



Promoting Access to Medicines Through Balancing Patent Rights and Responsibilities

Professor Joseph Straus
Munich

WIPO Conference on Intellectual Property and Public Policy Issues

Geneva
July 14, 2009

Points to Consider



MAX-PLANCK-GESellschaft

- **Existence of medicines - Precondition of access!**
- **The contextual role of patents**
- **Determinants of access**
- **Access promoting activities**
- **Balances inbuilt in the patent system**
- **Conclusions**

Precondition of Access to Medicines - Their Existence!



MAX-PLANCK-GESellschaft

- **R & D costs until FDA approval ~ US \$ 800**
- **R & D time incl. clinical trials ~ 10-15 years**
- **Only 8% of drugs entering Phase I of clinical trials - eventually approved**
- **4% of the approved drugs later on withdrawn from the market
→ reducing income + increasing costs - product liability**

[Caskey, 2007]

- **Moreover ~ US \$ 140 Million in R & D costs after FDA approval**

[DiMasi/Hansen/Grabowski 2003]

- **Total costs ~ US \$ 1 Billion**

The Contextual Role of Patents Shielding the Source of Medicines



MAX-PLANCK-GESELLSCHAFT

- **Incenting R & D investment → sustainable flow of new drugs**
- **Shielding the enormous risks of drug development**
- **Securing the recovery of R & D investment and profits through revenues in developed countries, including middle income countries**
- **Enabling charitable activities → donations & alternative programs & differential pricing for LDCs & low income countries**

Contextual Role of Patents

Barrier for Access?



MAX-PLANCK-GESellschaft

- **Only 19 of 319 items on the WHO-EML covered by basic patents post dating April 1, 1982**
- **Only 31% possibilities to apply for drug patents internationally used in practice by drug companies**
- **No patent barrier to accessing generic essential medicines in 98.6%**
- **Thus, as a rule neither a barrier in many developing countries to accessing affordable medicines - nor a necessity having patents on a global scale**
- **No substantial changes predicted for the future**

[Attaram, 2004]

Access Factors

Availability of Medicines - One Element Only



MAX-PLANCK-GESellschaft

- **Poverty**
- **Medical infrastructure for testing and treatment**
- **Training of health professionals**
- **Counselling**



Access Promoting Activities

Global Health Fund

- **to fight AIDS, TB & Malaria - funding in 140 countries worth US \$ 15.6 Billion (up from US \$ 1,5 Billion in 2002)**
- **Funds from public (e.g. Japan US \$ 1.7 Billion; Spain US \$ 213 Million; Dept. 2 Health Program: Germany, Australia, etc.) and private (e.g. Chevron, the Bill & Melinda Gates Foundation, etc.) sources**
- **provides for: 1/4 of all int. financing for AIDS globally, 2/3 for TB and 3/4 for malaria**

Access Promoting Activities



MAX-PLANCK-GESellschaft

- **Accelerating Access Initiative (AAI): UNAIDS, WHO, UNICEF, UNFPA, the World Bank & several research-based pharma companies**
- **President's (US) Emergency Plan for AIDS Relief (PEPFAR), US \$ 15 Billion (2003-2008) → 15 "focus countries" & US \$ 48 Billion through 2013 → 114 countries**
- **Global Alliance for Vaccination and Immunization (GAVI), by 2007 > US \$ 3.5 Billion → 75 countries (2000-2015)**

