

“TRIPS Flexibilities: Challenges and Chances for Least Developed Countries”

Local Production and Access to Medicines
Conference, Bonn – 21st February 2013

Astrid Berner-Rodoreda
Advisor for HIV and AIDS
Bread for the World

21.02.2013

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TRIPS Flexibilities: Challenges and Chances for Least Developed Countries

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Overview

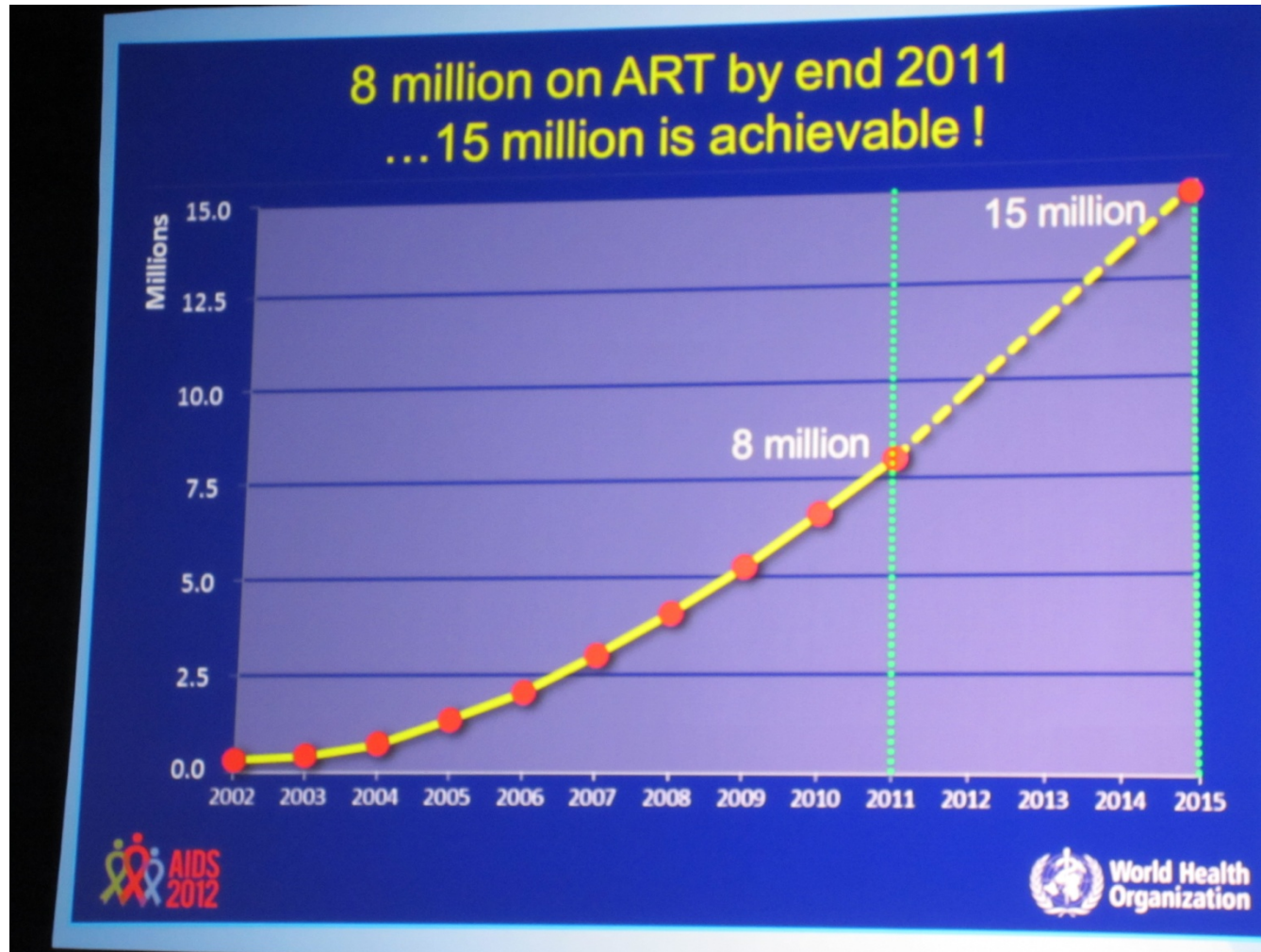
Low Cost ARVs and Scale up of Treatment TRIPS and TRIPS Flexibilities Way forward for access to ARVs for LDCs

