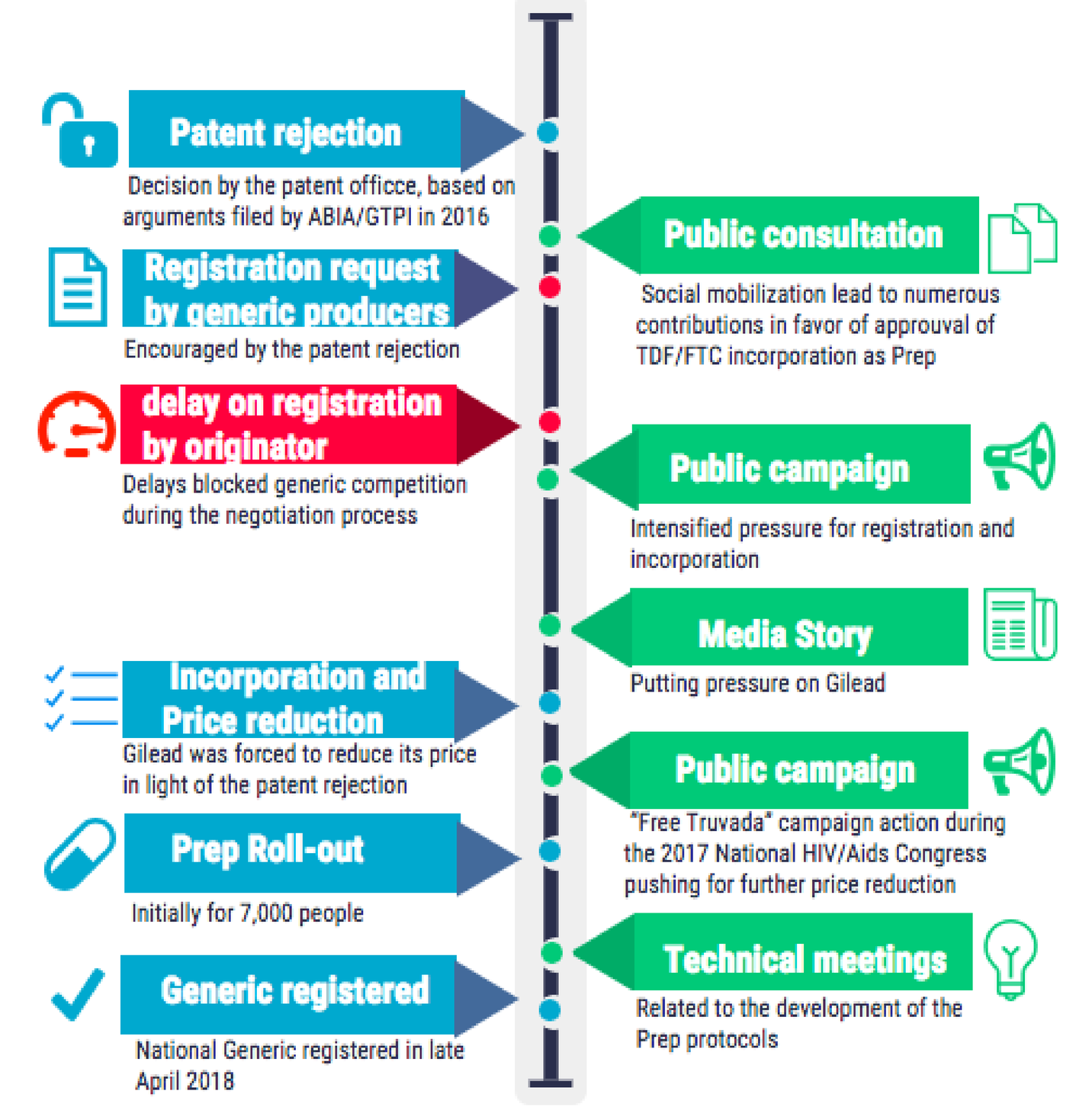
D5 – W020041004657

Código:5975ce1e23737deeb22c88e902a79153–versão1.3 –19/04/12 Página 2

TDF/FTC Timeline (2015/2016)



TDF/FTC Timeline (2017/2018)