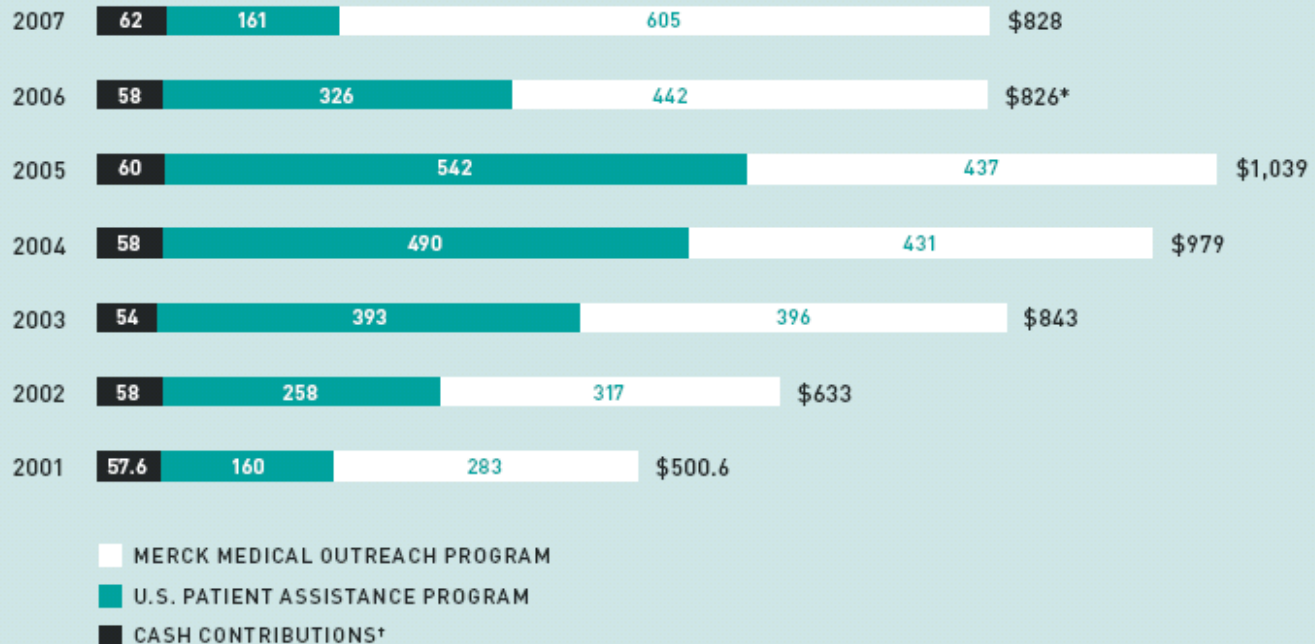
Access Promoting Activities, e.g. Merck USA



MAX-PLANCK-GESELLSCHAFT

MERCK CONTRIBUTIONS AND DONATIONS

DOLLARS (MILLIONS)



* Our philanthropic giving decreased after 2005 because of a reduction in the use of Merck's Patient Assistance Program, due mainly to an increasing number of patients with prescription drug coverage, including the Medicare Prescription Drug Program, which began January 1, 2006, and from the removal of ZOCOR[®] (simvastatin) and PROSCAR[®] (finasteride) from the eligible products list in 2007 once patients had broad access to lower-cost generic equivalents.

† Total Merck cash contributions are the sum of contributions from The Merck Company Foundation and Merck & Co., Inc.

Source: Merck and Co., Inc. "Listening, Responding and Working Toward a Healthier Future. Corporate Responsibility Report 2006-2007." Whitehouse Station, NJ. October 2008, page 61.



Access Promoting Activities, e.g. Novartis



MAX-PLANCK-GESELLSCHAFT

- Coartem[®] :
73.7 million treatments shipped in 2008 – cumulatively delivered >235 million treatments which helped save an estimated 600,000 lives
- Leprosy medication free of charge:
>4.5 million patients cured since 2000
- TB donations (DOTS):
500,000 patients in five years
- Gleevec[®] patient assistance:
Free to >35,000 patients in 80 countries
- NITD¹ in Singapore:
Focus on TB, dengue fever and malaria
- NVGH² in Siena, Italy:
Vaccines Research Institute for neglected diseases

2008:

- **74 m patients supported**
- **Programs and research valued at USD 1,26 billion³**

¹ Novartis Institute for Tropical Diseases; ² Novartis Vaccines Institute for Global Health; ³ Based on approximate market value

