
Measuring the Impact of Medicines Patent Pool Licenses: *A Civil Society Assessment*

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Overall benefit of MPP-Gilead license vs. status quo

	Original TDF voluntary licenses	MPP-Gilead TDF license*
Competitive Landscape	<ul style="list-style-type: none"> • Robust generic competition: 13 generic licensees as of Dec-2010 	<ul style="list-style-type: none"> • No new generic licensees to date • Any additional licensees unlikely to impact price given already robust competition
Geographic Scope	<ul style="list-style-type: none"> • 95 countries in licensed territory (34 LICs, 39 LMICs, 17 UMICs, 5 HICs) 	<ul style="list-style-type: none"> • Minimal expansion: 16 new but very low-volume countries (7 LMICs, 3 UMICs, 2 HICs, 4 unclassified territories)**
Patient access	<ul style="list-style-type: none"> • VLs covering 86% of people on ART in low- and middle-income countries 	<ul style="list-style-type: none"> • Newly licensed territories represent < 1% increase in coverage relative to original VLs (see next slide)

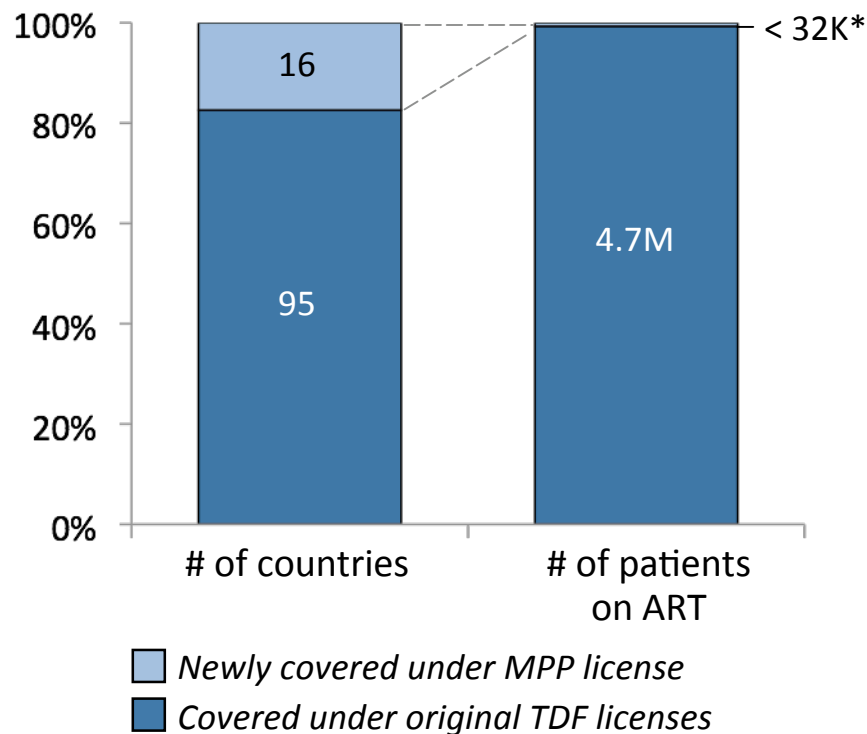
*New Gilead-MPP license also covers 2 new products in development: Cobicistat and Elvitegravir. It has not been established whether these 2 products will be superior to alternatives in terms of clinical efficacy, cost, and/or side effects. Until such facts are established, it is not possible to determine whether the products will be relevant for public health programs in developing countries.

**Gilead has indicated the addition of 17 new countries including the recently formed South Sudan. We did not count this territory as new as it was covered under the original VLs as part of Sudan. Of the 16 new countries, 8 are not tracked by WHO (in terms of patients on or in need of ART).

Sources: ; Gilead Sciences, "Evolution of the Gilead Access Program, 2003-2010," Jul 2011; Medicines Patent Pool/Gilead Licenses Q&A, Aug 2011; WHO Progress Report, "Toward Universal Access", 2010; World Bank income classifications

Will deal result in improvements to patient access?

Newly covered countries represent
< 1% increase in patient coverage



Impact on pediatric market has
been particularly overstated

MPP claims: MPP will facilitate development of new pediatric formulations

Actual impact: None of the 4 drugs included in MPP deal are currently indicated for pediatric use

Relatively small size of pediatric market will continue to be a barrier to R&D on pediatric formulations

*Patient data unavailable for 8 out of 16 countries newly covered under the MPP deal. Available patient data for other 8 countries was doubled to account for this, which likely represents an overestimation of patients in these territories.

