



INTELLECTUAL PROPERTY RIGHTS AND OTHER POLICY ISSUES IN THE DEVELOPMENT OF BIOTECHNOLOGY

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The International Regulation of New Medical Technology
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**BIOTECHNOLOGY
DIVISION**

**Views expressed are those of the author and
do not represent the views of OECD member countries.*

OECD  1 OCDE

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:** governments work together to address economic, social and environmental challenges of interdependence and globalisation.
 - **Source of statistics:** develops and collects comparative data so that analysis and forecasts can underpin multilateral co-operation and policy development.
 - **Peer review process:** to influence national policies, good policy practices are identified and country performance evaluated.

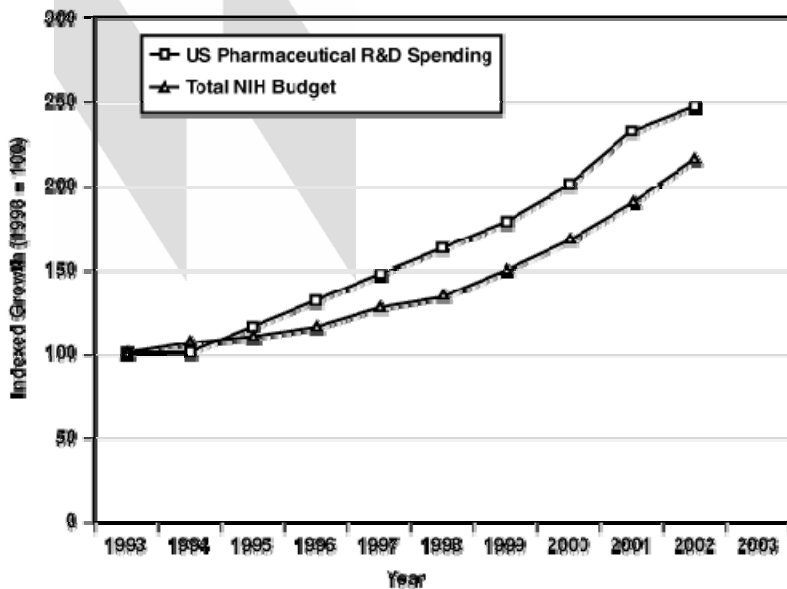


Areas to be Covered

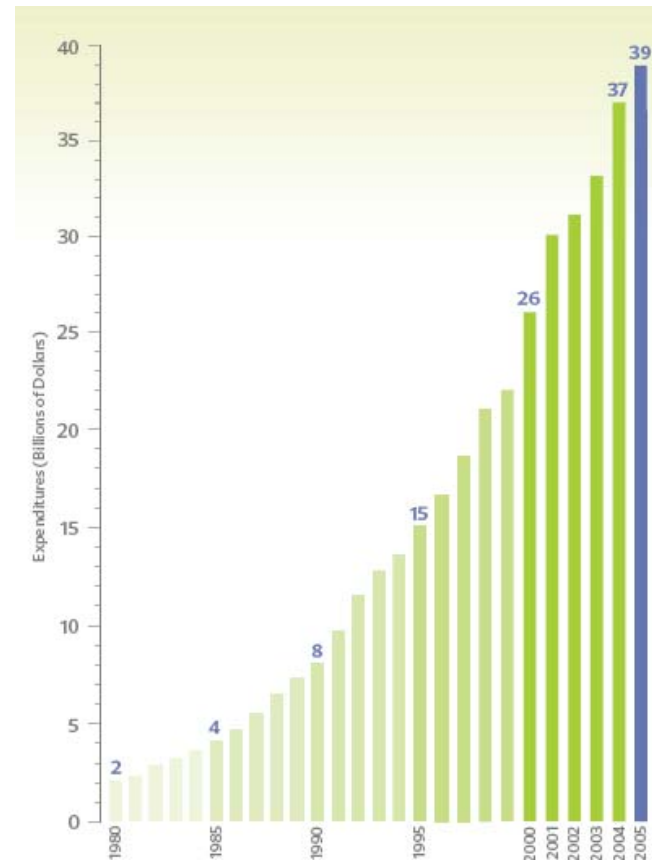
- Challenges facing the life sciences
- Intellectual Property
 - Guidelines for the Licensing of Genetic Inventions
 - Collaborative Mechanisms
- Other Policy Initiatives
 - Emerging Research Models
 - Accelerated Drug Discovery

