



# Licensing of Genetic Inventions

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on Genetics, Health and Society  
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# What is the OECD

- Intergovernmental Organisation - committed to democratic government and market economies
- 30 members and 70 participating countries
- BIAC & TUAC
- What do we do?
  - **Forum:** address economic, social and environmental challenges of interdependence and globalisation.
  - **Source of statistics:** comparative data analysis and forecasts to underpin multilateral co-operation and policy development.
  - **Peer review process:** influence national policies; soft law and legally binding instruments; and country performance evaluations.

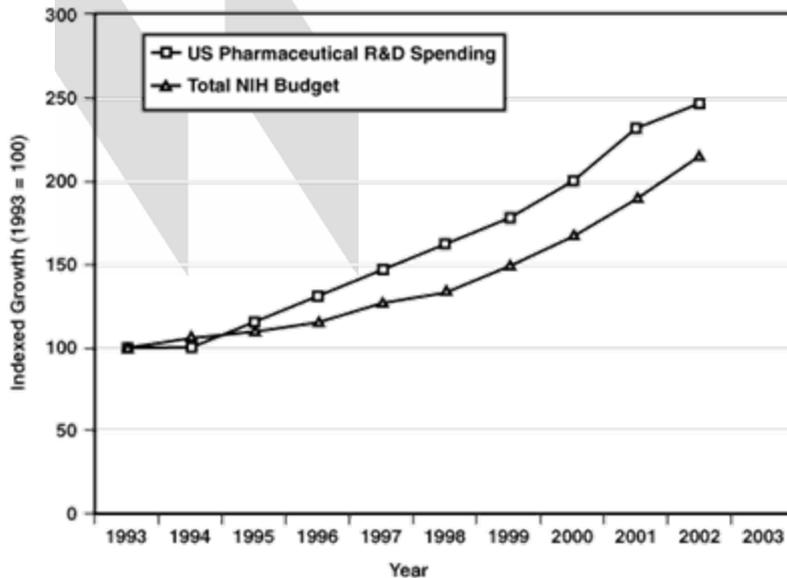


# Areas to be Covered

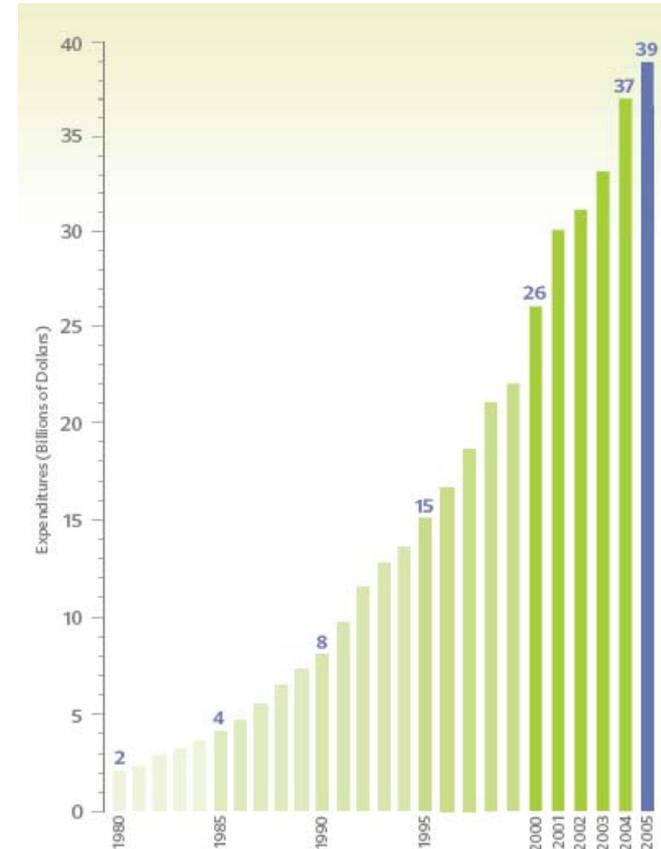
- Challenges Facing Life Sciences
- Context of Guidelines
- Overview of Guidelines
- Implementation and Impacts
- Collaborative Mechanisms for IP
- Conclusion