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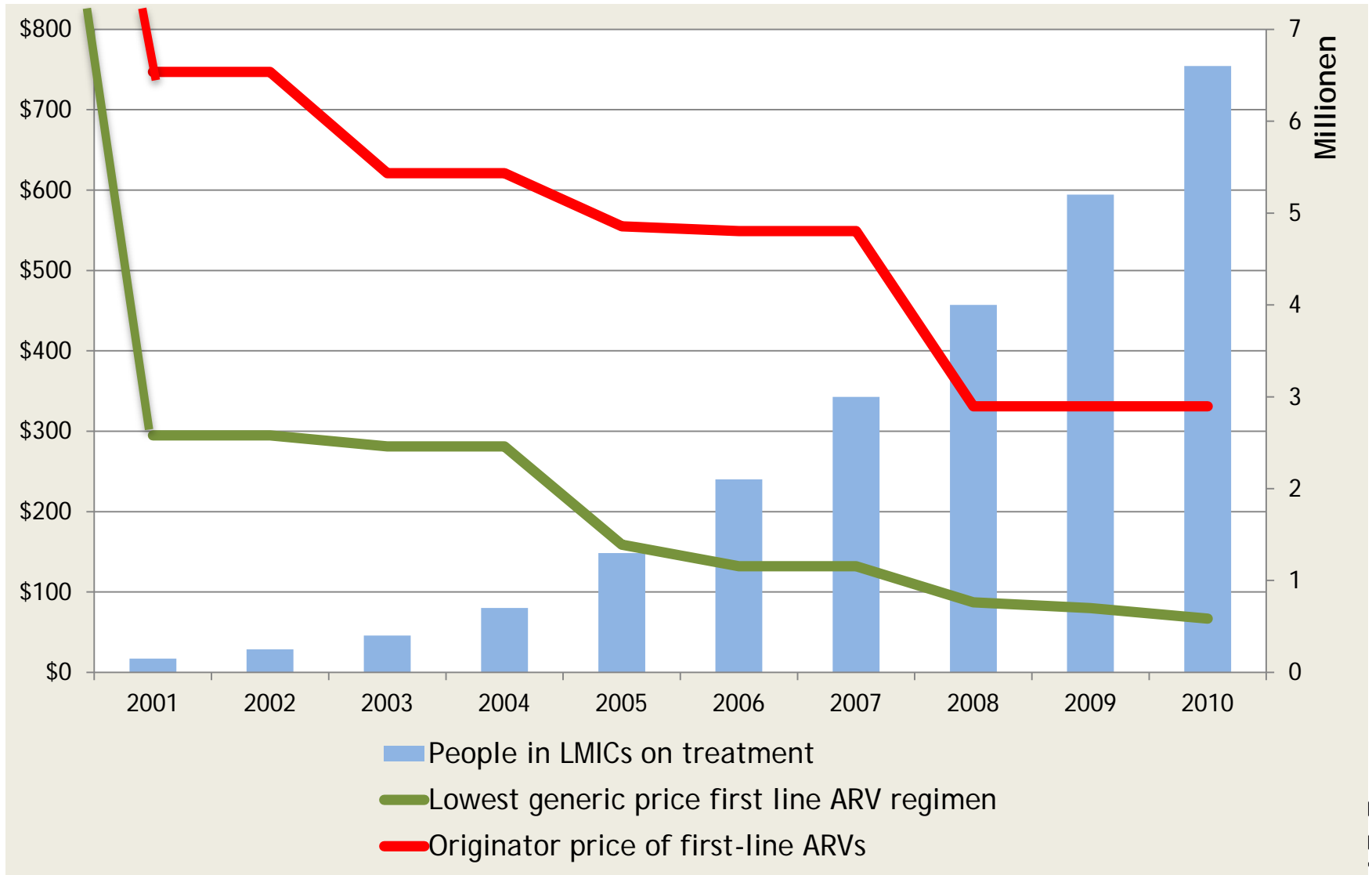
Access to ARV Treatment