Source: WHO Progress Report, "Toward Universal Access", 2010. Expert interviews. Medicines Patent Pool, "Innovation in ARVs to Meet Developing Country Needs," Chatham House, Jul 2011.

In 2009, MPP claimed large potential economic benefits, were these overstated?

Theoretical economic benefits claimed by MPP (2009)*

	Savings	Explanation
1. "New" medicines	34.6M+ (annual)	• Generic competition enabled by MPP will lower cost of new ARVs in perpetuity
2. Pediatric formulations	8.3M (annual)	• Development of cheaper pediatric solids and FDCs by generics will be enabled by MPP
3. FDC discount	5.5M (annual)	
4. Wide-spread licensing	3.6M (annual)	• MPP would enable widespread licensing, leading to lower prices
5. Reduced trans. costs for FDCs	0.2M+ (one-time)	• Less agreements to negotiate for FDCs when done through MPP ¹
TOTAL	\$52M+ annual savings (low-end estimate)	

I-MAK/ITPC counter-analysis*

Savings	Explanation
16.9M (one-time)	• Generic market entry and new formulation development would happen even in MPP's absence through direct VLs or other mechanisms ² • However, it is possible that MPP could accelerate generic time-to-market (e.g. by 6 months) through streamlining VL process
4.1M (one-time)	
1.9M (one-time)	
0	• MPP facilitates but does not cause widespread licensing. Companies can and have licensed broadly outside of MPP.
0.2M (one-time)	• MPP assumptions are sound
\$23M one-time savings (high-end estimate³)	

***All figures represent potential savings on a hypothetical deal. Actual MPP licenses may generate less or no savings, depending on product and license details.**

Note: Savings estimates based on hypothetical MPP deal examples. Detail on methodology can be found in "Financial Impact of MPP – I-MAK/ITPC counter-analysis" document.

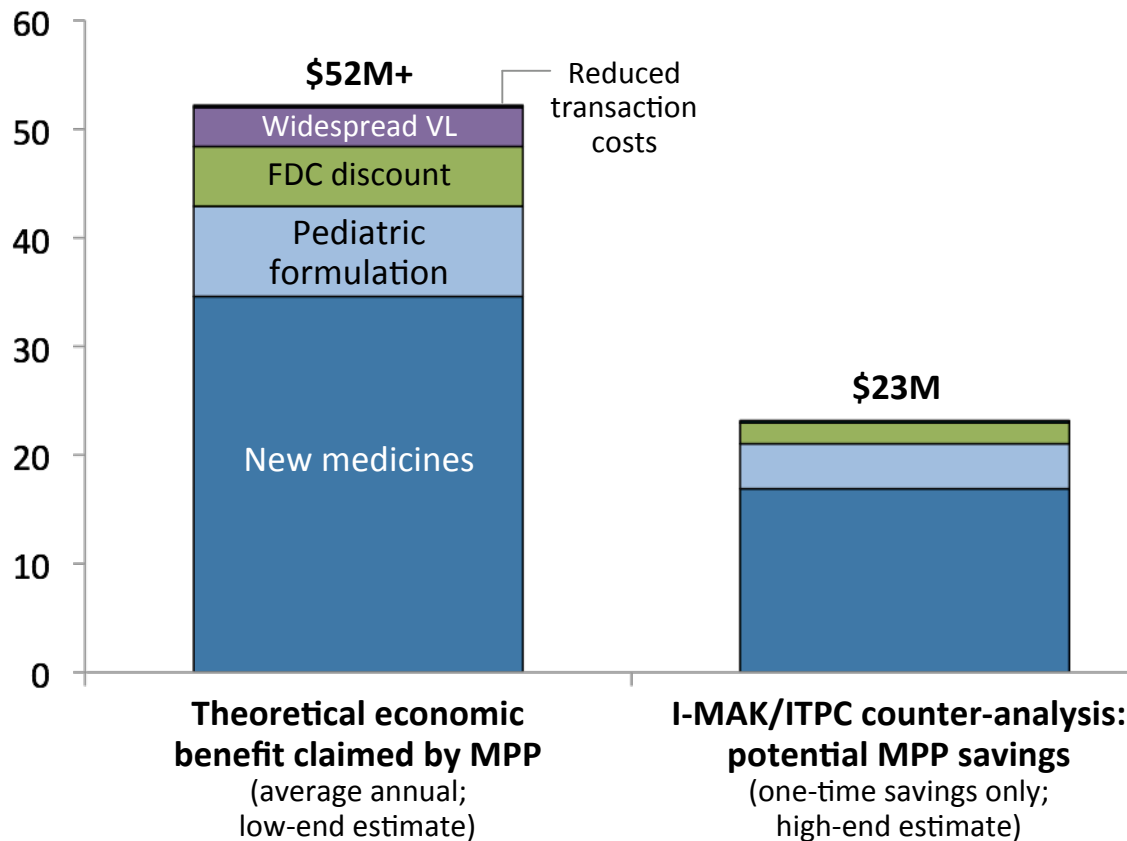
(1) For example, if 3 originators licensed to 5 generic companies, 15 bilateral agreements would be needed. With MPP, only 8 agreements are needed. 2) Assumes that new ARVs offering a significant public health benefit would either be licensed voluntarily by originators OR provided through use of flexibilities in IP laws (e.g. compulsory licenses).