# Challenges Facing Life Sciences

Figure 1: 10-Year Trends in Biomedical Research Spending

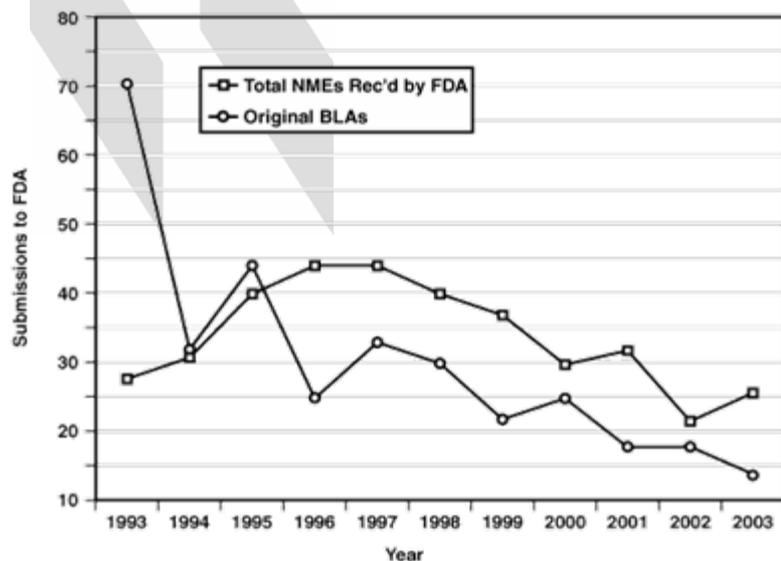


The figure shows 10-year trends in biomedical research spending as reflected by the NIH budget (Budget of the United States Government, appendix, FY 1993-2003) and by pharmaceutical companies' research and development (R&D) investment (PAREXEL's Pharmaceutical R&D Statistical Sourcebook 2002/2003).



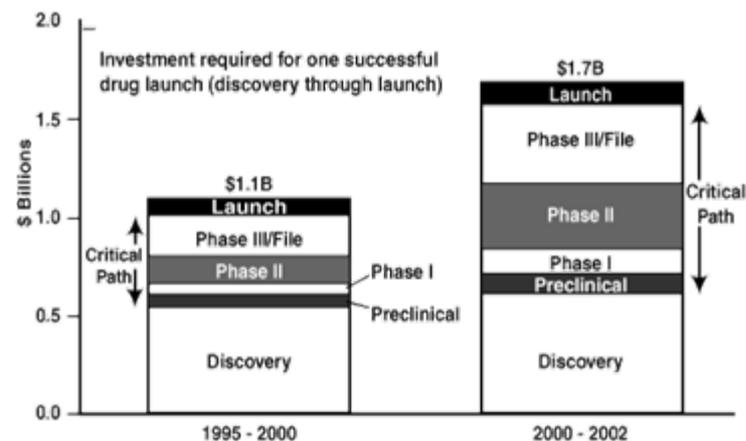
# Challenges Facing Life Sciences

Figure 2: 10-Year Trends in Major Drug and Biological Product Submissions to FDA



The figure shows the number of submissions of new molecular entities (NMEs) — drugs with a novel chemical structure — and the number of biologics license application (BLA) submissions to FDA over a 10-year period. Similar trends have been observed at regulatory agencies worldwide.

