



Making Medicines Affordable

# EGA

## Myths and Realities

of the pharmaceutical industry

*Myth*

Pharmaceutical inventions are less protected in Europe than in the USA.

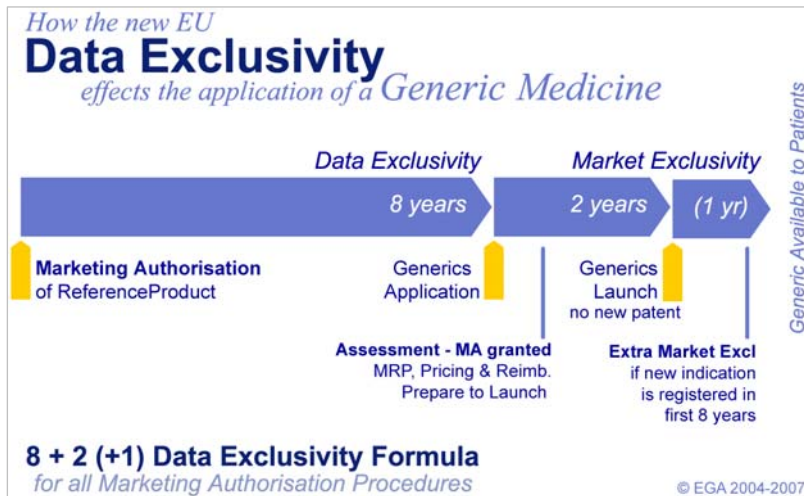
*& Reality*

Pharmaceuticals enjoy *far greater* IP protection and market exclusivity against generics competition in the EU than in the USA.

- Lower levels of IP protection in the United States has produced greater competition from generics medicines - and greater innovation.
- The EU has greatly increased its IP protection for pharmaceuticals since 1980, at the cost of declining innovation during the same period

Protection	USA	EU
<b>Basic Product Patent</b>	Yes 20 years	Yes 20 years
<b>Data Exclusivity</b> Blocks market authorisation procedures for generics	5 years	8+2+(1) years
<b>Patent Extensions</b> Supplementary Protection Certificates, etc.	Yes 14 years Maximum	Yes 15 years
<b>Bolar Provision</b> Right to perform generic R&D before patent expiration	Yes	Yes
<b>Immediate Generic Competition</b> Upon patent expiration	Yes	No*
<b>Generic Substitution</b> By pharmacists	Yes in all 50 states	No In many Member States
<b>Paediatric Extensions</b>	Yes	Yes
<b>Fees Waiver for Generics</b>	Yes	No

\* Pricing & reimbursement decisions create delays in most Member States.



*Pharmaceutical Properties*

**Eligible for Patenting\***

**1980s**

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

**1990s**

- 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

\*"Evolution of IPR and Pharmaceutical Discovery and Development", presentation by Eric Larson, Senior Director, Groton Site Head, Pfizer Global Research & Development (22 October 2001). Viewed on 24 May 2007 at: [www7.nationalacademies.org/step/Larson\\_ppt.ppt](http://www7.nationalacademies.org/step/Larson_ppt.ppt).

Formed in 1993, the EGA is the official representative body of the European generic pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the global pharmaceutical sector.