

Delinkage

The Economic Crisis and Access to Medicines in
Europe

Workshop in European Parliament

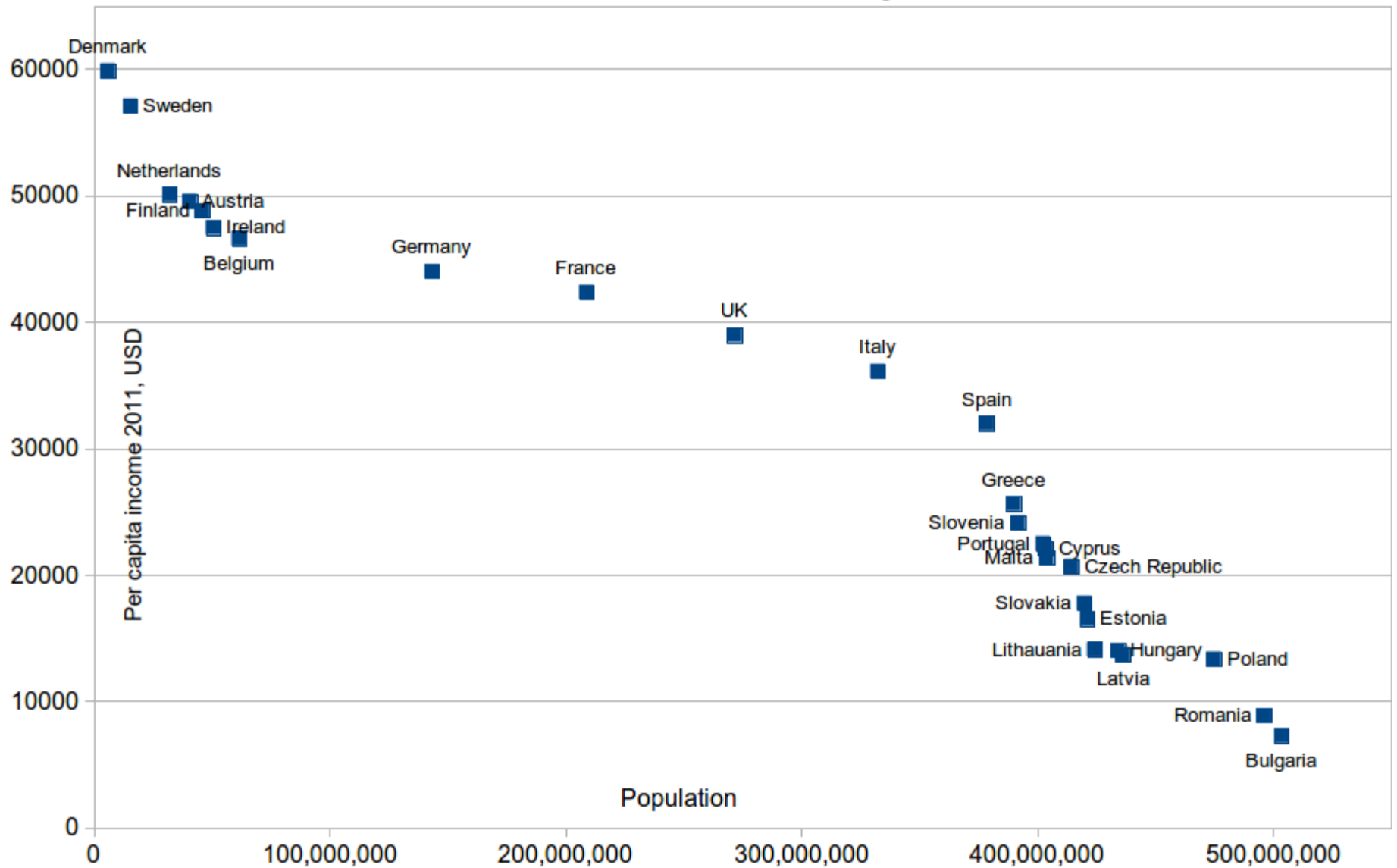
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The European Market (2011)

With constant income elasticity of demand



Global Private Sector R&D Global Revenues

Year	PhRMA member R&D (billions)	PhRMA member plus non-PhRMA member R&D (billions)	IMS Estimates of Global Sales (Billions)	Global R&D / Global Sales
2005	\$39.9	\$51.8	\$611	7.8%
2006	\$43.4	\$56.1	\$658	7.9%
2007	\$47.9	\$63.2	\$729	7.7%
2008	\$47.4	\$63.7	\$800	7.9%
2009	\$46.4	\$65.9	\$833	7.7%
2010	\$49.4	\$67.4	\$881	7.5%

Sources for both PhRMA member and non-member R&D spending are the 2011 PhRMA industry survey.

