





Intellectual Property, Competition and Access in Europe: The flawed incentives of the current model

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Current Model of Innovation

The dominant current model of innovation...

- Relies heavily on **Intellectual Property** protection.
- Rewards innovation with **market exclusivity** and **monopoly prices**.
- No competition, which leads to **high prices, high profits, high costs** → **poor access**

Costs and Competition

European countries devote a high percentage of their health expenditure to medicines and...it is still growing

- **A decade ago**, no industrialised country spent more than **10% of its health budget on medicines**
- **Now** In Germany: **15.2 %** , Spain: **22.8%**, Finland **16.3%**, France: **16.6 %**, Italy: **20.1%** (US 12.48%)

Competition is vital to drive down prices, support broader access, and open the field to more innovation

- Generic market entry: **25% decrease in prices** within first year; 40% after two years.

Limits of Current Model

- Product **pipelines are drying up**
- **Fewer truly novel medicines** on market, especially products that have a therapeutic benefit
- **Heavy focus on marketing** of new medicines that have potentially more adverse affects than established treatments.
- 35% of molecules submitted by originator companies' pending authorisation have been **acquired or in-licensed from external researchers.**
- **Large part of R&D is publicly funded.**

Model of Litigation and Marketing

- Many **blockbusters** are going off-patent
- Innovators have **profit-driven incentives** to hold on to market exclusivity
 - ➔ hinders competition
- **Business model** increasingly focused on litigation, excessive patenting, and marketing and promotion.
 - ➔ incentives structure contrary to citizen interests.



DG Competition Pharmaceutical Sector Inquiry

Investigation conducted between late 2007-mid 2010

Serious concerns about:

- **slow generic entry**
- **weak innovation**



Findings: DG Competition Report

- Revealed some **disturbing structural practices**
- Observed that pharmaceutical companies have...

...“designed and implemented strategies aimed at blocking or delaying generic entry”

AND

...used tactics that “reduce incentives to innovate” and “cause significant additional costs for public health budgets”.



Findings: DG Competition Report

- Calculated that EU health systems **could have saved more than 3 billion euros** between 2000 and 2007
- Found that innovator companies **spend 15 times more on marketing, blocking tactics and litigation** than on discovering new beneficial medicines.
- Identified a **‘toolbox’ of tactics** employed by originator company to discourage, delay, and prevent generic entry into the market.

Practices: Originator-Generics

- i. **“Patent clusters”** → substantial barrier to potential generic manufacturers
- ii. Patent-related **disputes and litigation**
- iii. **Settlements** with generic companies
- iv. **Misleading claims** about inferior quality of generics in decisions on product authorisation, pricing and reimbursement status
- v. Launching **follow-on products** in order to displace generic medicines based on the original product



Practices: Originator-Originator

Defensive patents → limiting the ability of rival companies to work R&D in that area

→ the very existence of the right makes development **less commercially attractive.**

→ **hampers innovation.**

Follow-up: DG Competition Inquiry

- **Regulatory frameworks:** Market authorisation / Patents and patentability / Pricing and reimbursement
- Enforcement of competition law: **Anti-trust cases**
- **Deterrence**

BUT, companies will still act according to the current framework of incentives:

Prioritising profits over public health needs

...WE NEED STRUCTURAL CHANGE



How to go forward

High prices and lack of innovation are at the core of the debate about **Access to Medicines on a global level.**

We have to **rethink the model of innovation** both for EU and developing countries

We don't need...

- More of the same
- Clever marketing
- Good lawyers
- Strategic patenting

We do need...

Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.



New Models that reward **Health Impacts** and **Real Innovation**

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Thank you

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