



Making Medicines Affordable

Patients Must Have Immediate Access
to Affordable Generic Medicines at
Day One After Patent Expiry



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



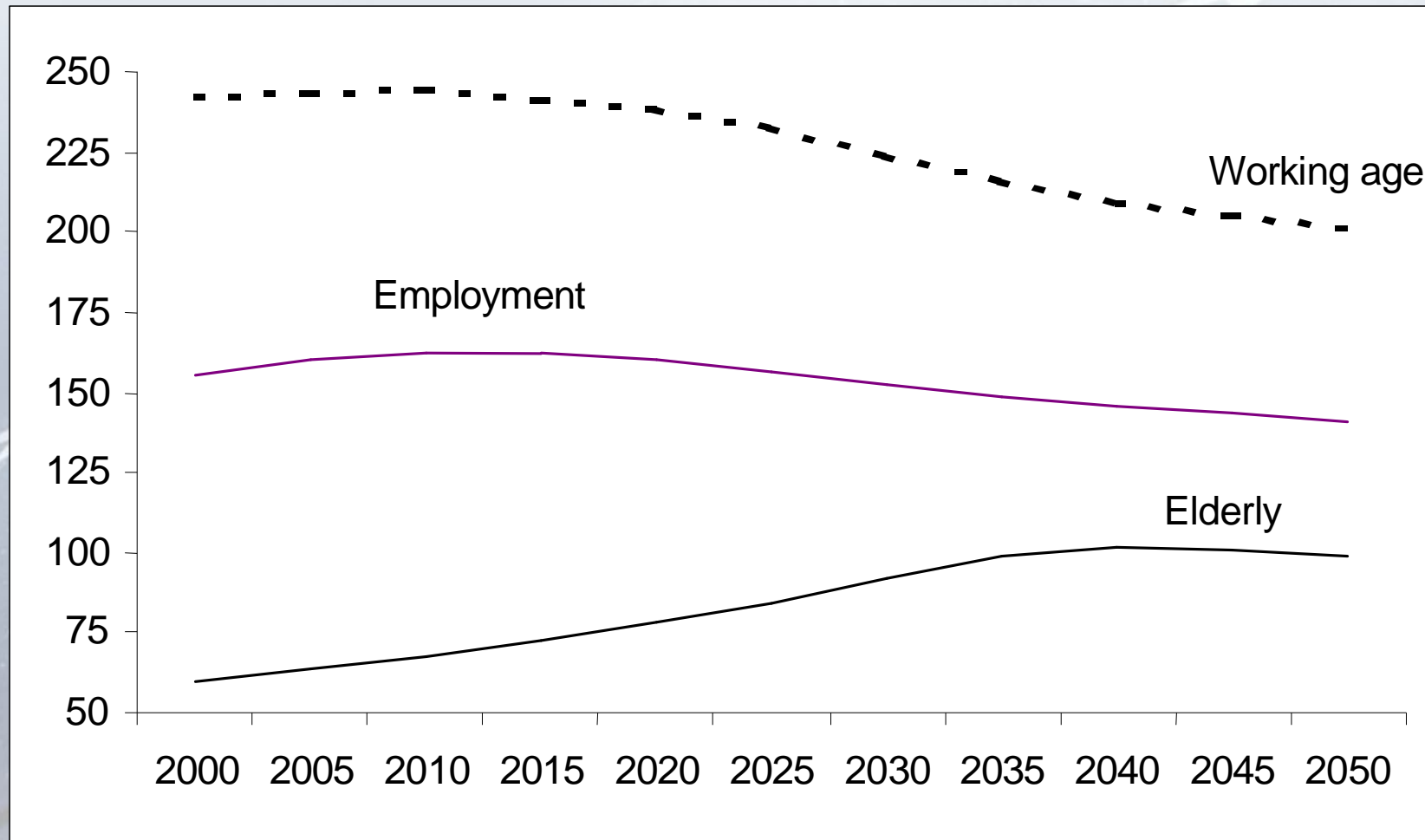
Generic Medicines: Healthcare Provision and Innovation

