



## **Trilateral Meeting The Hague 13 October 2008**

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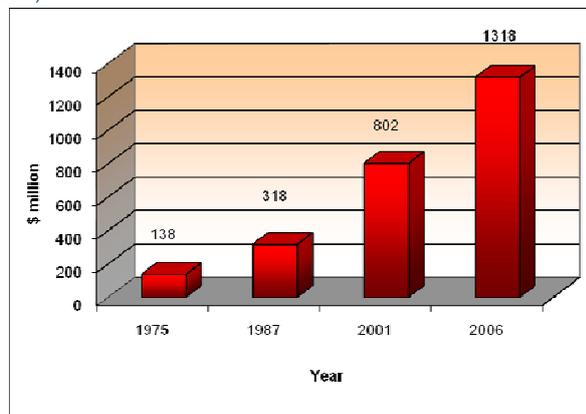


- 1) Why the pharmaceutical industry needs patents
- 2) How the system works
- 3) The PCT
- 4) The way forward?



## Patents and the Pharma industry

Estimated full cost of bringing a new chemical or biological entity to market (\$ million – year 2005):



Source: J.A. Di Masi and H.G. Grabowski, 'The Cost of Biopharmaceutical R&D: Is biotech Different?'  
Managerial and Decision Economics 28 (2007): 469-479

## Patents and the Pharma Industry

- It takes up to 15 years to develop a new drug;
- For every 5-10,000 molecules synthesised and screened for activity, only 250 reach pre-clinical development, only 5 reach clinical trials and only one reaches the market;
- Cost to develop a drug in 2006: € 1,059 million (\$ 1,318 million);
- Only 2 of 10 marketed drugs ever produce revenues that match or exceed R&D costs;
- Pharmaceuticals are generally cheap and easy to copy – generic companies enter mature markets developed by innovator with low entry costs;
- These features are probably unique to the pharmaceutical industry;

## Patents and the Pharma Industry

- Given these costs and risks, without a period of exclusivity against copyists (but not a period of therapeutic exclusivity), there would be no investment in pharmaceutical innovation;
- Patents and data exclusivity are the legal tools for providing the exclusivity;
- The exclusivity provided by patents promotes therapeutic and innovative competition;



## How the Patent System works

- Many scientists seeking to solve same problems in different or similar ways from similar starting points at the same time;
- The first to market is generally quickly followed by several others (The competitor can design around many patents - i.e. sell a product which does not infringe);
- The first on the market is rarely the most successful;
- The customer benefits from a range of products with differing characteristics;
- Upon expiry of first patents, competitors can sell original product – the market will determine the success of new versions;



## The Patent System benefits Society

- Patent System promotes disclosure of innovations;
- There would be no competitive therapeutic innovation without patents;
- Patents promote competition in innovation;
- No undue impediment to competitor entry;
- Consumers benefit;



## The Patent System

In an ideal Patent System:

- Patents only granted for inventions which are:
  - solution to a technical problem;
  - inventive, not obvious;
- Examination by skilled examiners;
- Design around possible if scope of exclusive rights narrow;



## Before the PCT

- Had to file patent applications in a multitude of countries before importance of invention clarified;
- Duplication of patent office activity;
- Expensive for applicant;



## The Benefits of the PCT

PCT system is of great value to Pharma Industry:

- Simple system for initial filing;
- Delays decision on national filings for 18 months – potential cost saving;
- Provides report on patentability that is of great assistance in less experienced patent Offices;
- Decreases procedural requirements for National Offices – i.e. assignment documents;
- Enables amendments to be filed centrally;



## The PCT

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The future of the PCT:

- Ensure quality of search and examination reports;
- Carry out supplementary searches if required;
- Ability to have more than one written opinion in Chapter II;
- Provide systems for centralised access and exchange of work results;
- PCT set up to address work sharing between Offices, shouldn't try to reinvent the wheel;

