Making Medicines Affordable

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

Brussels, 14 January

Elke Grooten
EGA Director Pharmaceutical Policy

Generic Medicines: Key to Healthcare Sustainability and Patient Care

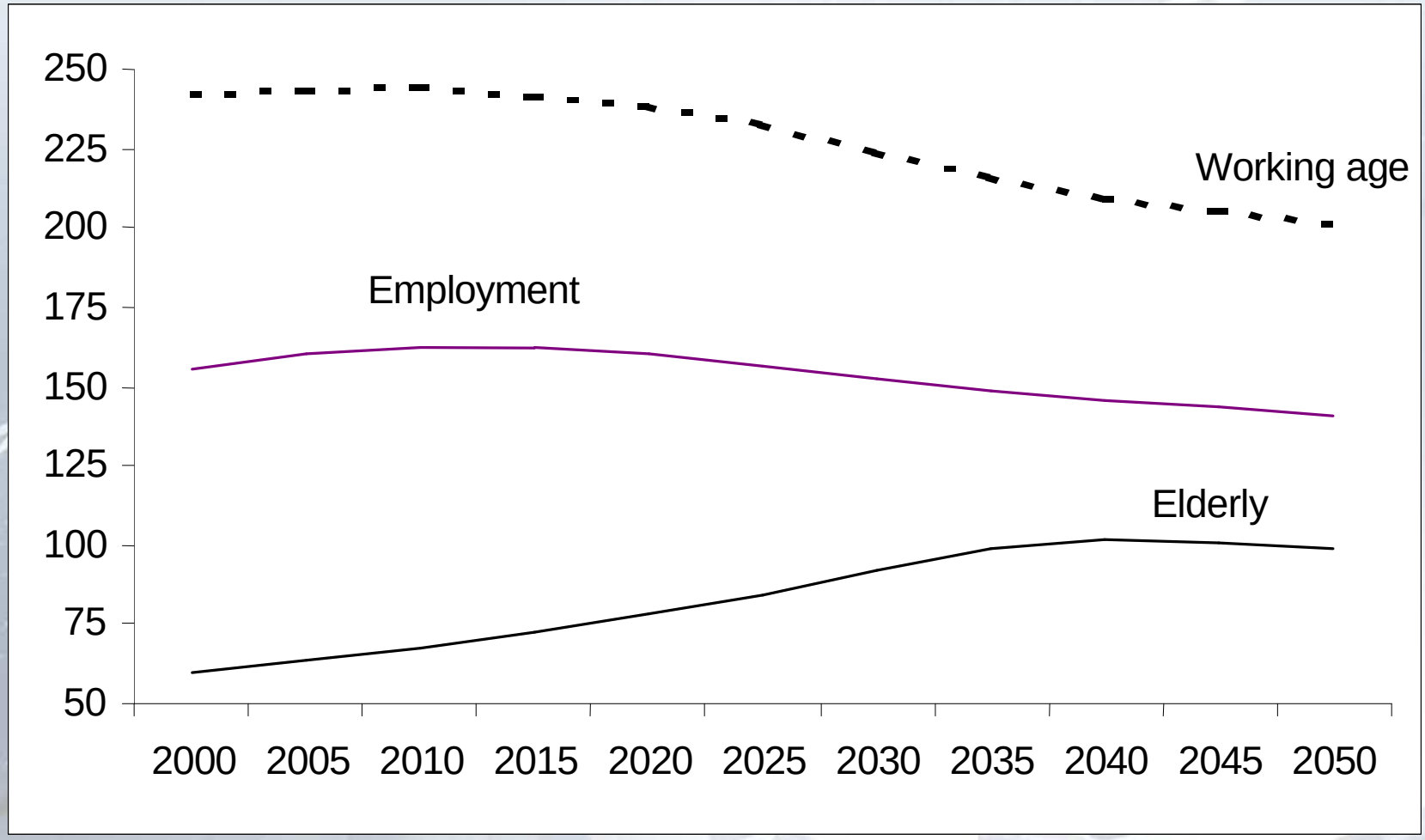
- EGA represents over 700 companies in 34 European countries
- Employs over 130,000 in the EU
- Generic medicines account for nearly 50% of packs dispensed in the EU and only 18% of pharmaceutical sales
- Generic medicines bring savings of over €25 Billion pa in the EU 27
- Generic companies cover a 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."