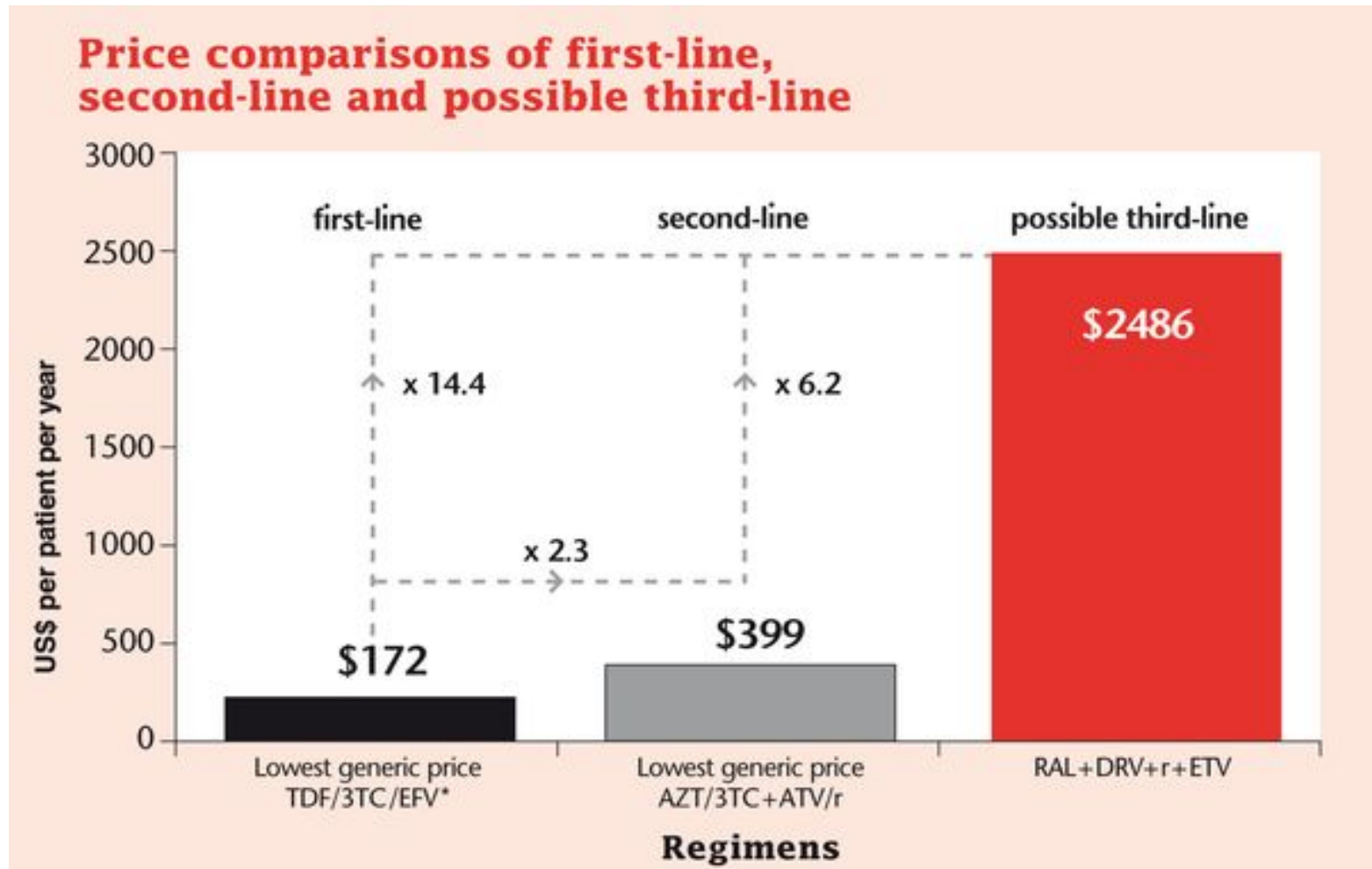


Generic Competition & Treatment Scale-Up - MPPF 2012

\$2700 \$10,400



Prices of ARVs - 1st - 3rd line - MSF Untangling the Web 2012





WTO- World Trade Organisation

1995 GATT, Uruguay Round

Objective: Removing Trade Barriers

Liberalization of International Trade

153 members

TRIPS – Agreement on Trade Related Aspects of
Intellectual Property Rights

TRIPS Compliance:

Middle Income Countries – 2005

Least Dev. Countries – 2016



TRIPS vs. adequate right to health

Pressure from Africa (HIV/AIDS Epidemic) lead to DOHA Declaration (Nov 2001)

- It reaffirmed flexibilities of TRIPS members in circumventing patent rights for better access to essential medicines where there is a national emergency or other circumstances of extreme urgency
- Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted



Why is India important for the provision of ARVs to developing countries?