“ 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

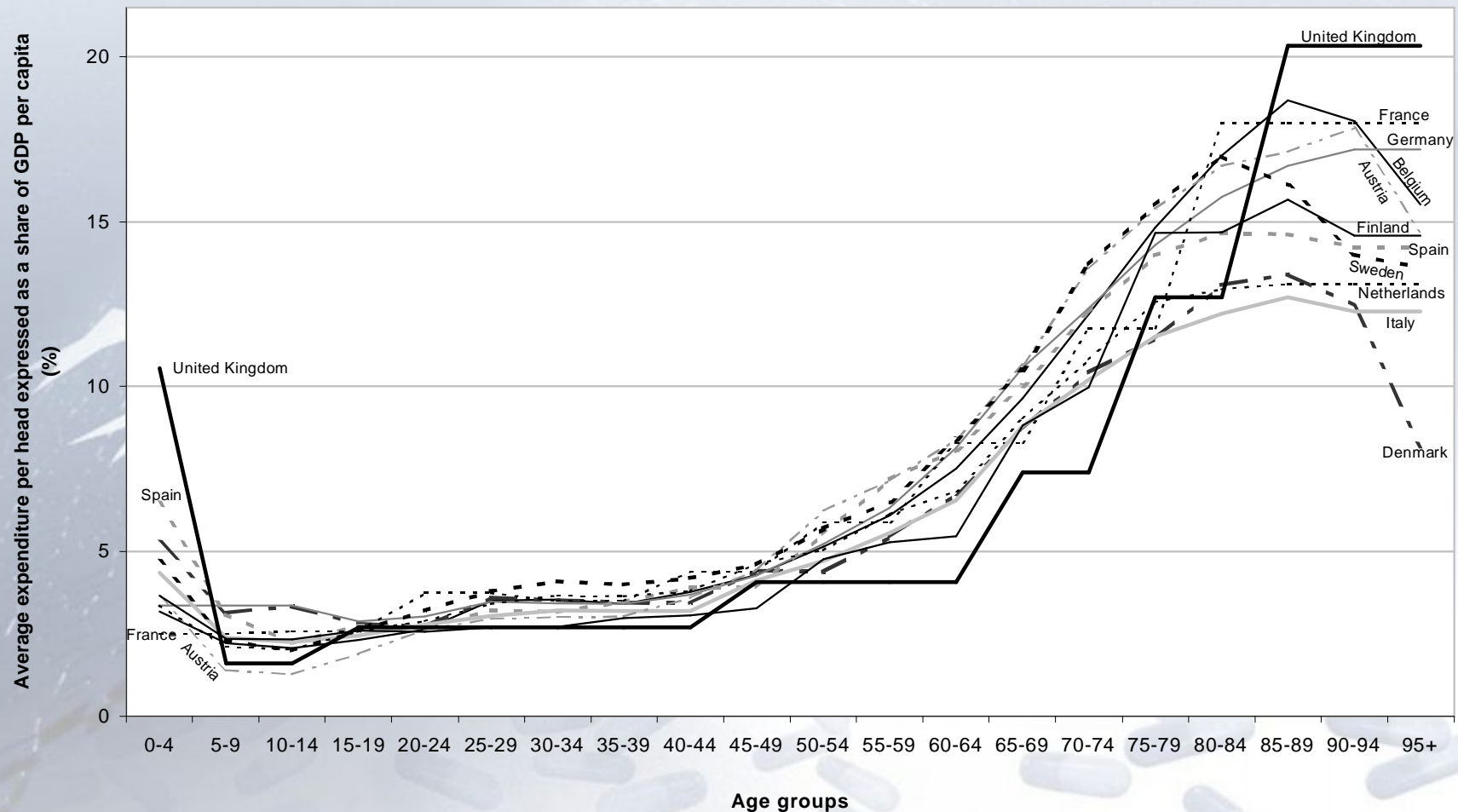
Pharmaceutical
FORUM

Europe's Ageing Population



Expenditure on Health Care In Relation to Age

Source: Economic Policy Committee (2001) "Budgetary challenges posed by ageing populations"

