



Making Medicines Affordable

How to Improve the Efficiency of the European Patent System

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 - Patent quality
 - Patent litigation
 - EGA recommendations on how to improve the patent system
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Generic medicines: key to healthcare sustainability and patient care



- EGA represents over 700 companies in 34 European countries
- Generic medicines companies employ over 130,000 people in the EU
- Generic medicines account for nearly 50% of packs dispensed in the EU and 18% of pharmaceutical expenditure
- Generic medicines bring savings of over €25 Billion per annum in the EU 27
- Generic medicines companies cover a full spectrum of pharmaceutical needs
- Generic medicines companies also undertake incremental innovation



Generic medicines: healthcare provision and innovation

“Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines.”

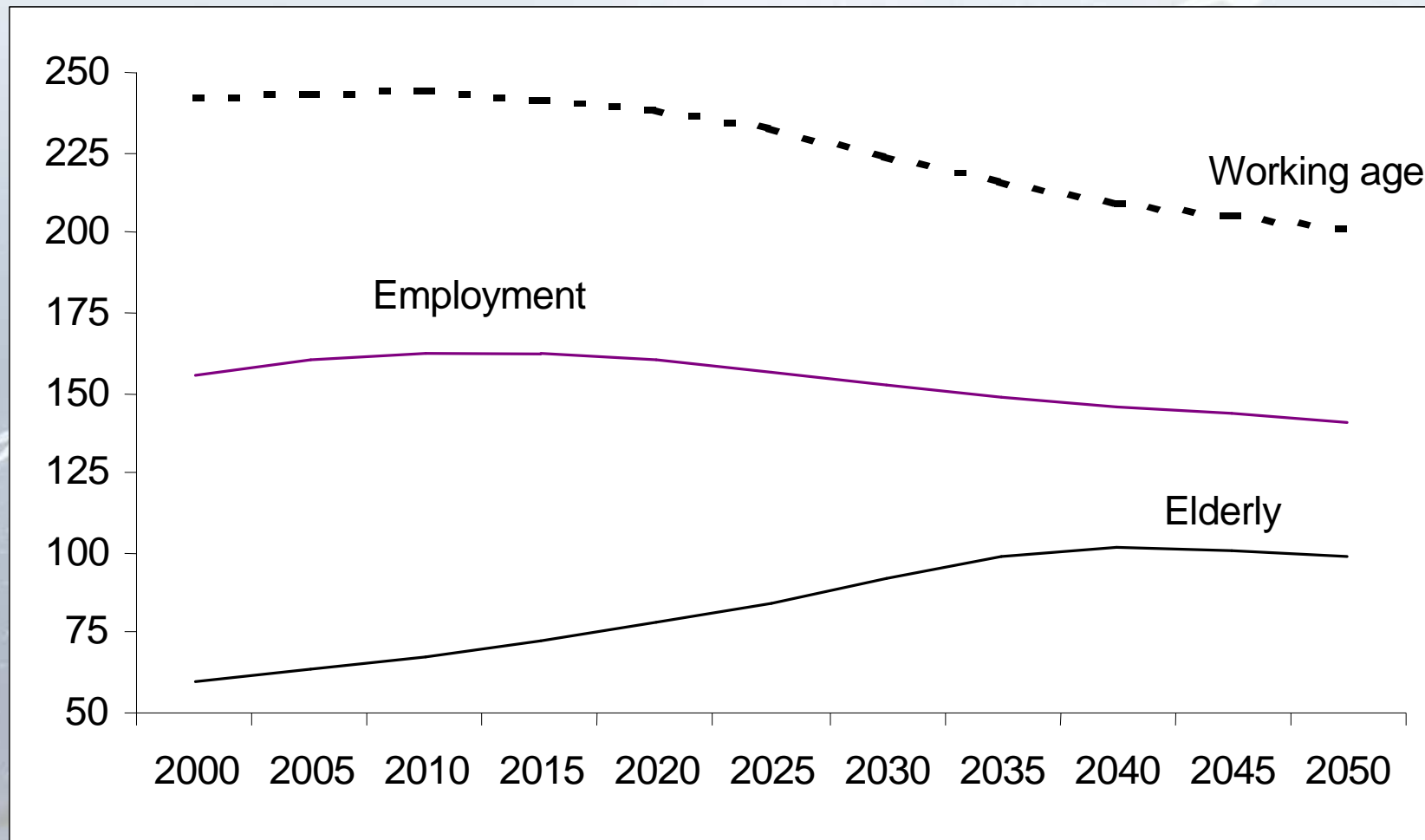
Pharma Forum
Progress Report June 2007

Pharmaceutical
FORUM

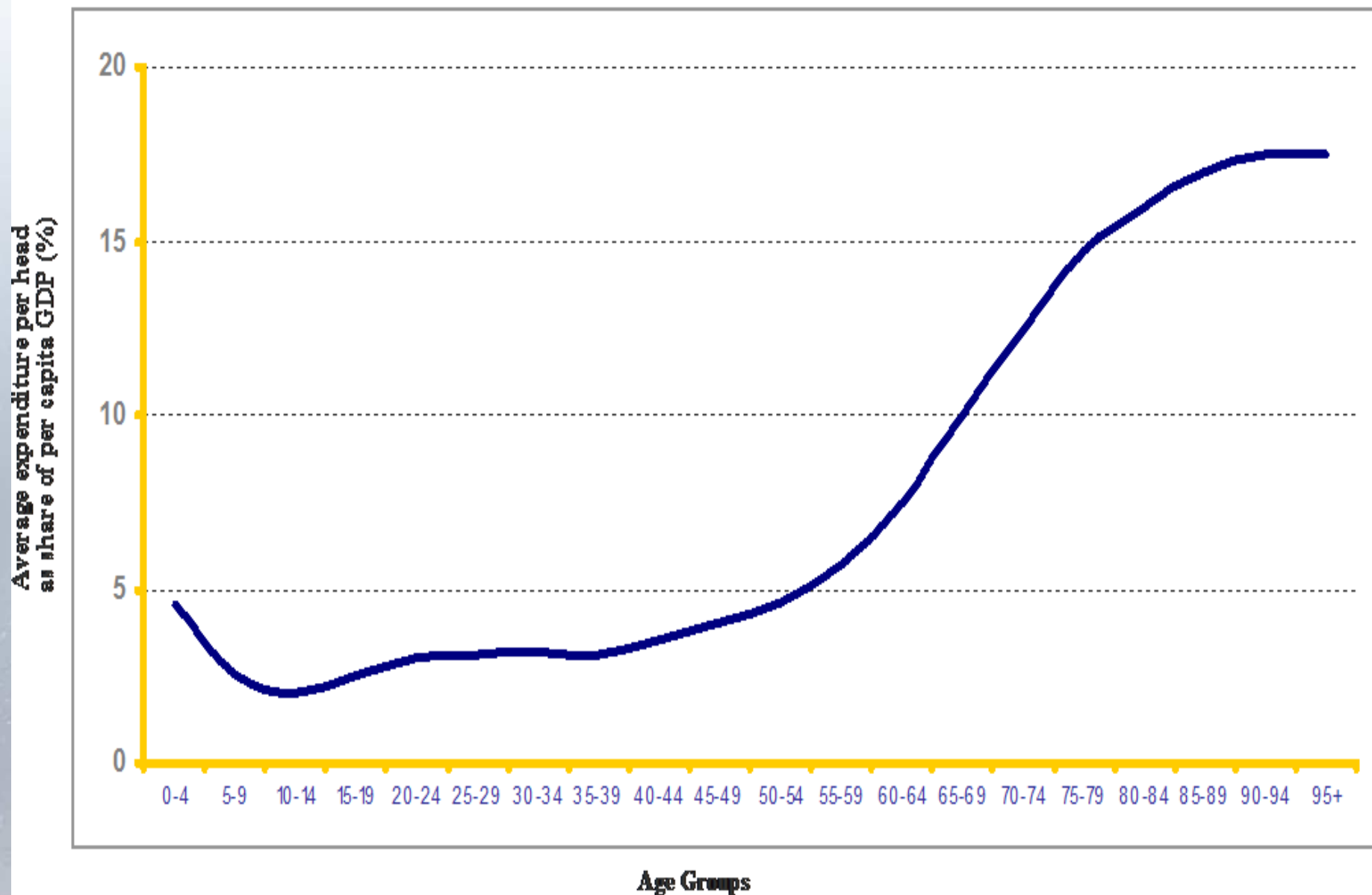


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Europe's Ageing Population



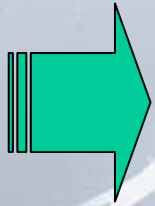
Average EU Healthcare Expenditure Per Head by Age Group