Challenges Facing Life Sciences

Figure 1: 10-Year Trends in Biomedical Research Spending

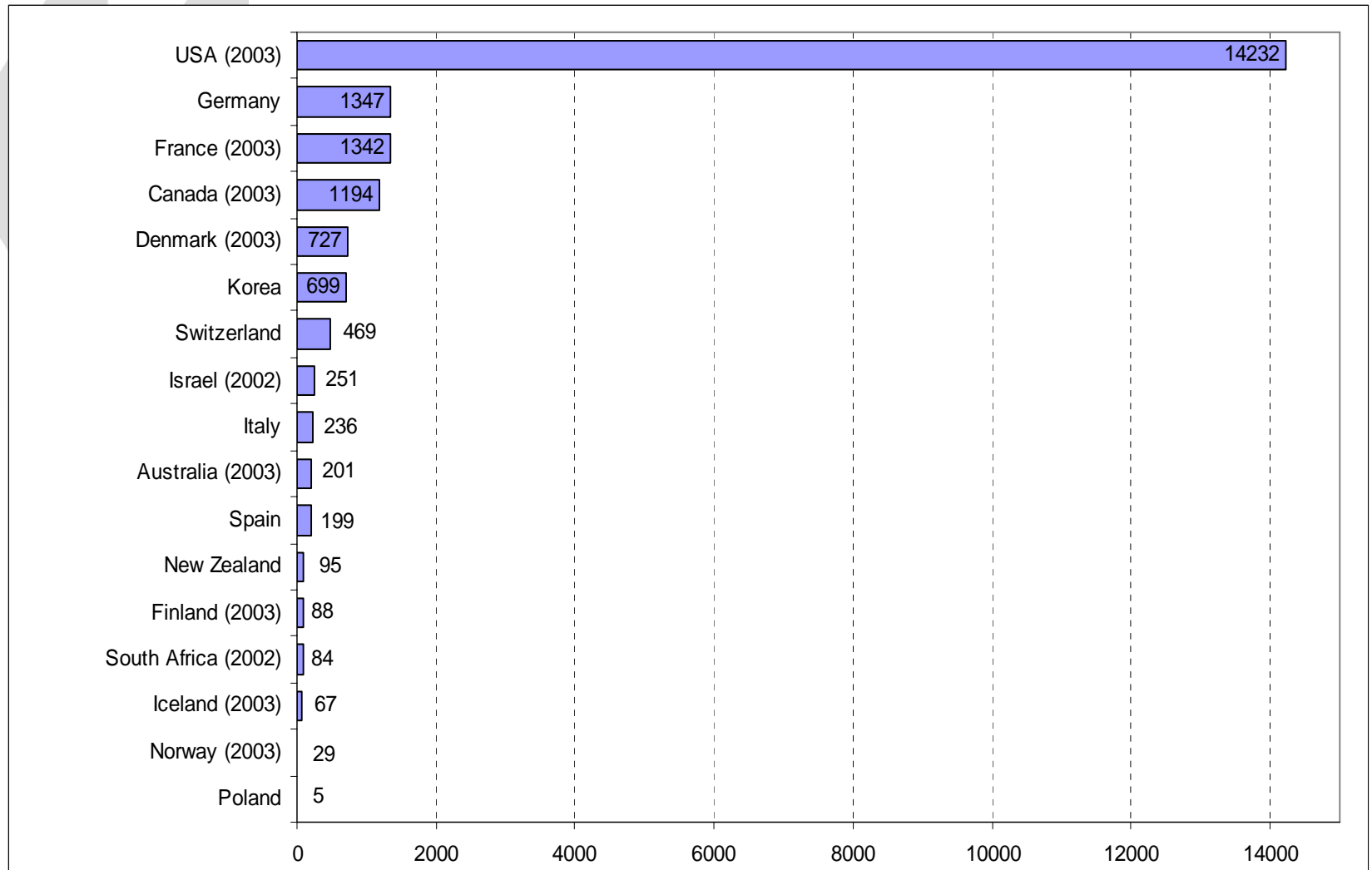


The figure shows 10-year trends in biomedical research spending as reflected by the NIH budget (Budget of the United States Government, appendix, FY 1993-2003) and by pharmaceutical companies' research and development (R&D) investment (PAREXEL's Pharmaceutical R&D Statistical Sourcebook 2002/2003).