(3) I-MAK/ITPC savings calculations are based on aggressive assumptions to determine a realistic upper-limit for potential savings.

Source: MPP document, "Economic Benefits of the Pool: Assumptions and Calculations," presented at UNITAID EB11. I-MAK/ITPC analysis.

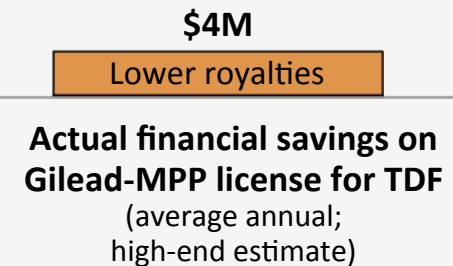
... And actual savings for recent Gilead deal?

MPP claims of hypothetical savings were significantly overstated (*see previous slide*)...



...and actual savings on recent Gilead-MPP deal are even lower

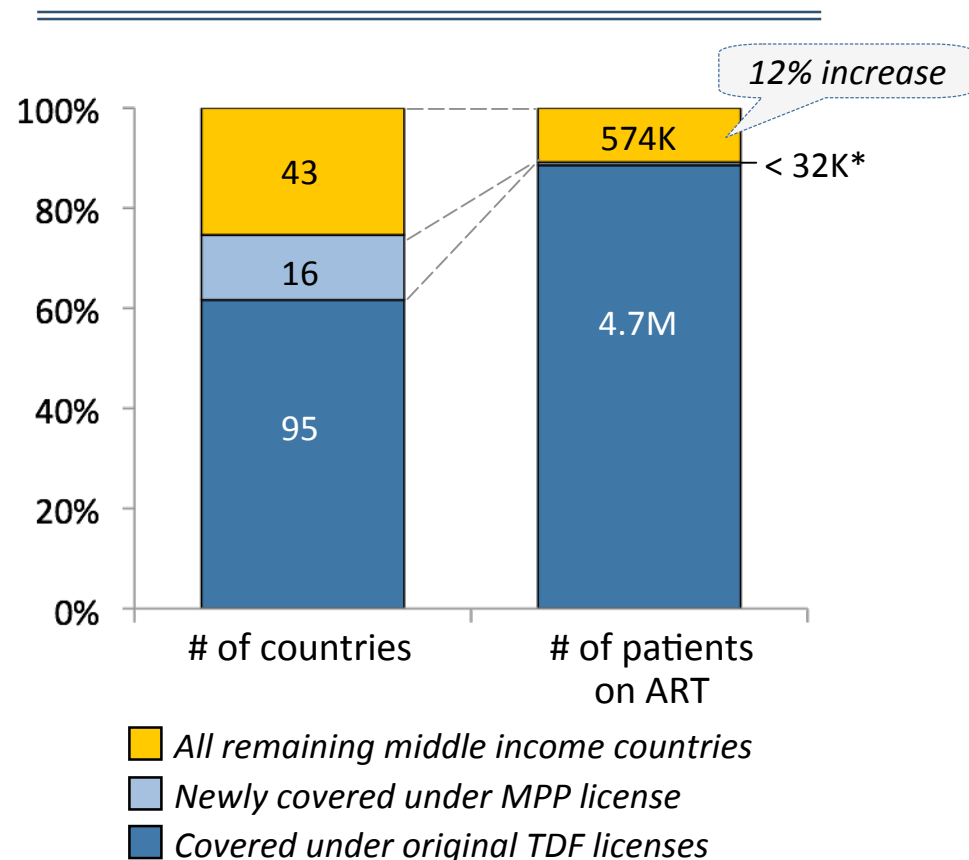
- *New Gilead-MPP licenses generate no savings against aforementioned categories*
- *However, small level of savings may result from the lower royalty rate negotiated by MPP**



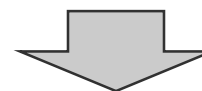
Note: *New Gilead-MPP license lowers royalties on TDF from 5% to 3% unless a patent is in place. Average annual savings of \$4M are possible assuming TDF continues to stay unpatented in India and other developing countries.
Source: I-MAK/ITPC analysis.