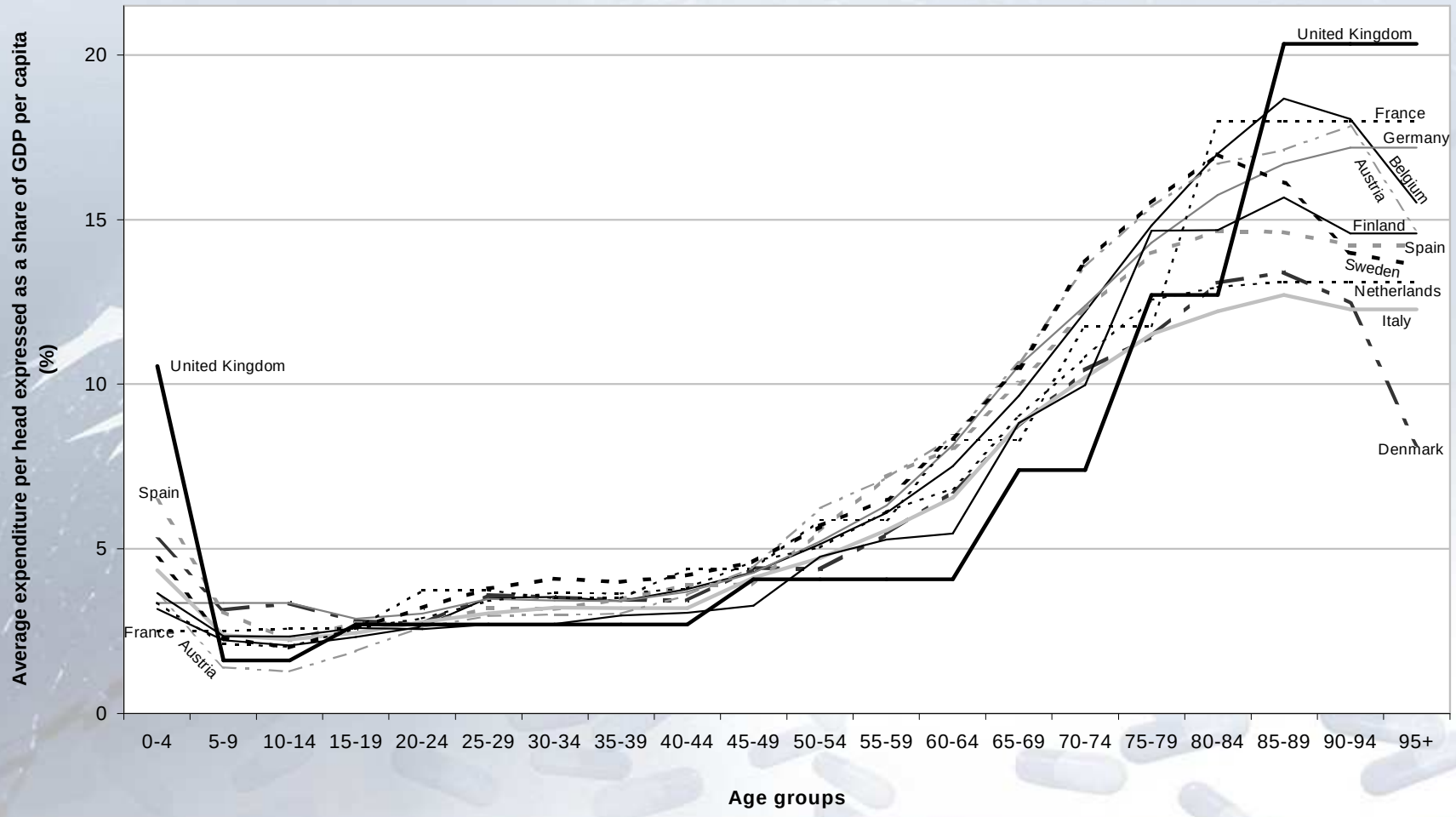
Pharma Forum
Progress Report June 2007

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 9/112005 at:
http://www7.nationalacademies.org/step/Larson_ppt.ppt