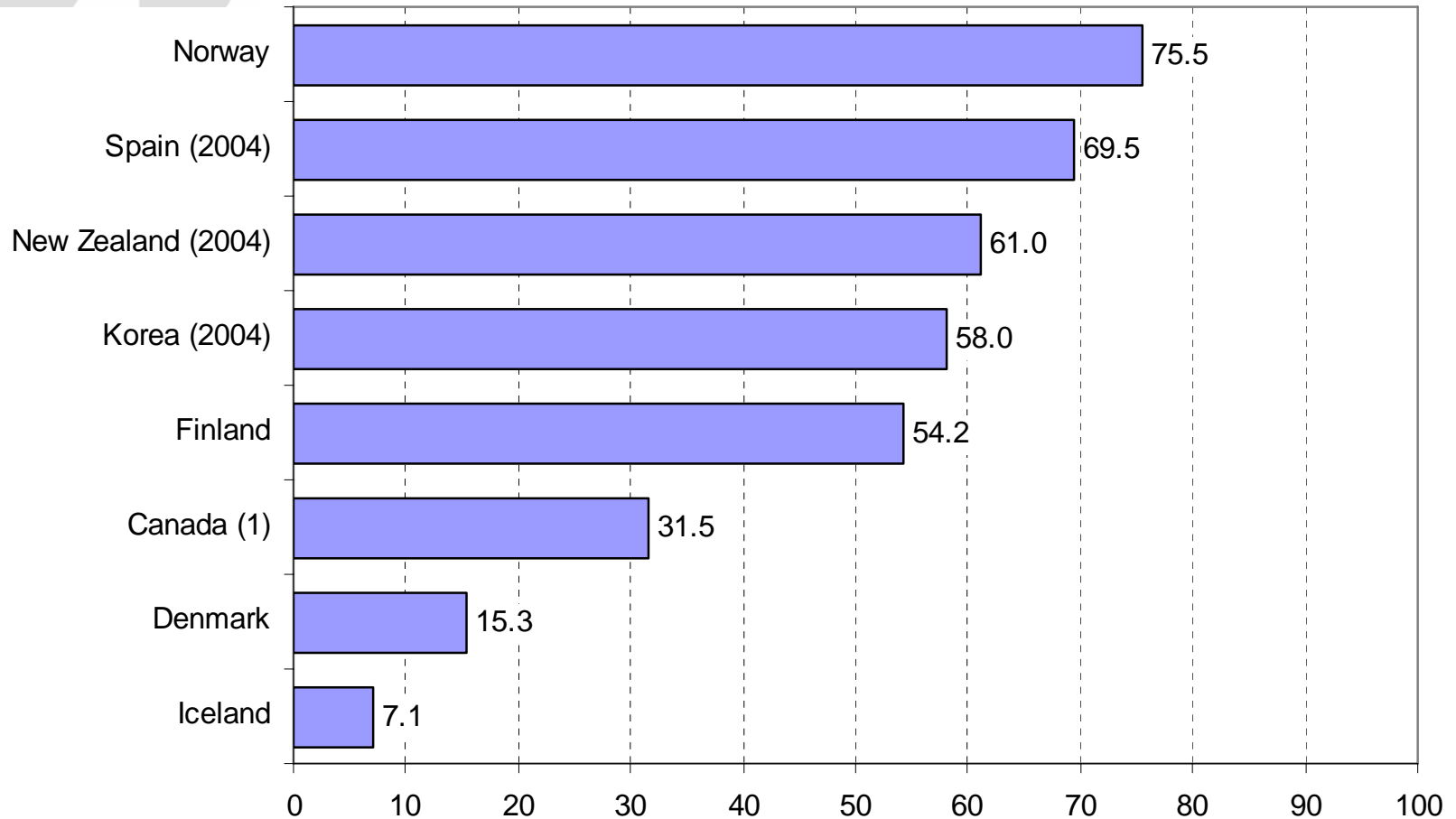
Challenges Facing Life Sciences

Total expenditure on biotechnology R&D by biotechnology-active firms, Million PPP\$, 2004