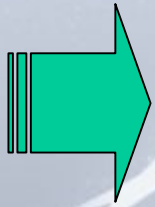




Getting the Right Environment for Generic Competition

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



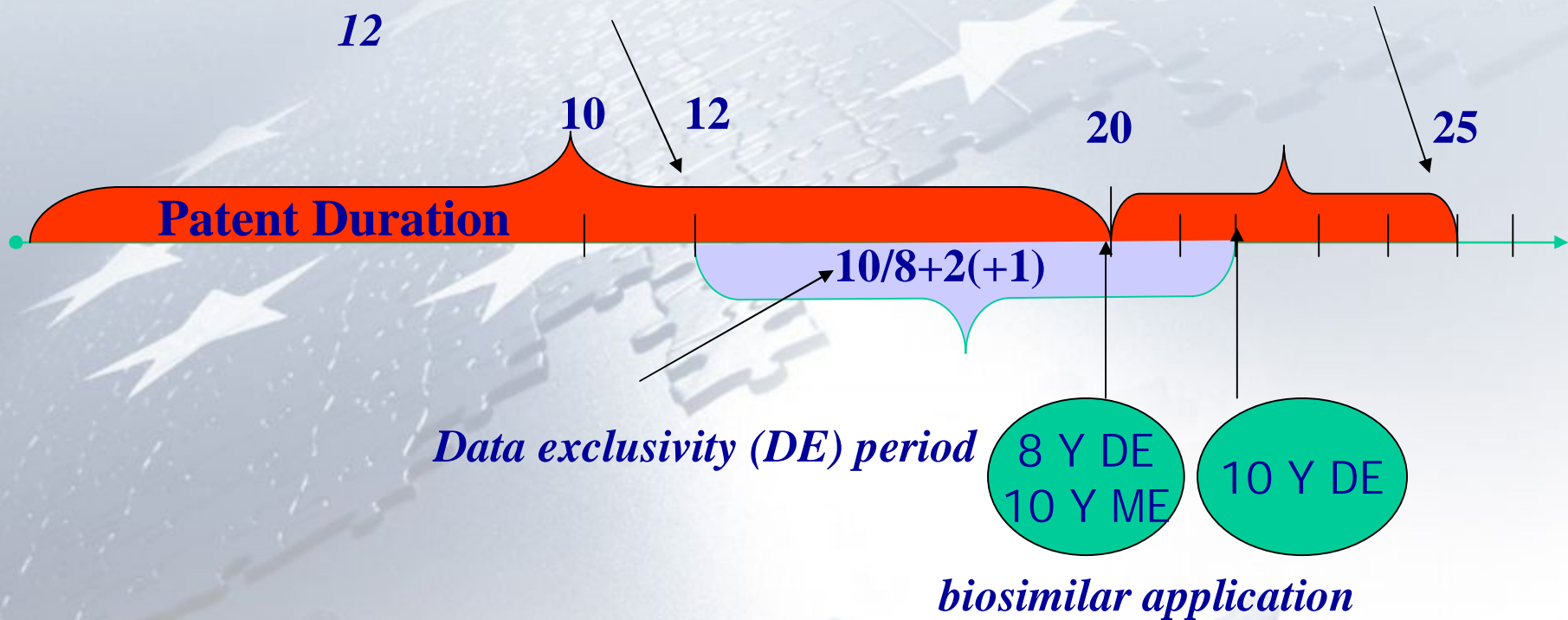
Increasing IP Protection: Example Europe

- 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”
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Market Exclusivity (due to patents & DE)

e.g. the marketing authorisation is granted to Reference Product in year 12

Maximum 5 years extension of Supplementary Protection Certificate (SPC)