1970: Patent Act

process patent for medicines (no product patent)
patent protection limited to 7 years
royalty fees for licences did not exceed 4%

Results:

scale-up of generic production of medicines incl. 1st line ARVs

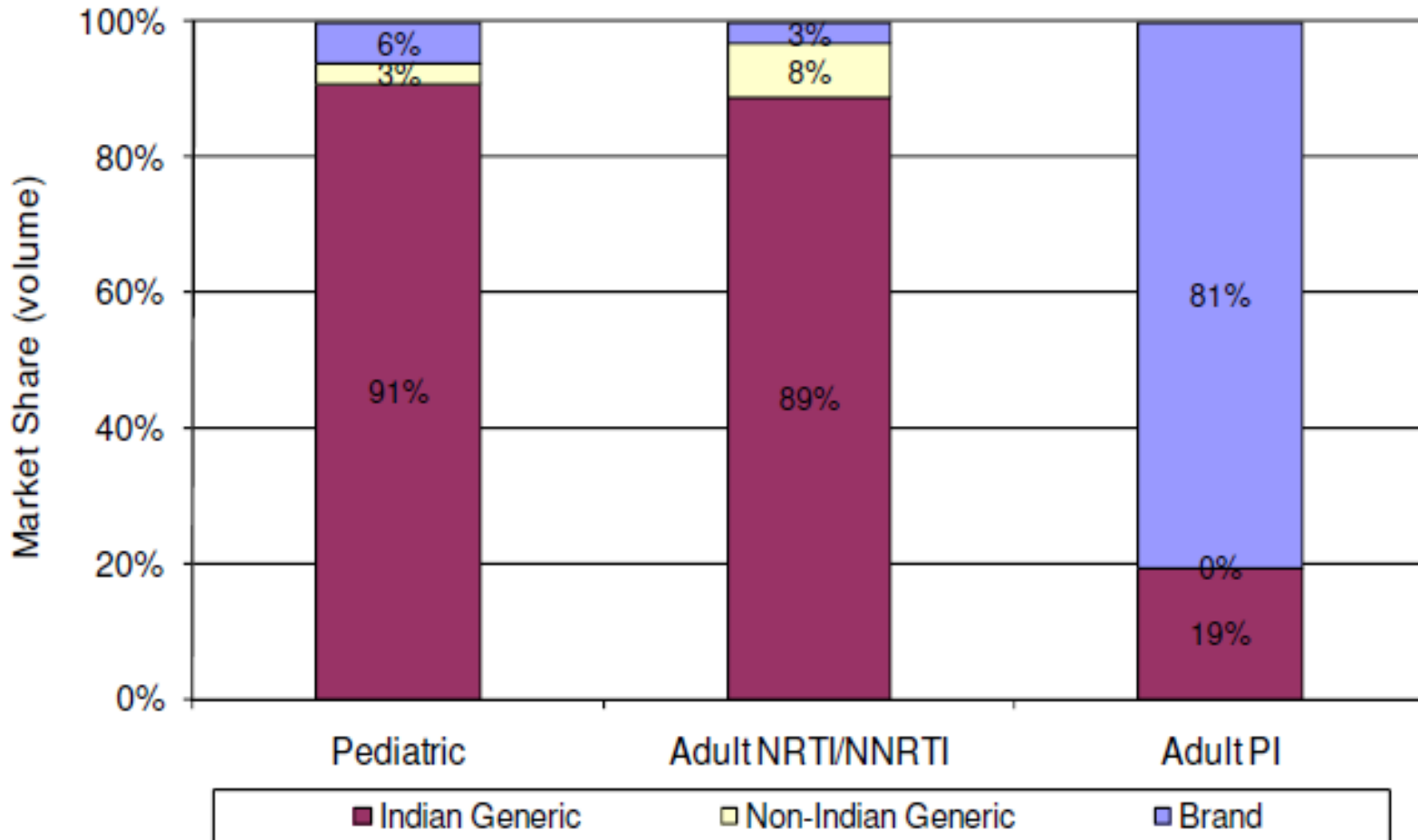
Production of FDCs

Export to Africa made treatment programmes in Africa affordable

Origin of ARVs utilized in LICs

Journal of International Aids Society 2010

Mitglied der
actalliance



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Indian Patent Law after 2005 - Important Amendments to the Patent Act of 1970