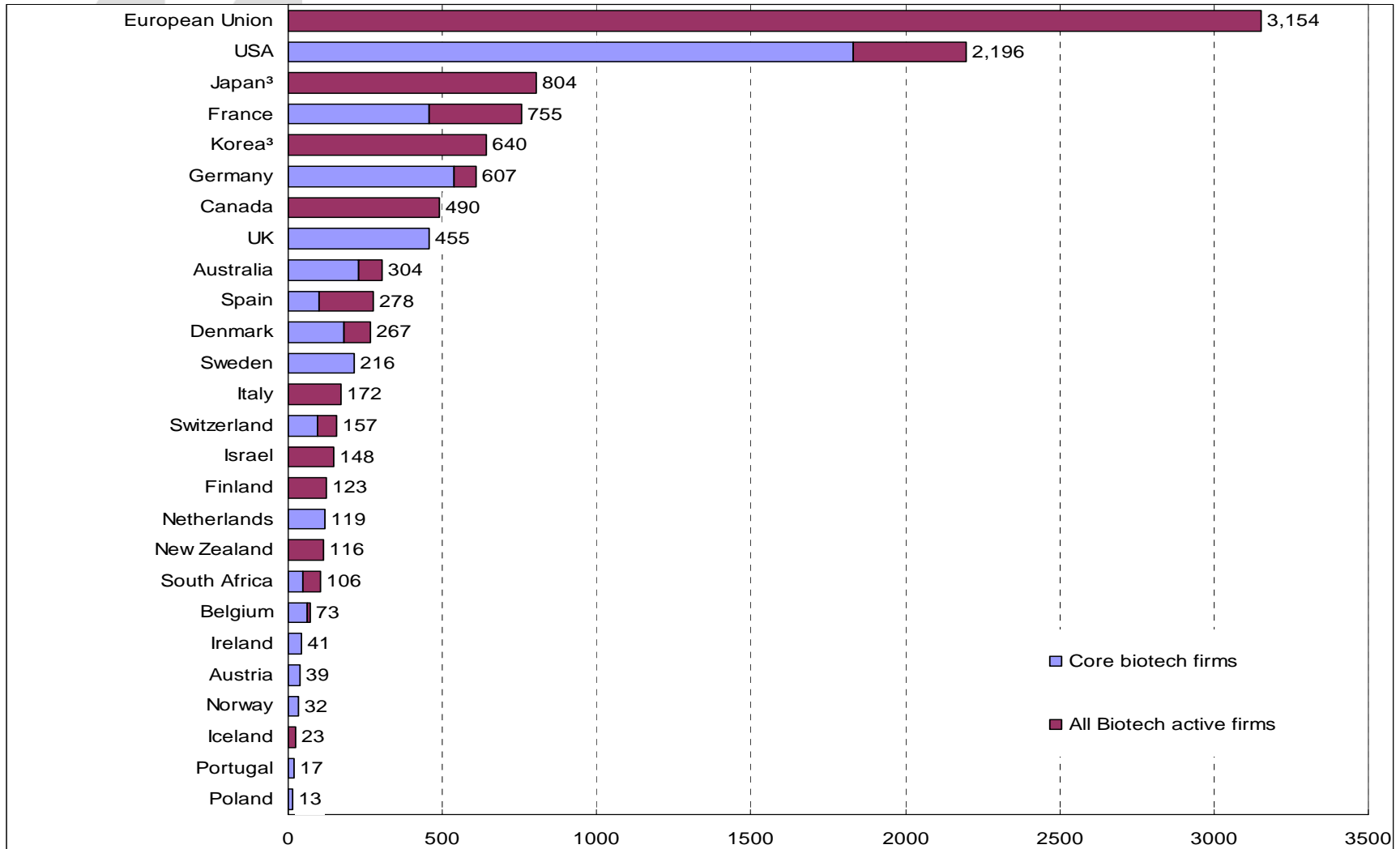
Challenges Facing Life Sciences

Public sector biotech R&D as a percentage of total expenditures (private and public sectors combined) on biotechnology R&D, 2003



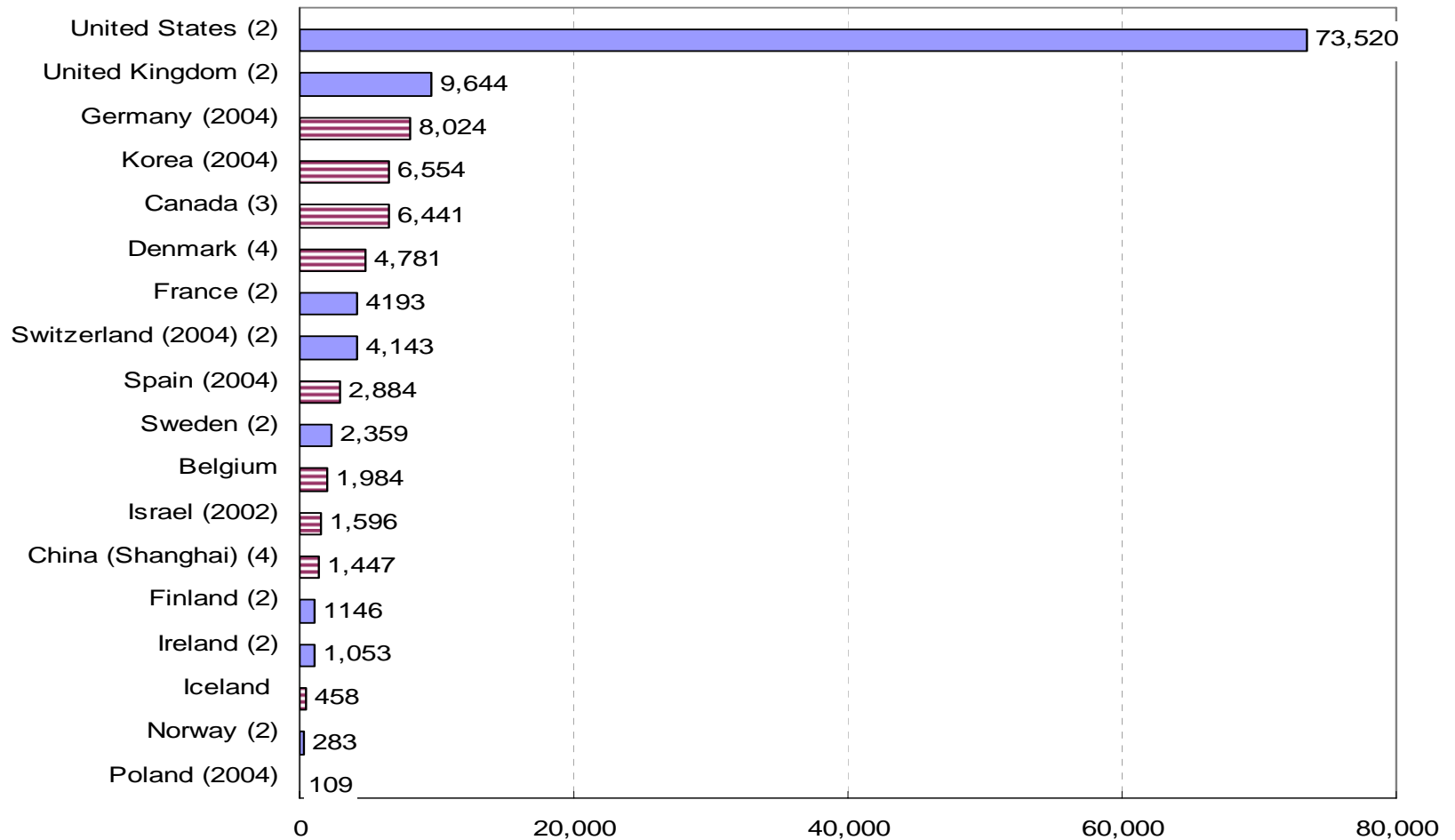
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No. of firms active in biotechnology, 2004