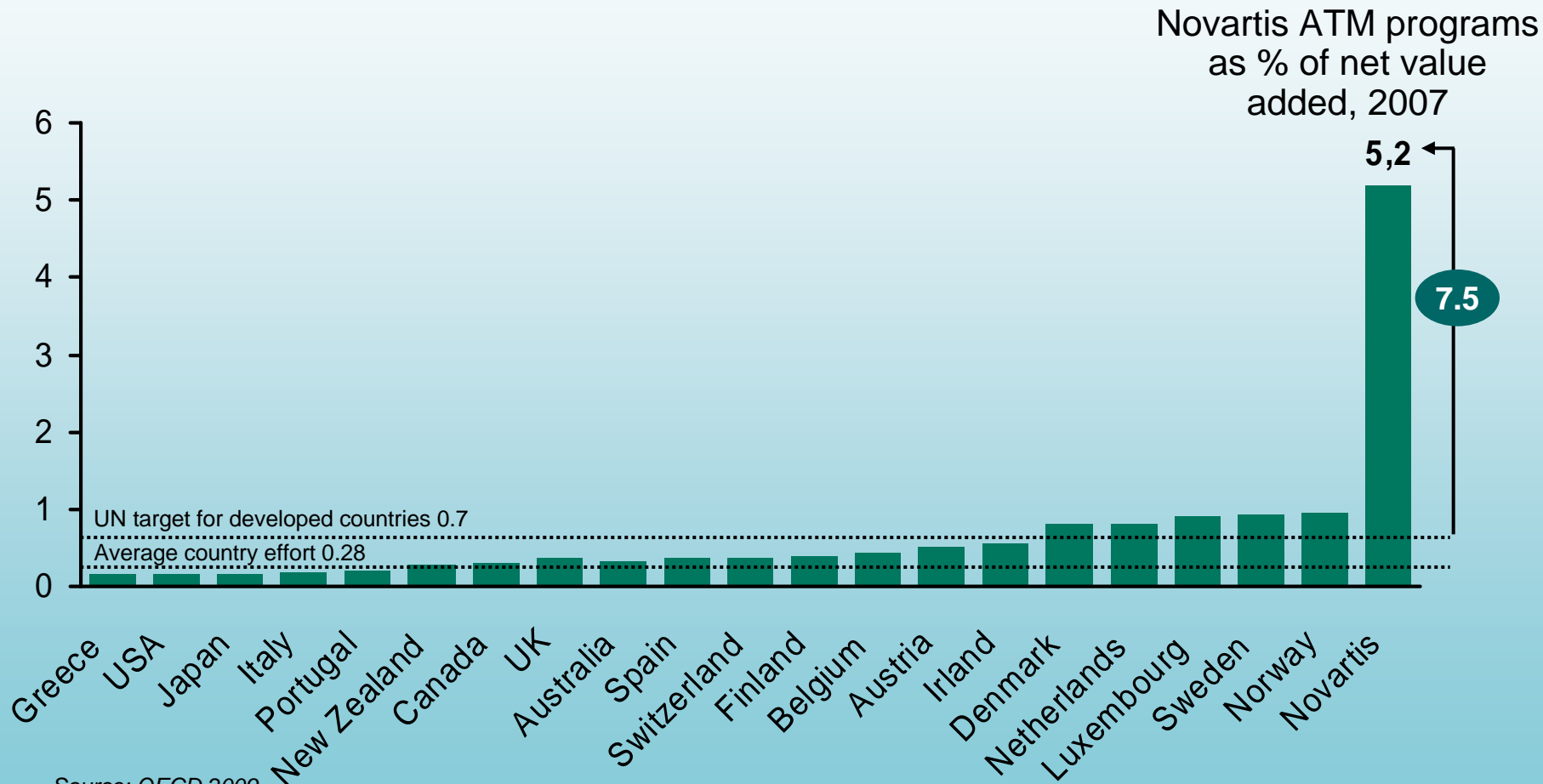


Access Promoting Activities, e.g. Novartis



MAX-PLANCK-GESELLSCHAFT

Net Official Development Assistance (ODA) in 2007 (% GNI)



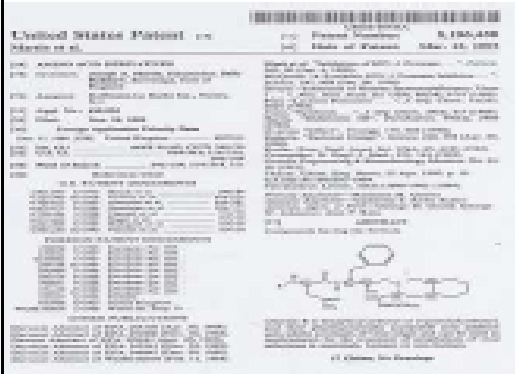
Source: OECD 2009

GNI: Gross National Income (GNI)



Pricing & Patent Policies

Clear, transparent and public



The screenshot shows a table with columns for 'Country', 'Product', 'Patent Status', and 'Price'. The table lists various Roche products and their pricing in different countries, including India, China, and others. The text is small and difficult to read, but the structure is clear.