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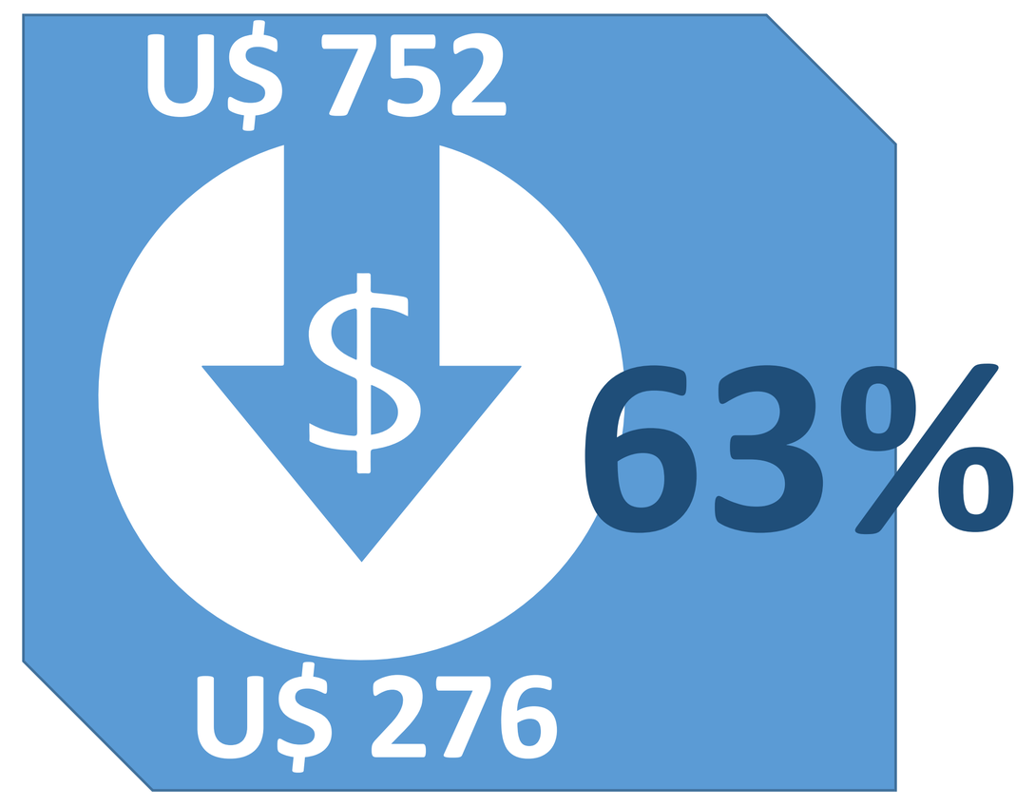

PATENT REJECTION

2016
Pre-grant patent opposition filed by ABIA/GTPI against the main patent application (PI0406760-6)

2017
Rejection decision issued by the patent officce based on ABIA/GTPI arguments


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INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL

RELATÓRIO DE EXAME TÉCNICO

N.° do Pedido:	PI0406760-6 N.° de Depósito PCT:US2004/000832
Data de Depósito:	13/01/2004
Prioridade Unionista:	US 60/440,308 (14/01/2003); US 60/440,246 (14/01/2003)
Depositante:	Gilead Sciences, Inc. (US)
Inventor:	Terrence C. Dahl, Mark M. Menning, Reza Oliyai
Título:	"Composições e métodos para terapia antiviral de combinação "

PARECER

PI0406760-6

Através da petição INPI nº020160006847 de 01/11/2016, a Associação Brasileira Interdisciplinar de AIDS (ABIA) apresentou complementação ao subsídio ao exame técnico, apresentado anteriormente através da petição INPI nº020100077610 de 20/08/2010, conforme facultado pelo art. 31 da LPI. Segundo tal documento, apesar de não ter sido publicado nenhum documento com a formulação propriamente dita, as características físico-químicas das substâncias possibilitam a formulação combinada de fumarato de tenofovir disoproxil (TDF) e emtricitabina (FTC). Uma vez que não há efeitos técnico inesperados, um técnico no assunto seria capaz de propor uma formulação envolvendo tais compostos. Com relação à estabilidade química, alega-se que a formulação é estável pois TDF não é degradado pela acidez de FTC, além dos testes necessários para verificar a estabilidade de comprimidos serem intrínsecos ao processo de desenvolvimento de um medicamento. Contudo, não foram apresentados neste subsídio referências e argumentos técnicos que embasem tal afirmação (degradação do TDF por FTC). Com relação à sinergia, alega-se que o efeito sinérgico pode ser obtido com a administração dos medicamentos em formulações separadas ou na administração de coformulações ou combinações medicamentosas. Em conclusão, a ABIA sugere que o pedido em tela seja indeferido por não atender aos artigos 8º, 10, 11, 13, 24, 25 e 32 da LPI.