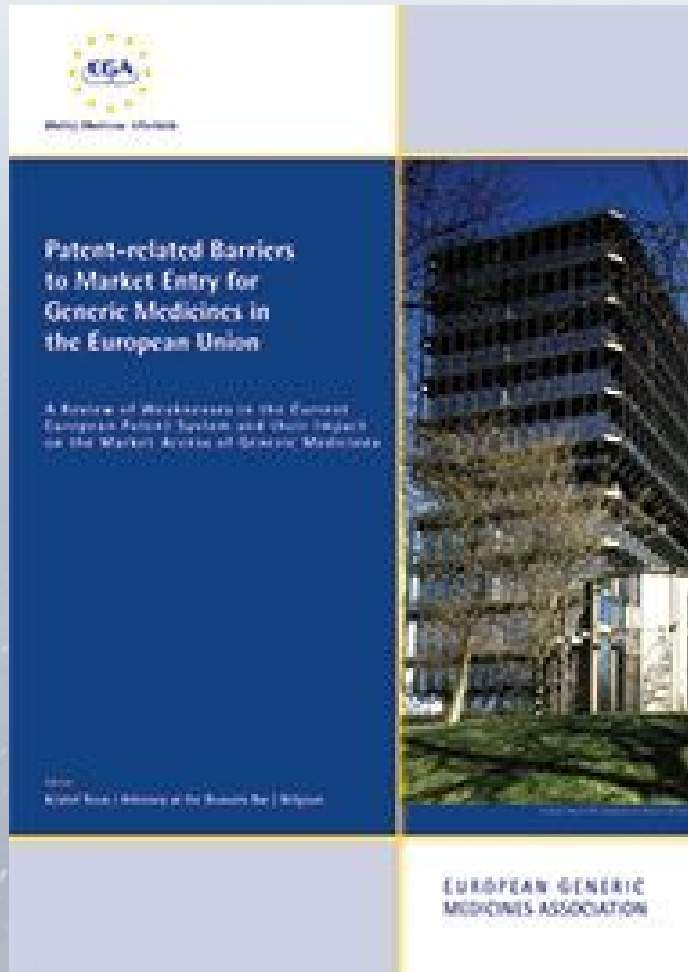


Also Generic Access is not being Optimised

- 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 generics
 - b) uncertainties created by patent system and consequential patent strategies



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

- Lack of rigorous application of patentability requirements (inventive step)
 - Poor quality applications
 - Inability of EPO to verify data in applications
 - Insufficient consideration of 3rd party observations
 - Prolonged opposition procedures
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Patent Thickets and Follow-on Patents

- Up to a thousand patents across the EU on one molecule
 - Give rise to an unjustifiable extension of the monopoly and confusion
 - No distinction between genuine incremental innovation and routine applications of standard techniques
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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 a	isomer
Alendronate 10 mg Osteoporose	Fosamax	April 08	Alendronate 70 mg	Fosamax	EP 70 mg revoked by several EU Courts

Patent Litigation

- Complex and unpredictable across Europe due to lack of a single system
 - Improper granting of interim injunctions
 - Misuse of court procedures to delay a finding on the merits
 - Inexperienced judges
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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.

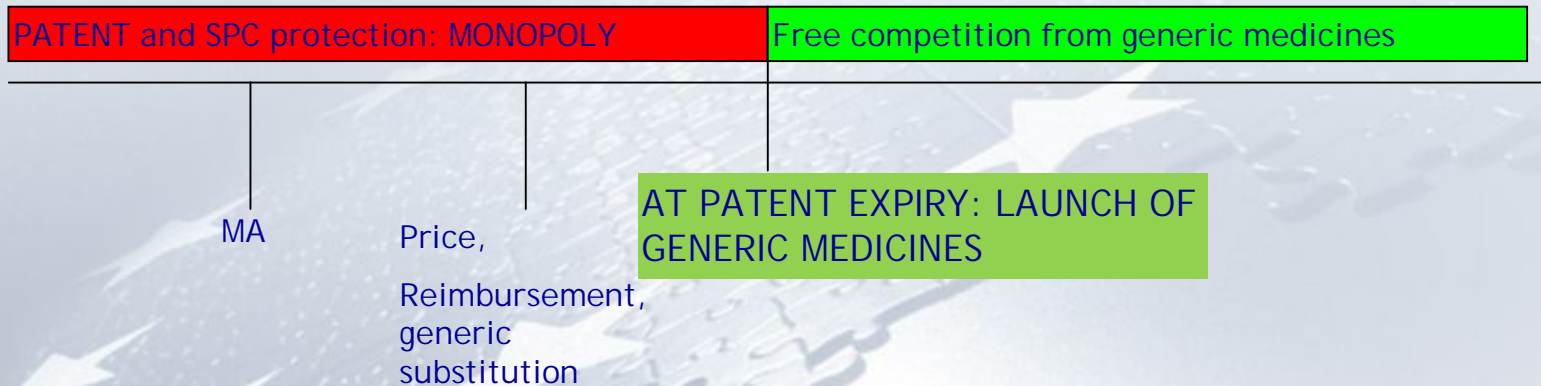
Patent Linkage - New threat

The practice of *linking* the *marketing approval* and/or the *pricing & reimbursement status* of generic medicines to the *patent status* of the reference product