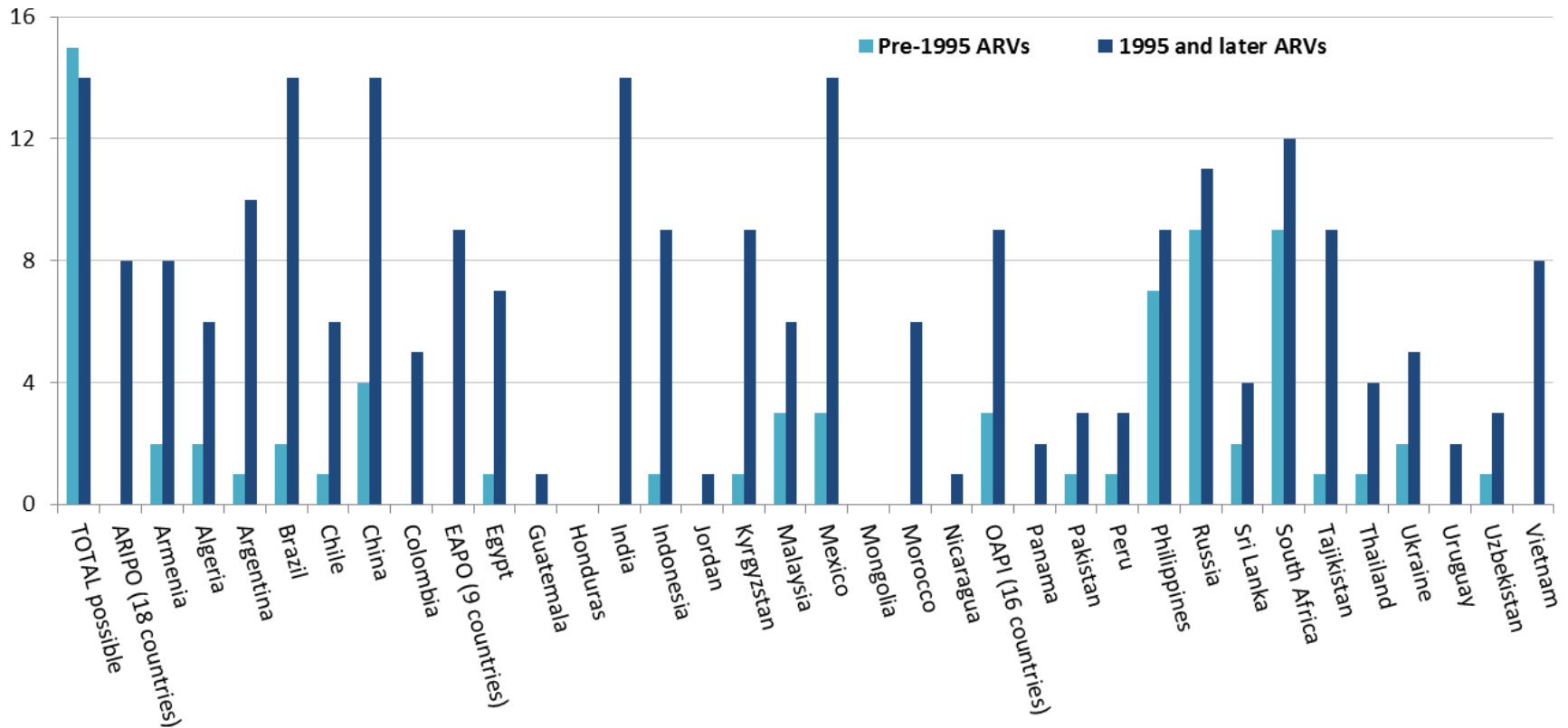
Section 5 which prevented product patents on drugs, chemicals and food items was abolished

To prevent 'ever-greening' – additions to section 3 (d) were made (addition in bold): **the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance** or the mere discovery of any new property or new use for a known substance or of the mere use of a known ~~process, machine or apparatus unless such known process~~