Getting the right environment for generic competition

Three Foundation Stones:

- Efficient Regulatory System
- Intellectual Property Balance
- National Measures Promoting Generic Medicines





Pharma properties eligible for patenting

1980s (5 properties)

- Primary uses
- Processes and intermediates
- Bulk forms
- Simple formulations
- Composition of matter

1990s (18 properties)

- Primary uses
- Processes and intermediates
- Bulk forms
- Simple formulations
- Composition of matter
- Expansive numbers of uses
- Methods of treatment
- Mechanism of action
- Packaging
- Delivery profiles
- Dosing regimen
- Dosing range
- Dosing route
- Combinations
- Screening Methods
- Chemistry Methods
- Biological Target
- Field of use

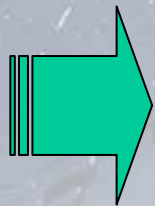
Source: "Evolution of IPR & Pharmaceutical discovery and Development", Eric Larson, Sr Director, Groton Site Head, Pfizer Global Research & Development.

Viewed on 9/11/2005 at:
http://www7.nationalacademies.org/step/Larson_ppt.ppt



Increasing IP protection: example Europe

- 1992 SPC regulation granting up to 25 year patent life.
- 1992-94 introduction of Product Patents for pharmaceuticals in CEE and South Europe.
- Mid 1990s increasing secondary patents
- 1994 introduction of TRIPS.
- 2004 data exclusivity increased to 8-11 yrs.
- By 2007 over 8500 Patent extensions granted through SPC Regulation



Despite increased IP the rate of “innovation is declining”



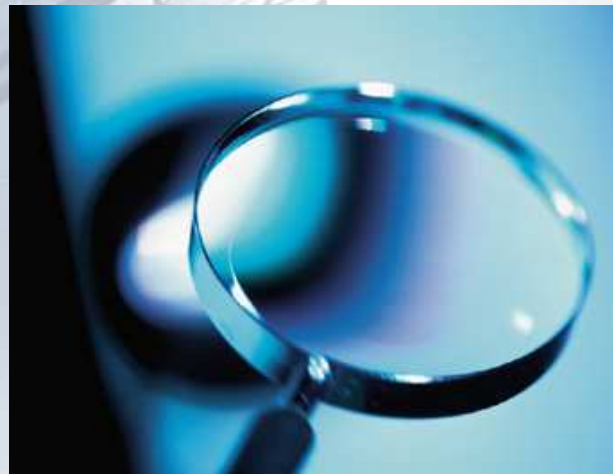
Generic medicines access is not being optimised

- EGA in a study prepared for Pharma Forum observed that of the top 35 off-patent molecules in some cases the first generic medicine only entered the market up to 20 months after the patent expired.
 - Causes are
 - a) lack of government measures to promote generic medicines
 - b) uncertainties created by patent system and consequential patent strategies
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Patent Quality and the EGA report on IP Barriers to Generic Competition





EGA IP barriers to innovation and competition



- “Patents have a key role in incentives & rewarding crucial pharmaceutical research & development”
- Misuse of the patent system however will
 - a) restrict access/affordability and
 - b) discourage real innovation.

Obtain this report from www.egagenerics.com

Patent quality: identified hurdles (i)

- Lack of rigorous application of patentability requirements
- Poor quality applications
- Difficulties for the EPO to verify data
- Insufficient consideration of 3rd party observations
- Prolonged opposition procedures



Filing of divisional applications identical to the parent are used to block market entry

Identified hurdles (ii)

- No distinction between genuine incremental innovation and routine applications of standard techniques
- Leads to patent thickets and follow-on patents that aim to extend monopoly rather than innovate
- Up to a thousand patents across the EU on one molecule (or 40 to 50 per Member States).



