

Intellectual Property and Access to HIV Medicines in the Developing World

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About Gilead Sciences

- ◆ **Worldwide presence**

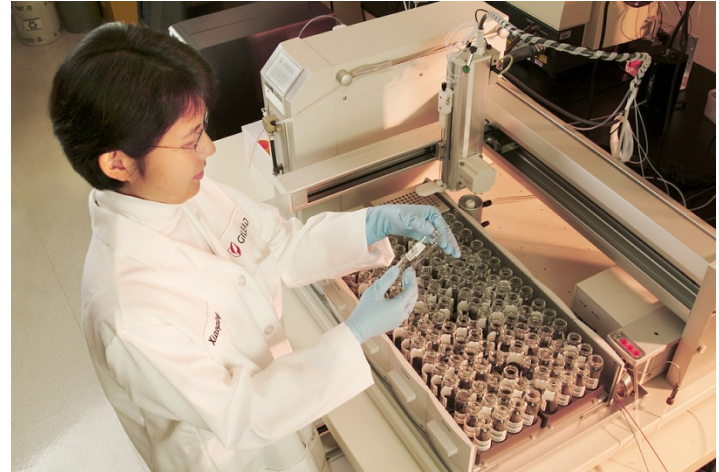
- More than 4,500 employees
- 31 offices in 24 countries

- ◆ **14 marketed drugs; active R&D program**

- Primary therapeutic areas: HIV/AIDS, liver disease, serious cardiovascular and respiratory conditions, oncology
- 10 successful acquisitions, growing company reach

- ◆ **Committed to ensuring global access**

- Believe our responsibility to patients extends beyond the lab, and beyond developed-world markets



Our HIV Products and Pipeline

Single Agents

Fixed-Dose Combinations

Single-Tablet Regimens

Current Medications



Viread®
Tenofovir (TDF)
Approved 2001



Emtriva®
Emtricitabine (FTC)
2003



Truvada®
TDF+FTC
2004



Atripla®
TDF+FTC+EFV
2006



Complera®
TDF+FTC+RPV
2011

In the Pipeline



Elvitegravir
(EVG)



Cobicistat
(COBI)

Approval expected 2013



GS 7340
Tenofovir prodrug (Phase 2)



Other Fixed-Dose Combinations
E.g., COBI+DRV



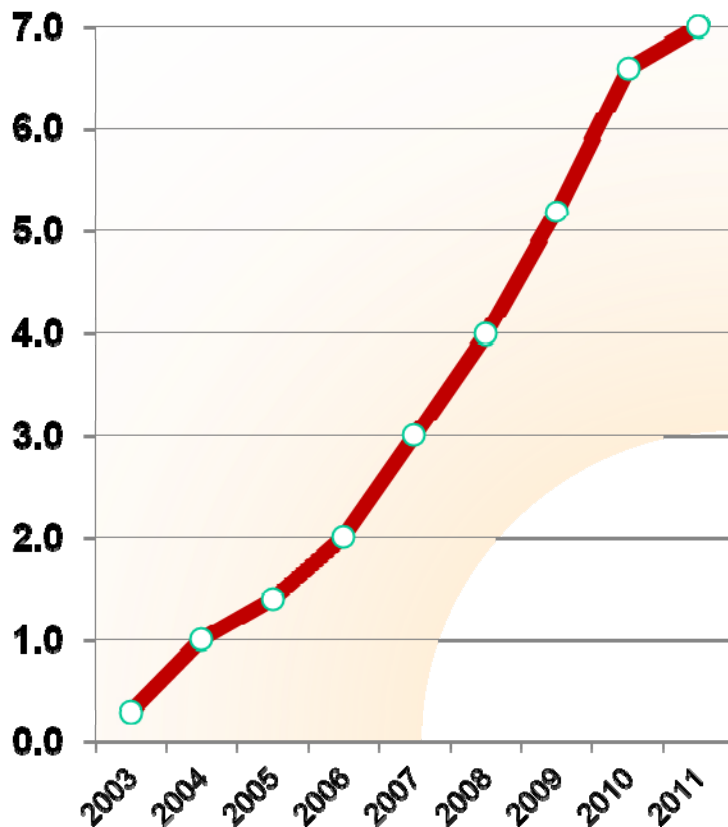
Quad
EVG+COBI+TDF+FTC
Approval expected 2012



Other Single-Tablet Regimens
E.g., 7340+COBI+FTC+DRV

Global HIV Treatment Scale-Up

Global Access to Treatment
(Millions)



Source: World Health Organization

◆ **Significant progress on global treatment access**

- More than 7 million people on HIV treatment worldwide

◆ **Yet tremendous unmet need**

- 34 million people living with HIV; more than 7 million people need treatment now and do not receive it
- WHO guidelines: Begin treatment at CD4 count of 350 cells/mm³. (HHS guidelines recently revised to CD4 500)
- Early treatment may reduce transmission risk up to 96% (HPTN 052 study)