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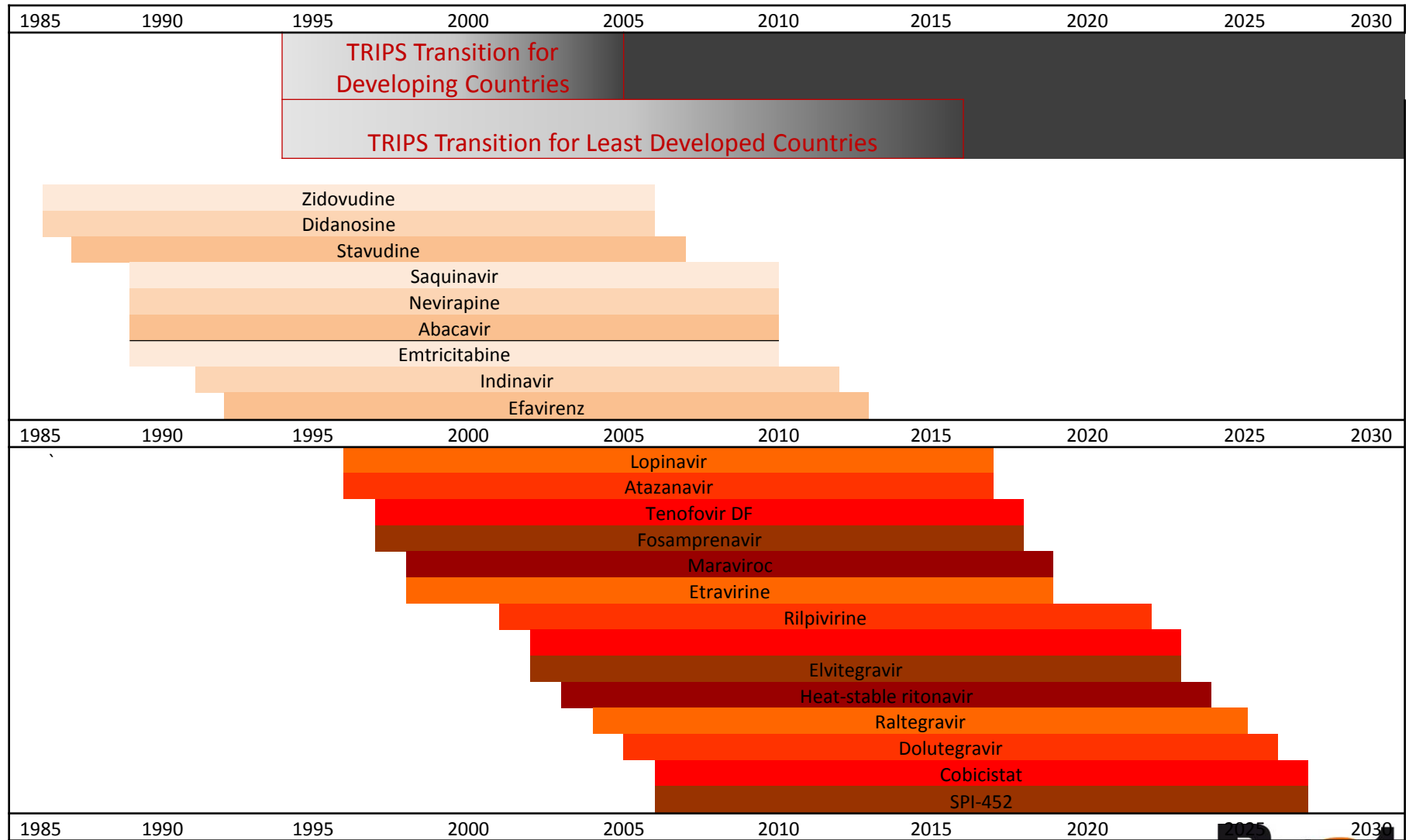
Patent landscape pre- and post-

Total number of product patents pending or granted, by jurisdiction, for older compounds (pre-1995) and newer compounds (post-1995)*



Source: MPPF 2012

Changing ARV Patent Landscape, MPPF 2012





Sustainable Access to ARVs for Developing Countries

Mitglied der
actalliance

- Period for WTO compliance for LDCs needs to be extended beyond 2016 - Initiative by Group of LDCs to extend transition period for LDCs for as long as country is classified as an LDC.
- We need to prevent TRIPS plus provisions in FTAs and other trade agreements
- We need to weigh up, if local production or import from India provide better access to medicines.
- If LDCs do not use the period to produce newer ARVs, there may be little benefit in local production, as 1st line is usually produced at much lower prices in India.

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Thank you very much for your attention

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