List follow-on medicines which lack established added value

Molecule	Brand name	Expiry date patent	Follow on molecule	Brand name	Remarks
Omeprazole Anti-acid	Losec	Jan 03	Esomeprazole	Nexium	isomer
Citalopram Anti-depressive	Cipramil	Dec 06	Escitalopram	Spiralex	isomer
Alendronate 10 mg Osteoporose	Fosamax	April 08	Alendronate 70 mg	Fosamax	EP 70 mg revoked by several EU Courts



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Excessive Patent Litigation





Identified hurdles on patent litigation

- Complex and unpredictable system across Europe; lack of a single system
 - Too easy granting of interim injunctions
 - Misuse of court procedures to delay a finding on the merits
 - Judges lack experience and technical knowledge
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Example of frivolous litigation

■ Teva vs Abbott case

- In May 2007, Abbott request pre-judgement seizure of documents, asserting there was imminent infringement of Abbott's patent rights.
 - A search was conducted in the Teva offices in Utrecht and Haarlem including a search of the computer server.
 - However, the District Court found the seizure to be unlawful and should be lifted.
 - The Court recognised that it was of the utmost importance to generic companies that they be in a position to enter the market as soon as possible after the relevant patent protection expires.
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Link with the Preliminary Findings of the EC Sector Inquiry



EC sector inquiry report

- The patent system is the corner stone of a system that seeks to provide incentives for innovation

 - However, relevant findings of the inquiry:
 - Numerous patents for the same medicine are granted resulting in patent clusters or patent thickets
 - EC is concerned that abuses in the filing of divisionals might be part of originators' strategies to create uncertainty and delay generic competition
 - Originators use a “tool box”
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EC sector inquiry report

- **Problems for the generic industry: litigation**
 - National litigation: generic companies won the majority of cases: 62% -> validity issues
 - EPO opposition proceedings: generic companies prevailed in 75%
- **So there are clear signs of patent quality issues, already identified in EGA IP Barriers report**

EC sector inquiry report

Some Key Findings

- Patent applications doubled between 2000-7
 - Total litigation cost for cases analysed for 2000-2007 is over €420 million
 - € 3 Billion lost savings just for the products analysed
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Patent quality:

- Improve applications
- Need to raise bar for patent granting

- Concerns over increase in patent litigation
- Lack of unitary system & specialized judges

- Concerns on patents & competition
- Use of defensive patent strategies (patent clusters)

EGA	✓	✓	✓
EC pharma inquiry	✓	✓	✓
STOA report	✓	✓	✓



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Key Recommendations



EGA key recommendations

■ On quality (i):

- Rigorous assessment of patentability requirements
 - Duty of candour on patentees to ensure that all information relevant to the patent being examined by the EPO is disclosed by the applicant
 - EGA welcomes any internal changes in EPO guaranteeing quality applications and full disclosure of relevant prior art by the applicant.
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EGA key recommendations

■ On quality (ii):

- Third parties to be involved in the application process
 - Accelerate opposition procedures
 - Regular and public communication of patent policy decisions made by the Administrative Council of the EPO.
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EGA key recommendations

■ On patent clusters:

- To reject outright all divisional applications that exactly duplicate or do not vary significantly from the claims of the parent patent (this problem of so-called double patenting is supposed to be prohibited by EPO).
 - EGA welcomes the proposal by the EPO Committee on Patent Law to tighten the rules of procedure regarding filing of divisionals.
 - Limit the scope of second medical use patents
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EGA key recommendations

■ On litigation:

- A Europe-wide litigation framework with technically and legally qualified judges
 - Publish all patent decisions
 - A central, European patent judiciary: EC's initiative on the EU Patent Court is welcome
 - Involve reimbursement bodies in interim injunction applications
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Final points



- EGA would like to continue a dialogue with the European Parliament and the EPO aimed at improving the efficiency of the European patent system
 - More transparency from EPO is encouraged
 - EPO regular consultation process with experts and all stakeholders
 - EGA welcomes STOA's proposal to create a standing committee within the EP to improve patent awareness among MEPs
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Conclusion

Better patents

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Better Medicines





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Thank you

www.egagenerics.com

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