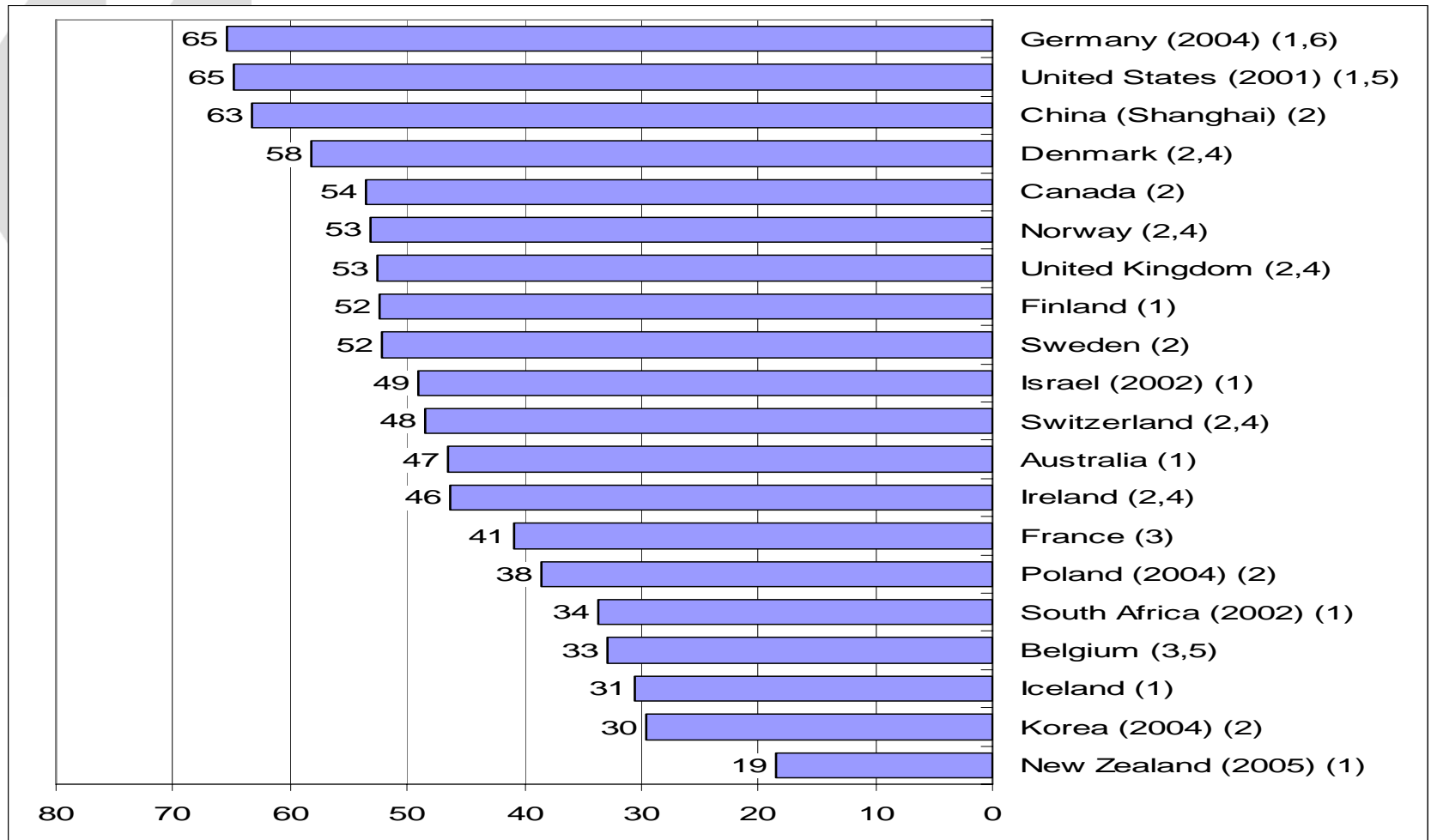
Challenges Facing Life Sciences

Biotechnology R&D employees, headcounts 2003

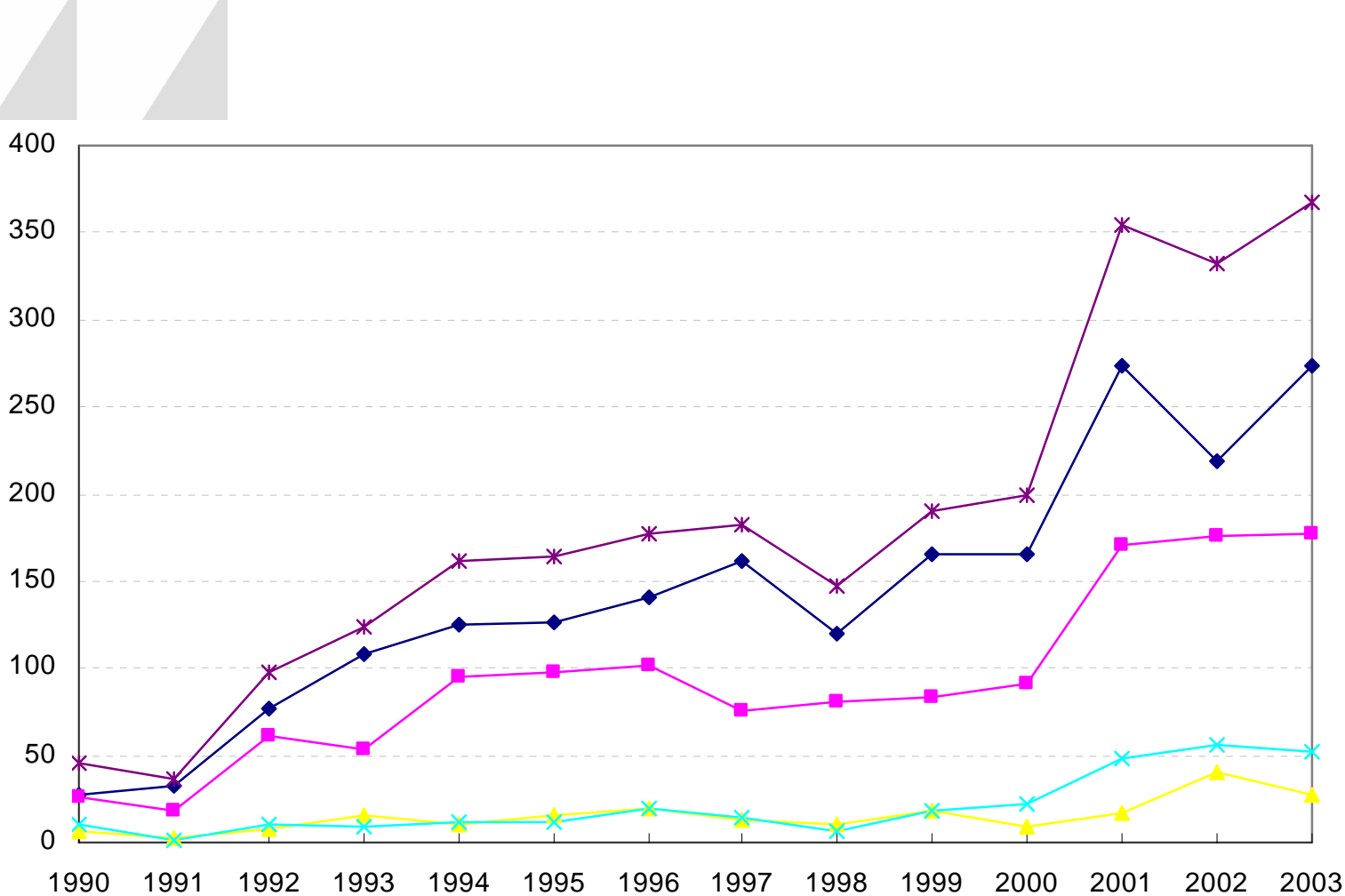


Challenges Facing Life Sciences