Lessons Learned

As regards to Dolutegravir, civil society efforts were essential for reversing the denial of incorporation and for the expansion in the offer from third-line to first-line through decree 35. Demand creation coupled with public pressure also resulted in price drop from U$ 9.88 per unit to U$1.53. In relation to TDF/FTC, campaigning has led to 3.543 submissions in the public consultation over the protocol for use of TDF/FTC as PrEP, enabling its approval despite opposition by conservative forces. Patent opposition filed by ABIA/GTPI in 2016 led to a patent rejection in 2017, which was instrumental to bring the price down from U$ 752 to U$ 276.

Dolutegravir Case

- In 2015, the roll-out of DTG expressed rich and poor countries divide in relation to optimal treatment.
- Mass education about treatment options was a key strategy to democratize scientific information and knowledge, enabling civil society to develop its own narrative about DTG.
- The process of demand creation started with pressure for review of national outdated guidelines, that were discussed for the last time in 2013 altought the law establishes a review every year.
- Strong comunity based demand on incorporation of DTG was motivated by many patients experiencing side effects with the first line options.
- Civil society faced resistance from the government and international agencies, that considered exagerated the demands for review in the national treatment guidelines. Multistakeholder dialogues were crucial to reverse this trend as they directly influenced technical staff from the Ministry of Health and also attracted support from the medical community, that played a key role in technical discussion on the incorporation of DTG.
- The most effective arguments used in DTG case were: Life quality for PLHIV must guide decisions over treatment protocols and any comercial or political barriers to the offer of better treatments must be jointly confronted by civil society and government
- The DTG case helped to revive Compulsory Lincense in the political vocabulaire, at least for technical staff at the Ministry of Health.
- Patent oppositions on DTG can be successful and open the way for generic competition

TDF/FTC Case

- Prep strategies and policies are confronted with strong criticism by conservative forces.
- The right to prevention must be put in equal foot to the right to treatment
- Close monitoring of patenting and registration strategies adopted by the originator company to delay generic competition must be performed in a regular basis to ensure the negative impacts of such strategies can be minimized on time.
- The proliferation of (at times spurious) patent applications, and delaying tactics of the originator companies (systematic appeals submitted at the latest possible time) leads to long backlogs in the patent examination and appeals process.
- Public consultations can be used as a hook for social mobilization
- In December 2017, PrEP service was implemented in 36 public health units across 22 cities, primarily for high-risk populations. There is now increased pressure for a rollout and expanded offer that relies on further price reductions.

Patent oppositions as Strategy:

- Civil Society participation through patent opposition procedures effectivelly contribute to the quality of the exam
- Civil society's action catalysed action by other stakeholders
- Patent rejections for DTG and TDF/FTC are based on strong grounds
- The policy environment has been unfavourable for a proper uptake of the patent rejections
- High prices are sustained also through strategic weakening of public health safeguards, especially patent examination regulations and standards

Compulsory License (CL) as strategy:

- The demand for CL is a practice of citzenship, that emerges to reverse a process of extreme exclusion and contributes with the development of the notions of democracy and ethics
- In Brazil, the fight for a CL contributed with the larger agenda of the health movement focused on maximizing equity inside a neoliberalizing state.
- CL is a key flexibility not only because its positive effects but also because it exposes very clearly that Intellectual Property is not only a technical issue, but also a highly political issue.
- Therefore, the CL process politicizes the IP arena, wich is key to ensure the right to health.
- The Brazilian government commitement with the right to health however is decreasing fast.
- Political will is a key piece for CL and it has been challenging to rebuild it in Brazil

Conclusions/Next steps

Incorporation of technologies relies as much in technical debates as in political debates. Civil society ensures that a rights-based approach prevails in both levels.

- 22 years after the ARV triple therapy, from 36.7 millions of people living with HIV/Aids, only 19.5 millions are on treatment (UNAIDS - 2016)
- The IP system remains as an structure that sustain an insufficient response to the HIV/Aids epidemic and that promotes subtraction of resources from public health systems. Above all, the regular violation of human right to health is intractably linked to the functioning of the IP system
- National legislations created to protect the right to health are also constantly attacked by pharmaceutical companies
- There is no international treaty to blame and punish pharmaceutical companies for such direct and indirect violations: Architecture of impunity
- We need an innovation model that de-links the investment on R&D from the final price of the product and ensure the fruits of innovation are considered as common goods
- A reform towards a pharmaceutical innovation system based in health needs and common goods requires frameworks to reduce the power and impunity of phamaceutical coorporations.

"**we demand the suspension of the WTO TRIPS agreement for health technologies; we oppose every measure included in FTAs that negatively impacts access to medicines, like those under the UE-Mercosur FTA; we support new R&D models that can promote open and accessible technologies for all peoples, regardless where they live and whose results (data, process and products) can be considered common goods**." Declaration at the People's Summit – Buenos Aires, December 2017.