Gilead's Access Programs

- ◆ Gilead's Access Program was launched in 2003 as a **sustainable, market-based** approach for facilitating global access to our medicines
- ◆ **Regional distributors** distribute steeply discounted branded Viread and Truvada to more than 130 low- and middle-income countries
- ◆ Branded products have a **tiered pricing system** that reflects each country's ability to pay and are based primarily on a country's gross national income per capita and HIV prevalence
- ◆ Gilead has **voluntarily extended licenses** to 14 Indian manufacturers and one South African company to produce generic Viread and Truvada for low- and middle-income countries
- ◆ Licensing partners receive a **full technology transfer** of the manufacturing process and set their own product prices, using their expertise in making large quantities of high-quality medicines at low cost

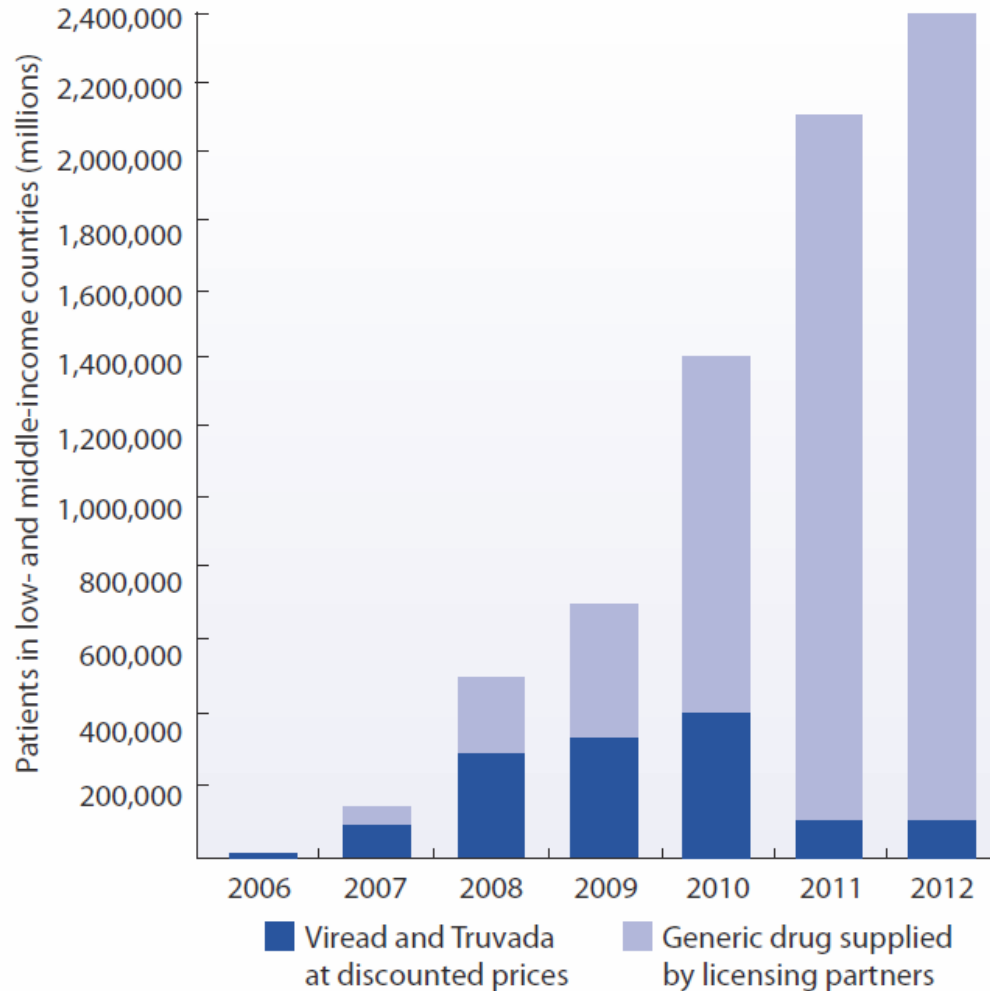
Recent Program Innovations

- ◆ Gilead extended generic licenses to Indian partners in 2011 to produce three **pipeline medicines** for HIV once they receive U.S. regulatory approval: elvitegravir, cobicistat and the Quad single tablet regimen.
- ◆ In July 2011, Gilead signed agreement with the **Medicines Patent Pool** (MPP), established by UNITAID in 2009 to facilitate access to essential medicines through patent sharing/licensing.
 - Gilead is the first and only innovator company to sign with MPP.
 - MPP was granted similar terms as Indian partners: TDF license plus future rights to pipeline products.
 - MPP can sub-license Indian manufacturers to produce these medicines for developing countries.



Results

Access to Gilead HIV Medicines



A proven model reaching 2.4 million HIV patients, more than a third of all those on treatment in developing countries

Looking Ahead: IP and Access Policies

The framework we hope to work toward:

- ◆ Patents should be issued and enforced based on the merits of the science and innovation
- ◆ There have been and will continue to be situations in which compulsory licenses are the right course of action
 - At the same time, essential that due process is in place to assess merits of compulsory licenses on a case-by-case basis

Gilead remains strongly committed to its access programs:

- ◆ A proven model reaching 2.4 million HIV patients
- ◆ Financially self-sustaining, market-based, scalable and replicable
- ◆ Lessons still to be learned – and we remain open to program evolution and innovation



GILEAD

Advancing Therapeutics.
Improving Lives.

Thank You