- No patents for any Roche medicines in LDCs
- No enforcement of ARV patents in LDCs or sSA
- No profit prices for 2 ARVs for LDCs and sSA
- Significantly reduced prices for low & lower-middle income countries
- Prices published on www.roche-hiv.com

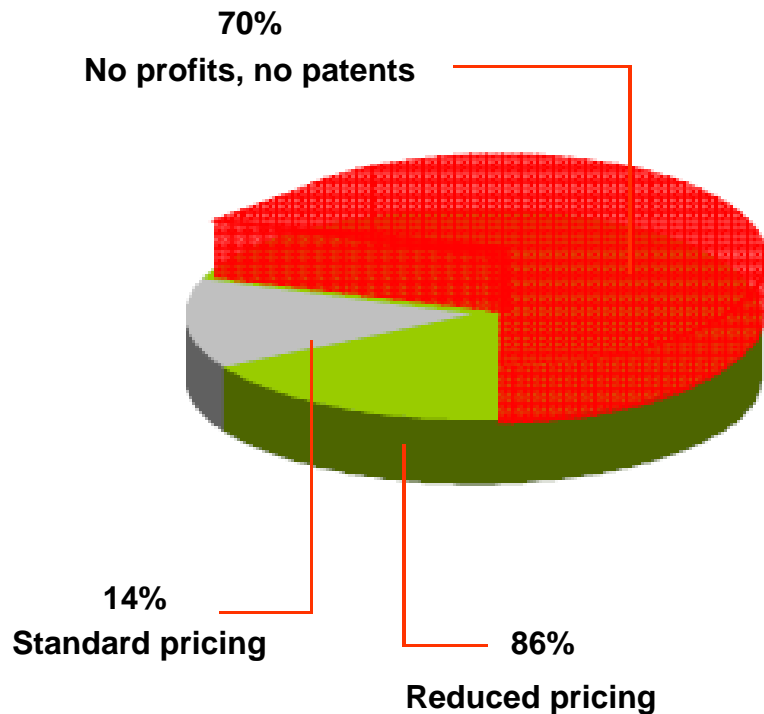
Young, 2008

Access Promoting Activities, e.g. Roche



MAX-PLANCK-GESELLSCHAFT

For Roche HIV/AIDS is not "Business as usual"



- **Reduced pricing** applies to 86 % of all people living with HIV/AIDS worldwide*
- Both **patents and profit removed** for 63 countries encompassing 70 % of all people living with HIV/AIDS*
- Standard prices apply to 14 % of global patient population*

* From UNAIDS data, published November 2007



- **Expanded Access → Viramune® (nevirapine) & Aptivus® (tipranovir) → voluntary licensing to many companies for LDCs & low income countries**
- **No enforcement of patents → non assert declarations for supply in eligible countries → Aspen (ZA), Aurobindo, Cipla, Emcure, Ranbaxy and Strides (all India)**
- **Royalty-free license → Apotex (Ca) → Rwanda**
- **Preferential pricing for anti-retroviral drugs (avr)**
- **Prevention of Mother-to-Child-Transmission Viramune® Donation Program**

Balances Inbuilt in the Patent System



MAX-PLANCK-GESellschaft

- **Research exemption → improvement & further developments & clinical trials also for marketing approval (Art. 30 TRIPS)**
- **Compulsory licenses incl. compulsory licenses for dependent patents (Art. 31 TRIPS)**
- **Compulsory licenses "Doha" type**
- **International exhaustion of patent right**

Conclusions



MAX-PLANCK-GESellschaft

- **Highest mid & long term priority → continuous flow of new drugs**
- **Access to medicines & generation of (new) medicines - inseparable**
- **National legislators and international community of states responsible for adequate legal framework for both**
- **Patents instrumental for generating new medicines - the basis for access & follow on generics & charitable activities & differential pricing, etc.**
- **Patentees responsible for prudent & balanced exploitation of their rights**



- **"Medicine is for people, not for profits!"**

[George W. Merck, founder of Merck, 1950]

- **However, no profits → no new drugs → no access promoting activities → no charity, etc.**
- **Not all drug companies - research based or generics - have already entirely committed themselves to their responsibilities "for people" → still room for improvements!**
- **But same is true also for other stake holders - governments, other branches of industry, NGOs, journalists, etc. → fight against poverty & medical infrastructure & training & counselling - also and even primarily their responsibility**



Thank you!