Figure 3: Investment Escalation per Successful Compound



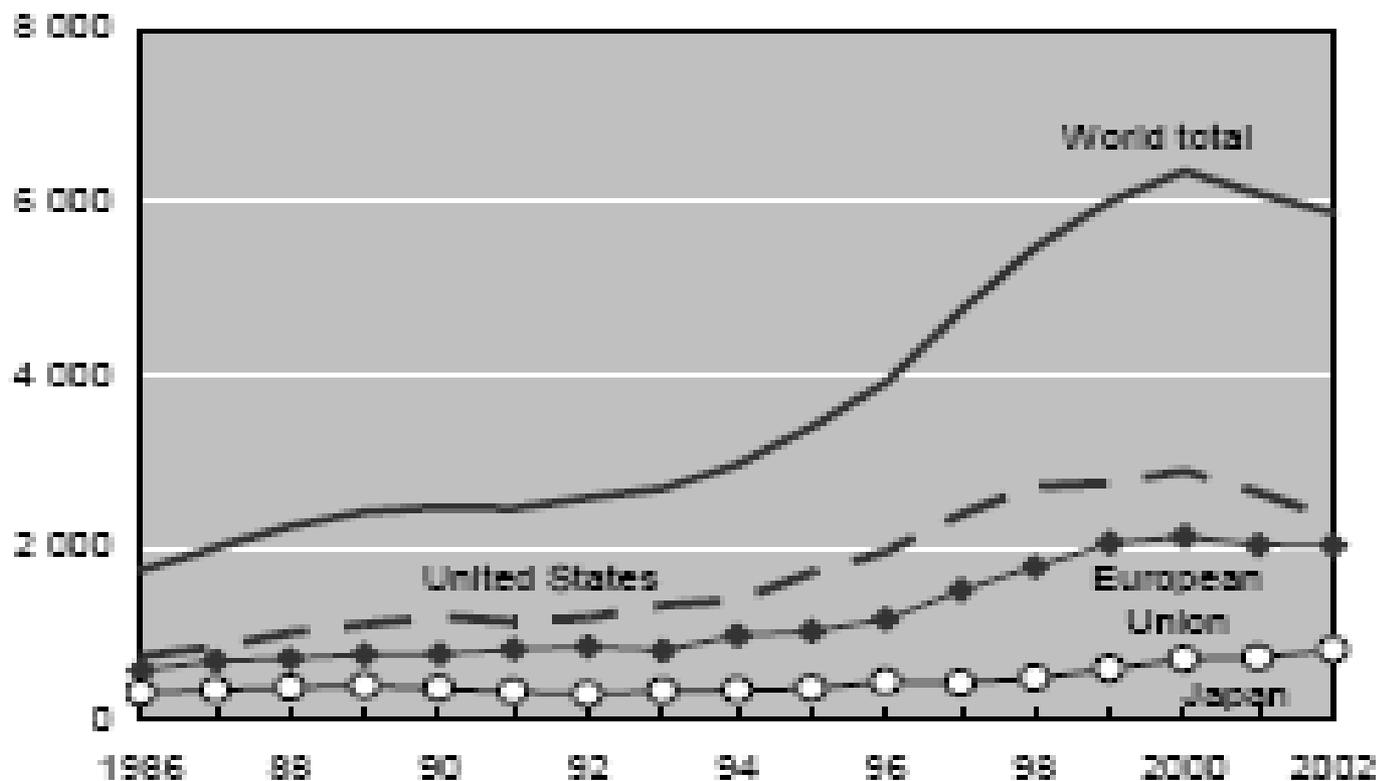
SOURCE: Windhover's In Vivo: The Business & Medicine Report, Bain drug economics model, 2003

The figure shows one estimate of the total investment required to "launch" (i.e., market) a successful drug in two time periods. Most of the recent cost increases are within the "critical path" development phase, between discovery and launch.

The overall increase between 1995 - 2000 and 2000 - 2002 is estimated to be 55 percent.