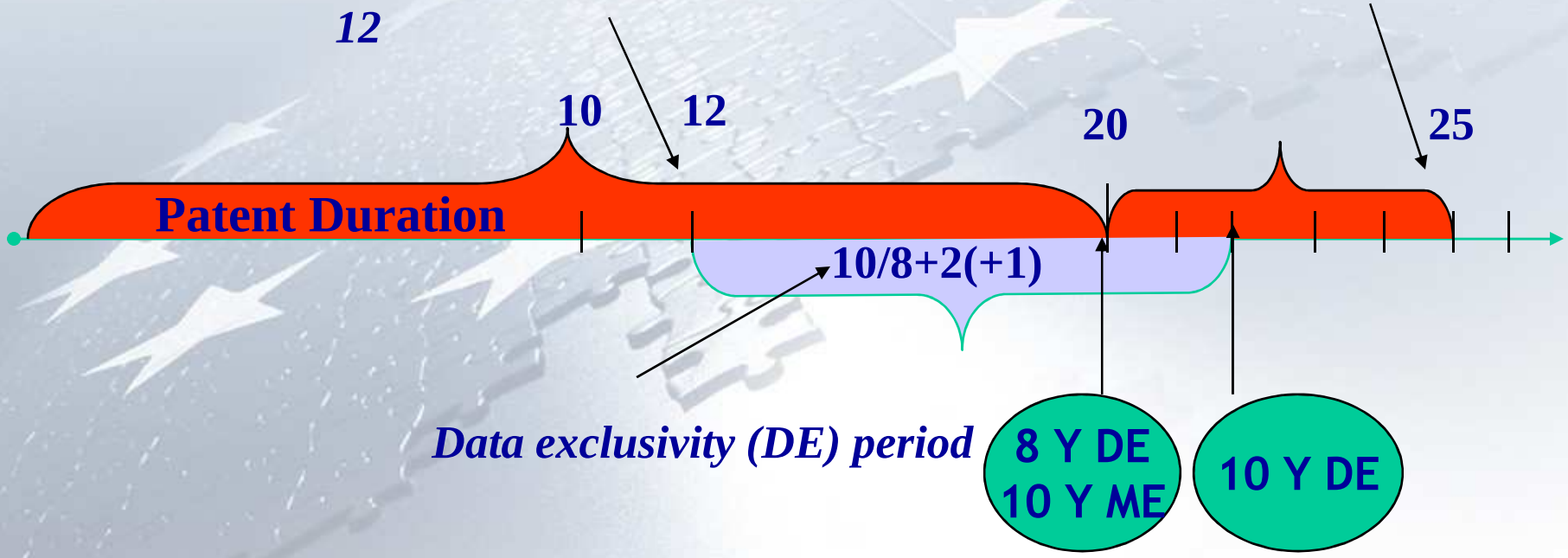
Increasing IP Protection: Example Europe

- 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"

Market Exclusivity (due to patents & DE)

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

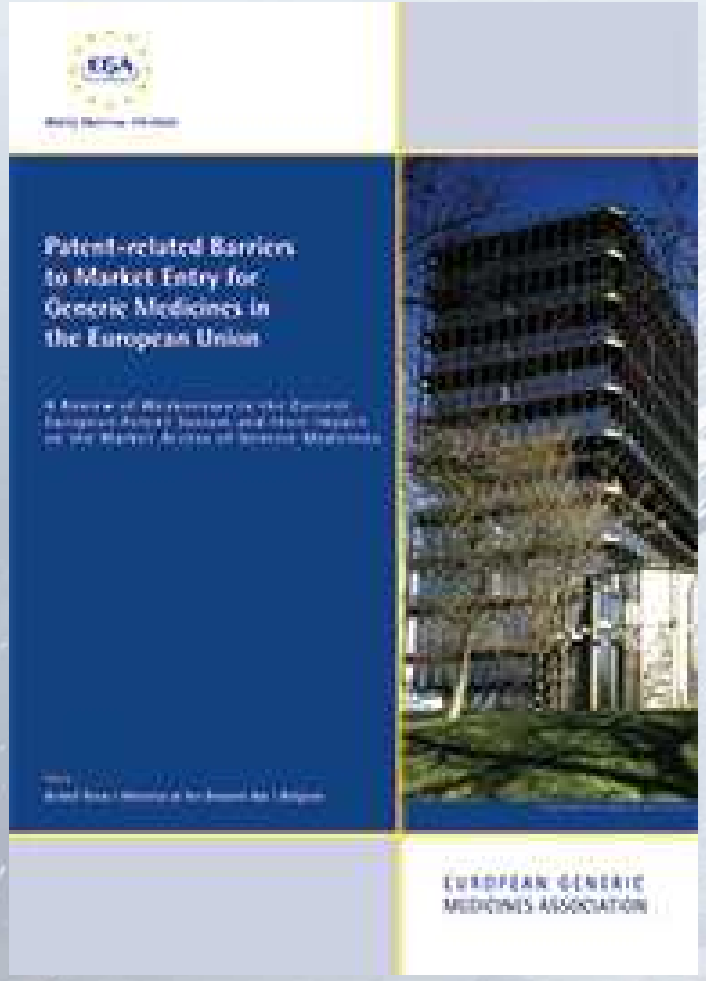
Maximum 5 years extension of Supplementary Protection Certificate (SPC)