Data on development risks from Orphan Drug Act

Data Jan 1, 1983 to May 16, 2013

- Total Matching Designations: 2822
- Total Matching Approved Indications: 436
- Designations / Approved = 15.4 percent

Orphan Drug tax credit, designations, and approvals

Year	Credit (millions)	Designations	Approvals	Approvals / Designations
2005	\$232.2	123	19	15.5%
2006	\$310.0	142	24	16.9%
2007	\$381.3	117	16	13.7%
2008	\$450.2	165	14	8.5%
2009	\$533.2	164	20	12.2%
2010		195	14	7.2%
2011		203	26	12.8%
2012		190	25	13.2%
Total		1299	158	12.2%

2012 USPTO Patents for Class 435/ CHEMISTRY: MOLECULAR BIOLOGY AND MICROBIOLOGY

Search terms	Hits	
Patents granted	6810	
Patents Assigned to US owner	4160	61% of patents granted
Patents with US Government rights in patents	911	13.4% of patents granted
Patents assigned to US owner with US government rights:	888	21.3% of patents assigned to US owners
Patents assigned to “university”	1028	15.1% of patents granted

The monopoly problem

- In theory
 - Create temporary monopoly, and state regulates monopoly to advance public interest
- In practice
 - Monopoly power leads to political power. Monopoly regulates state (and other institutions) to advance private interests.

Universal access

- All models for funding R&D that rely upon the the grant of monopolies are inconsistent with universal access to new medicines.
- Price regulation or negotiations with monopolists are necessary in the foreseeable future, but this approach will not eliminate rationing of access, financial hardships on persons who pay for products, or well known inefficiencies in R&D incentives.
- Serious campaigns for universal access must embrace delinkage.

Basic Idea of Delinkage

- Eliminate monopoly on products
 - Realize huge savings on drug purchases
- Fund R&D through combination of direct grants, subsidies and incentives (pull financing)
- Address trade related aspects of R&D financing through global norms on R&D spending, multi-country funding of incentives such as innovation inducement prize funds, etc.

End product innovation prizes

1) High threshold prizes

Requires insight into the specification of end point of innovation, and size of prize. Examples would be proposals for prize for low cost diagnostic for TB, prize4life.org biomarker for ALS, etc

2) Low threshold prizes, with competitive valuation.

Examples of proposals include S. 626 Prize Fund for HIV/AIDS Act, various WHO proposals for innovation prizes, Cancer prize fund, etc

Innovation Prize Fund: End Product with Competitive Valuation

- Prize fund with fixed size
- Products that are approved and provide treatment benefits qualify for prize money
- Evaluation of health benefits annual, for 10 or 15 year period of participation in the prize fund
- Prize fund money divided among suppliers of innovations, in zero sum competition

Open Source Dividend

- A fraction of innovation prize fund money (or sales if OSD is implemented without end prizes) is given to persons, communities, non-profits, universities or companies that provide royalty free non-discriminatory access to knowledge, materials, technology and data.
- One approach: After product is registered, appoint jury, accept evidence regarding claims, and make allocations

Two relevant prize funds

- S. 626, Prize Fund for HIV/AIDS
 - US ARV market now about \$10 billion
 - Elimination of monopoly lowers prices, a lot
 - \$3+ billion per year into prize fund rewards innovators
 - \$150+ per year allocated to open source dividend
- Cancer prize fund
 - Share of cancer budget allocated to prize fund
 - De-monopolize cancer drugs

Short term ask

- Governments should model prize fund alternatives

Proposed National Academies Study

- (1) Whether a system of large innovation inducement prizes could work as a replacement for the existing product monopoly/patent-based system..
- (2) How large the innovation prize funds would have to be in order to induce at least as much research and development investment in innovation as is induced under the current system of time-limited market exclusivity.
- (3) Whether a system of large innovation inducement prizes would be more or less expensive than the current system of time-limited market exclusivity, calculated over different time periods.
- (4) Whether a system of large innovation inducement prizes would expand access to new products and improve health outcomes.
- (5) The type of information and decisionmaking skills that would be necessary to manage end product prizes.
- (6) Whether there would be major advantages in rewarding the incremental impact of innovations, as benchmarked against existing products.
- (7) How open-source dividend prizes could be managed, and whether such prizes would increase access to knowledge, materials, data and technologies.
- (8) Whether a system of competitive intermediaries for interim research prizes would provide an acceptable solution to the valuation challenges for interim prizes.