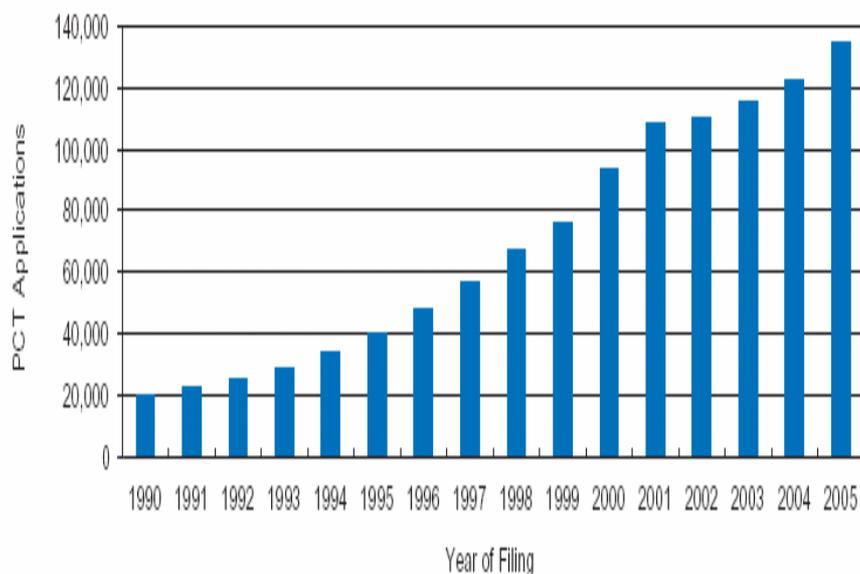
# Challenges Facing Life Sciences

- Trends in biotechnology patents

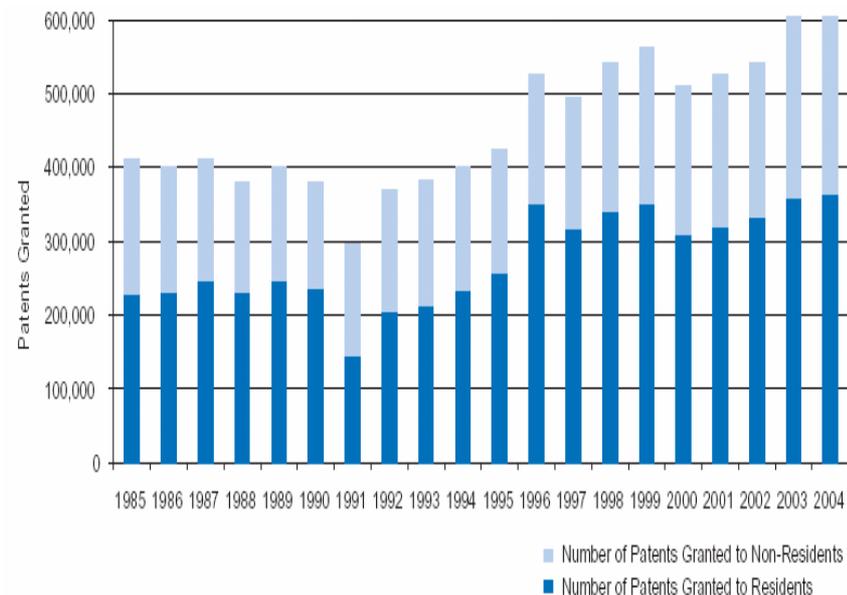


# Challenges Facing Life Sciences

## ● Trends in patents



Source: WIPO Statistics Database



Source: WIPO Statistics Database

# Context of Guidelines

- **AIM: FOSTER R&D, innovation, access and diffusion**
- **Guidelines provide guidance and encourage good market place behaviour so as to encourage ACCESS**
  - For the delivery of health care products and services
  - For research -AND-
  - For commercialisation purposes.
- **Nature – ADOPTED by OECD Council**
  - Not Legally binding, **STRONG** moral commitment
- **Development involved breadth of stakeholders**
- **Implementation involves breadth of stakeholders**



# Overview of Guidelines

# Licensing Generally

- 1.A Licensing practices (LP) should **foster innovation** in the development of new genetic inventions related to human health care -and- should ensure that **therapeutics, diagnostics** and other products and services employing genetic inventions are made readily available on a **reasonable basis**.
- 1.B LP should encourage the **rapid dissemination** of information concerning genetic inventions.



# Health Care and Genetic Inventions

- **Access –and- Choice:** LP should not be used to **restrict the choice** of other products or services.
- **Health Care Provider –and- Patient:** .... available to **patients** and their **health care providers**.
- **Privacy:** ... **patients** benefit from the **highest applicable standards** with respect to **privacy, safety and good laboratory method**



# Research Freedom



- **Access & Sharing of Information/Publication**
  - Clear, well defined and narrow confidentiality clauses with sunset clauses
- **Academic Freedom**
  - Commercial considerations should not unduly hinder academic freedom
- **Education**
  - Commercial consideration not hinder education