However, significant improvements to access could have been achieved with stronger emphasis on MI countries

Broad MI country coverage would result in significant improvement in patient access*



- MI countries excluded from license currently pay ~**40% more** for TDF given limited generic accessibility and tiered pricing
- Broad access to generic TDF alone could **save MI countries an estimated \$3-5M** per year, which could be used to treat an additional **15-30K** new patients**



To significantly improve patient access, MI countries must be included

*List of excluded MI countries is based on data from the WHO Progress Report, "Towards Universal Access, 2010" and World Bank income classifications as of July 2011, and may not be comprehensive. Other methodologies for classifying countries would expand this list and should be used to determine how to ensure access.

**Assumes average per-patient cost of treatment is \$180-190 (weighted average cost of first and second-line regimens in LI and MI countries)

Source: WHO Progress Report, "Toward Universal Access", 2010; World Bank income classifications; pricing data from GF PQR; I-MAK/ITPC analysis.

Benefits must outweigh costs

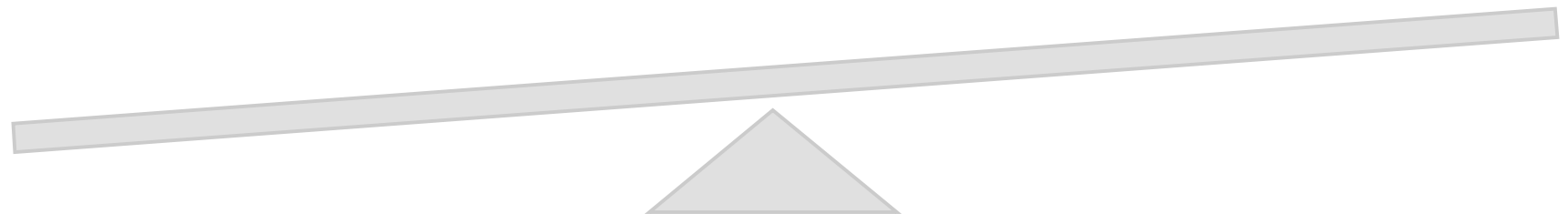
Benefits

- MPP should only pursue deals that lead to **significant gains** in patient access
- Negotiating improvements to **MI country access** should be a top priority for MPP

must outweigh

Costs

- MPP can **detract from other IP strategies*** that may lead to superior outcomes
- Overly **restrictive license terms** will curb competition.
- **Licenses for unpatented products** (e.g. TDF) **may create higher costs**, as royalties are paid even in the absence of patents
- MPP should focus on eliminating these outcomes when pursuing future deals



The Civil Society community has serious concerns about the current benefits and potential impact being claimed.

Annex: List of countries newly added to MPP license vs. list of MI countries excluded

New MPP territories = <32,000 patients*

- 1 Armenia
- 2 Ecuador
- 3 El Salvador
- 4 Fiji
- 5 Georgia
- 6 Kazakhstan
- 7 Nauru*
- 8 Palau
- 9 Sri Lanka
- 10 Tonga*
- 11 Turkmenistan*
- 12 Aruba*
- 13 Anguilla*
- 14 British Virgin Islands*
- 15 Montserrat*
- 16 Turks & Caicos*

*Patient data unavailable for 8 countries. ITPC/I-MAK high-end estimate.

MI Countries Excluded from MPP = 574,000 patients

- | | |
|-------------------------------|---------------------------------------|
| 1 Albania | 23 Malaysia |
| 2 Algeria | 24 Marshall Islands |
| 3 American Samoa | 25 Mayotte |
| 4 Argentina | 26 Mexico |
| 5 Azerbaijan | 27 Micronesia |
| 6 Belarus | 28 Montenegro |
| 7 Bosnia and Herzegovina | 29 Morocco |
| 8 Brazil | 30 Panama |
| 9 Bulgaria | 31 Paraguay |
| 10 Chile | 32 Peru |
| 11 China | 33 Philippines |
| 12 Colombia | 34 Romania |
| 13 Costa Rica | 35 Russian Federation |
| 14 Egypt | 36 Serbia |
| 15 Iran (Islamic Republic of) | 37 Macedonia, FYR |
| 16 Iraq | 38 Tunisia |
| 17 Jordan | 39 Turkey |
| 18 Kosovo | 40 Ukraine |
| 19 Latvia | 41 Uruguay |
| 20 Lebanon | 42 Venezuela (Bolivarian Republic of) |
| 21 Libyan Arab Jamahiriya | 43 West Bank & Gaza |
| 22 Lithuania | |

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