Percent of biotechnology firms active in health applications, 2003

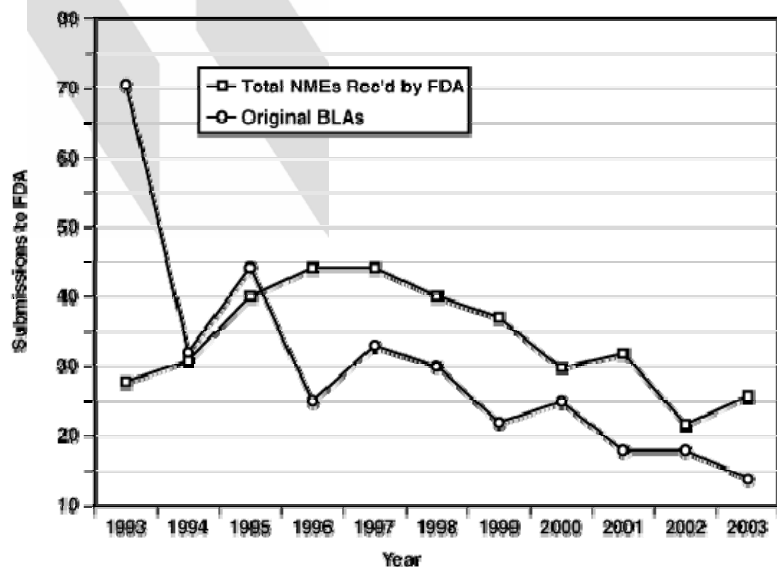


Number of biotechnology alliances, 1990 to 2003



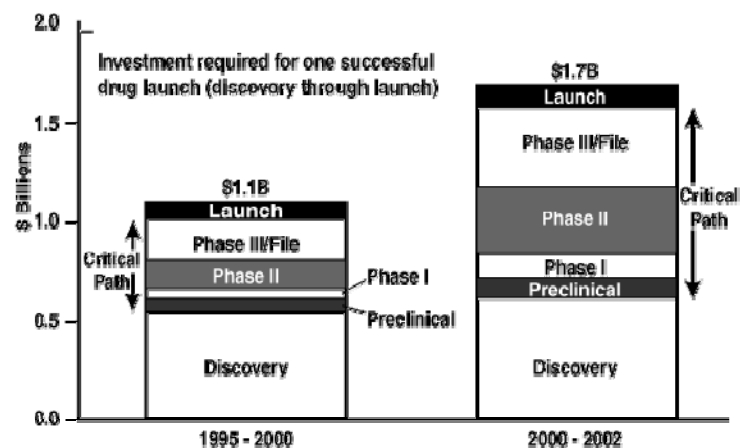
Challenges Facing Life Sciences