# Commercial Development



- **Create opportunities & foster commercialisation**
- **Royalty stacking & Multiple patents/licences**
  - Transaction costs
  - Reach-through rights
- **Exclusive licensing**
  - must ensure patented technology is exploited

# Competition



- **Compliance**
- **Behaviour**
  - Avoid tied-selling
  - Avoid non-compete clauses
  - Not expand breadth of exclusive rights beyond scope of rights
- **Foundational genetic Inventions**
  - Should be licensed non-exclusive



# Implementation & Impact: *Fruit for Thought*

- **Countries**

- Diffusion & Translation
- Funding policies
- Government research centers

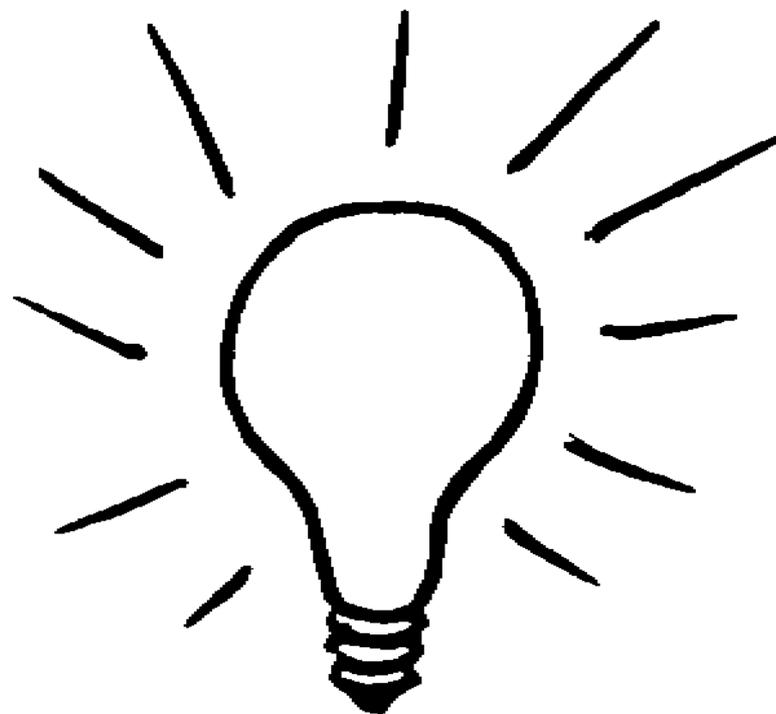
- **Private Sector = “corporate social licensing”**

- Engagement
- Diffusion

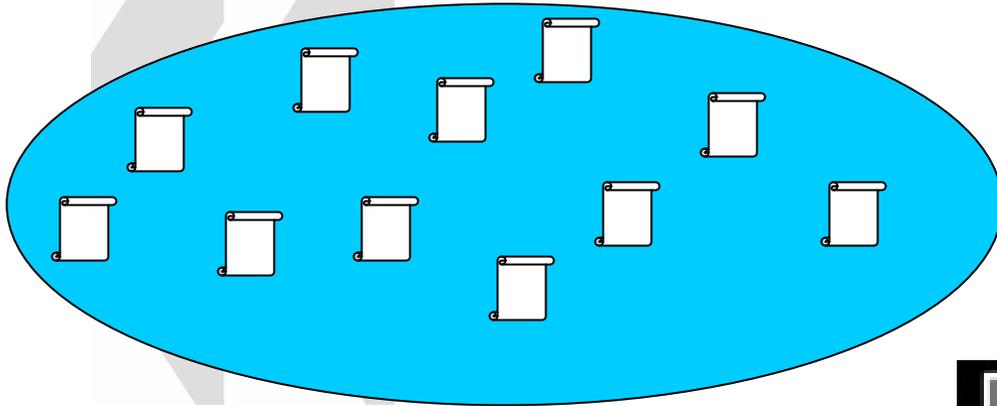
- **Public Sector**

- Diffusion
- Engagement

# Collaborative Mechanisms For IP



# Collaborative Mechanisms For IP



# Conclusion





THANK YOU!!

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[www.oecd.org/sti/biotechnology](http://www.oecd.org/sti/biotechnology)