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

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

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**	Spiralexa	**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

Example of Frivolous Litigation

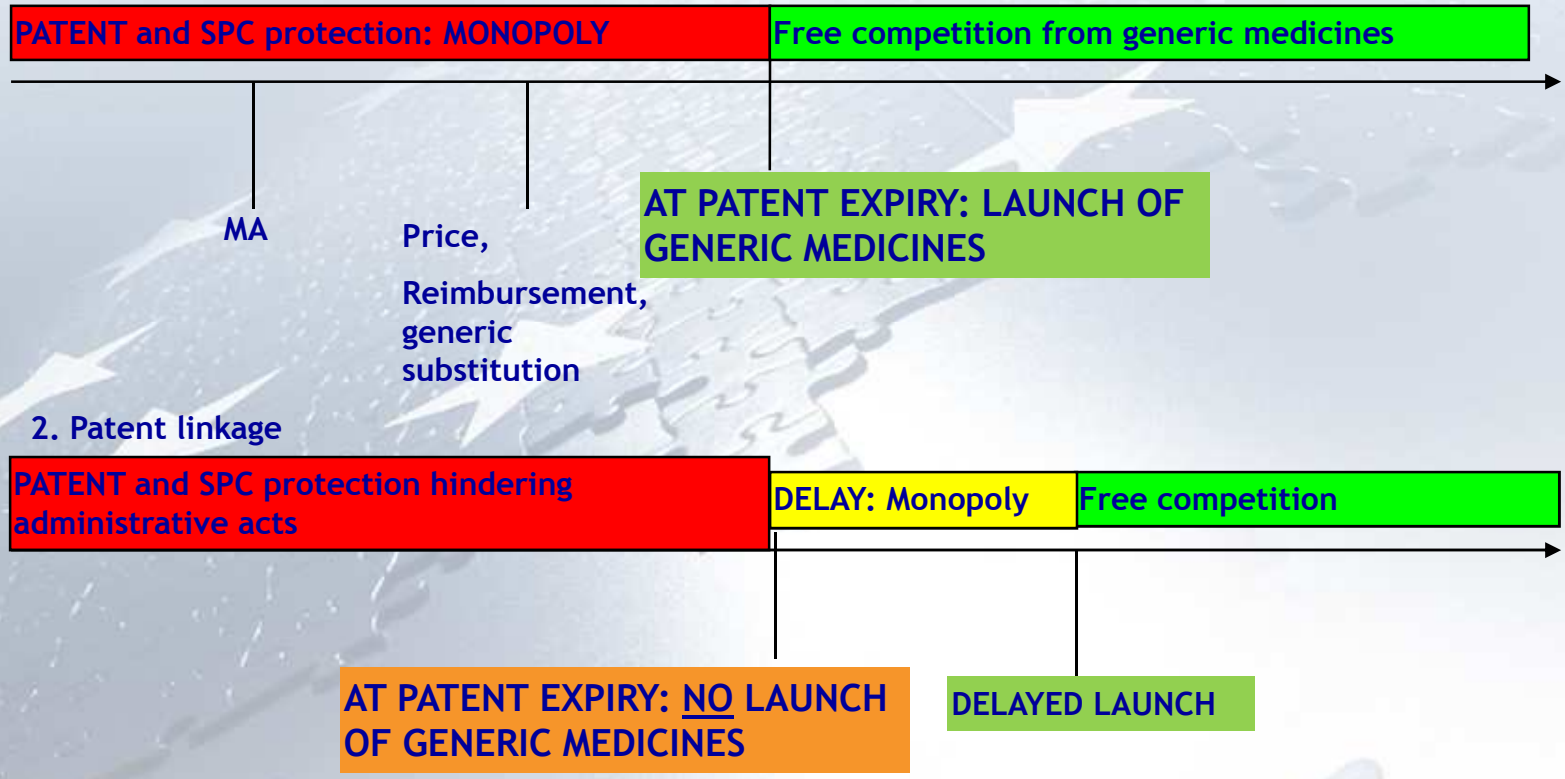
- **Teva vs Abbott case**
  - In May 2007, Abbott request pre-judgement seizure of documents, asserting there was imminent infringement of Abbott's patent rights.
  - A search was conducted in the Teva offices in Utrecht and Haarlem including a search of the computer server.
  - However, the District 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



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

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

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

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

Making Medicines Affordable

Better Patents
=
Better Medicines