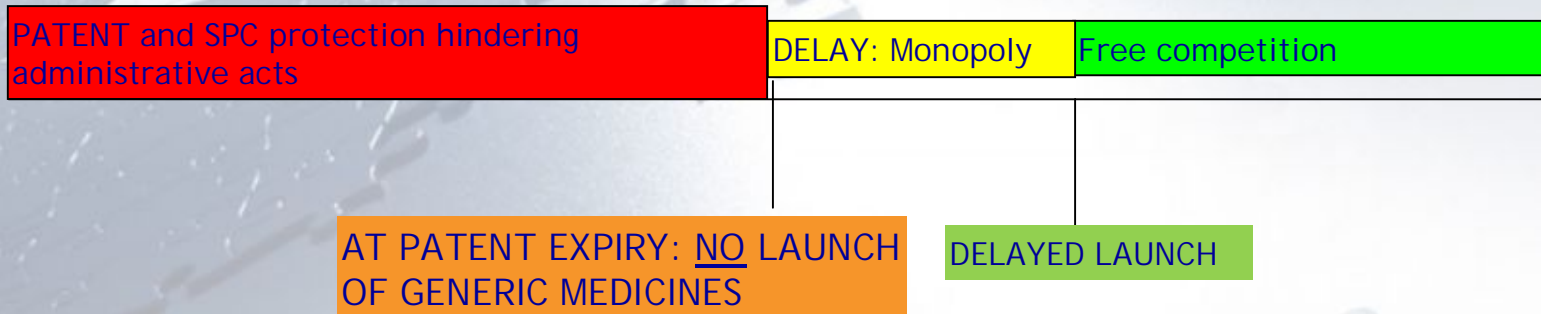


Aim of Patent Linkage

1. No patent linkage



2. Patent linkage



An Example: Portugal

- Since July 2007, generic medicines have been effectively blocked from access to the market
- More than 70 court cases against generic medicines companies and national authorities
- Based on market authorisation (MA) was granted before patent expiry, which is in fact justified by the Bolar Provision

(Art 10.6 of Directive 2001/83/EC as amended)

EGA Key Recommendations

■ On quality:

- better resourcing for EPO
- duty of candour on patentees
- Better application of inventive step - raising the bar

■ On follow-on patents:

- prohibit the filing of identical divisionals
 - limit the scope of second medical use patents to genuine incremental innovation
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EGA Key Recommendations

■ On litigation:

- a Europe-wide litigation framework with technically and legally qualified judges
- a central, European patent judiciary
- involve reimbursement bodies in interim injunction applications

■ On patent linkage:

- Clarify that all administrative requirements can take place in advance of patent expiry
 - Prevent all intervention in generic medicines' regulatory procedures by originators
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Sector Inquiry Report

Some Key Findings on IP

- Patent applications doubled between 2000-7
 - Total litigation cost for cases analysed for 2000-2007 is over €420 million
 - € 3 Billion lost savings for products analysed
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Sector Inquiry Report

Some Key Findings on IP

- Patent strategies used to extend protection not innovation
 - Patent clusters lead to uncertainty for generic companies when they could launch
 - Originator companies used litigation not for the merits but to deter generic entrants
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Final Note on Regulatory Framework

- Preliminary Report identifies bottlenecks due to regulatory procedures
- EGA recommends:
 - Full introduction of principle of Mutual Recognition for registration procedures
 - Automatic price and reimbursement approval (including positive list)
 - No price control other than for medicines reimbursed and dispensed in the member state (i.e. Recommendation 6 of G10)



Making Medicines Affordable

Better Patents
=
Better Medicines