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



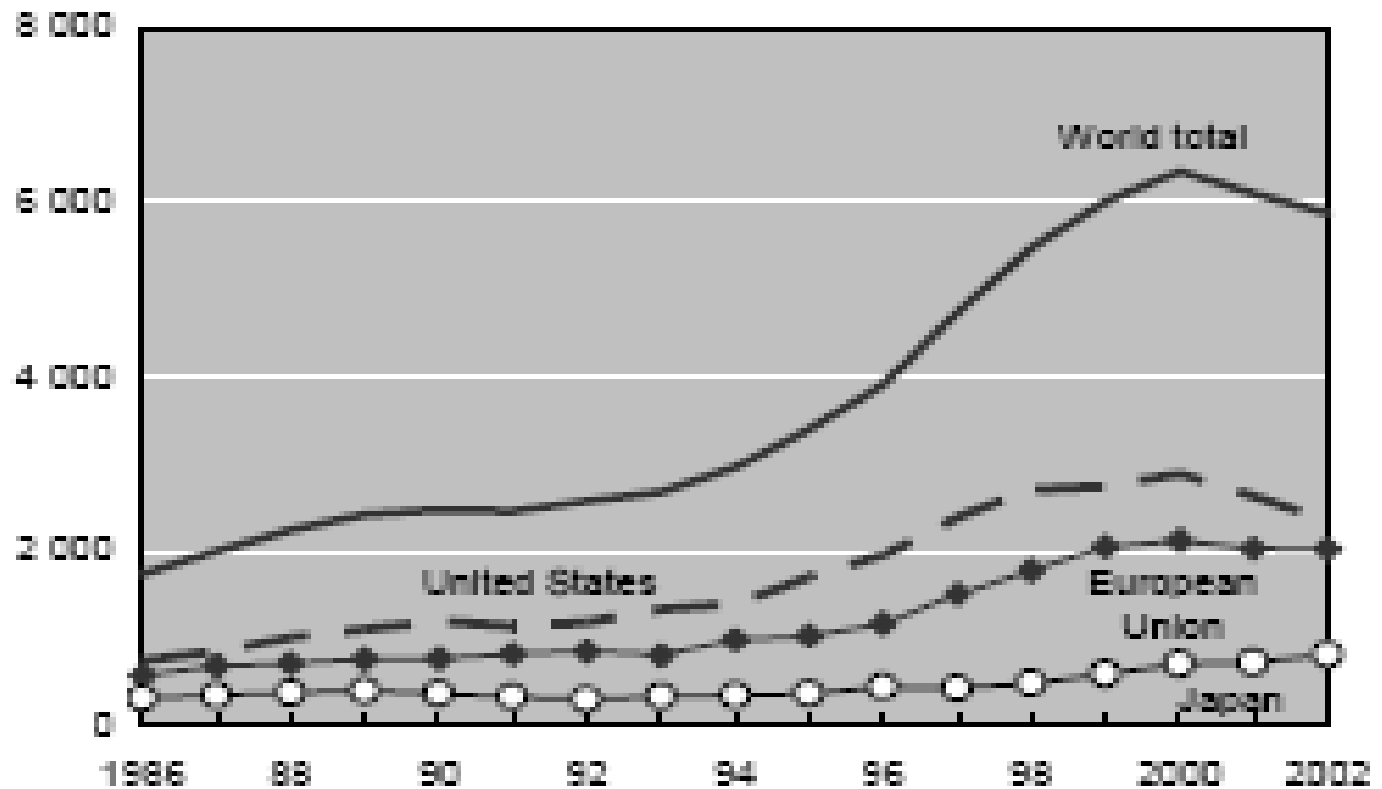
SOURCE: Windhover's In Vivo: The Business & Medicine Report, Dain drug economics model, 2003

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.

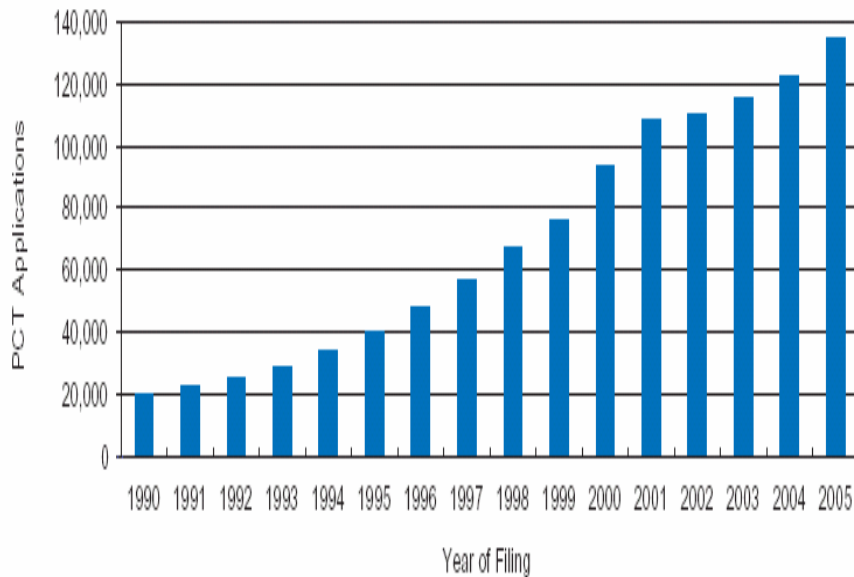
Challenges Facing Life Sciences

- Trends in biotechnology patents

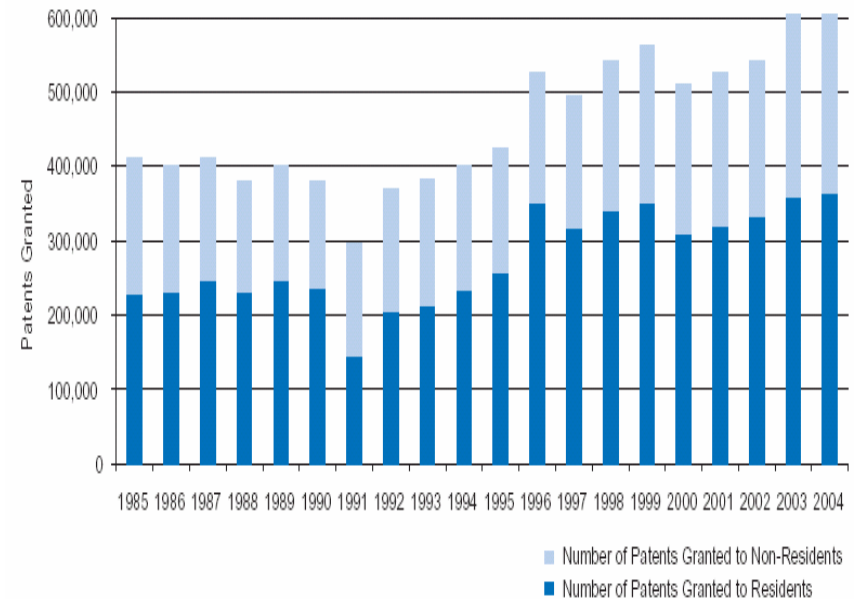


Challenges Facing Life Sciences

Trends in patents



Source: WIPO Statistics Database



Source: WIPO Statistics Database

Government & Industry

● Governments/Countries

- **AUSTRALIA:** Law Reform Commission 99 - *Genes and Ingenuity: Gene Patenting and Human Health* (2004)
- **CANADA:** Expert Working Party on Human Genetic Materials, Intellectual Property and the Health Sector to the Canadian Biotechnology Advisory Committee - *Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians* (2005)
- **UNITED STATES:** National Academies of Science Report - *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (2005)
- **OECD:** Working Party on Biotechnology – *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002)

● Industry

- Number of life sciences companies seeking novel approaches to fostering innovation + R&D.



Biotech Programme

- ***Intellectual Property Rights***
- ***Human Health & Innovation***
- ***Statistics and Indicators***
- Sustainable Industrial Development
- Infrastructure Development



Intellectual Property

- ***Guidelines for the Licensing of Genetic Inventions***
- ***Collaborative Mechanisms***
- Patent Classes Statistics
- Counterfeiting of Pharmaceuticals

Guidelines for the Licensing of Genetic Inventions

- Guidelines establish a set of principles and best practices intended to assist the private and public sector
 - in the consideration of whether or not to license; and
 - in the negotiation of licensing agreements or material transfer agreements with the intent to promote the diverse interests in a balanced manner.
- AIM – to encourage good licensing/technology transfer practices
- Guidelines were adopted by the OECD Council as a Recommendation in February 2006

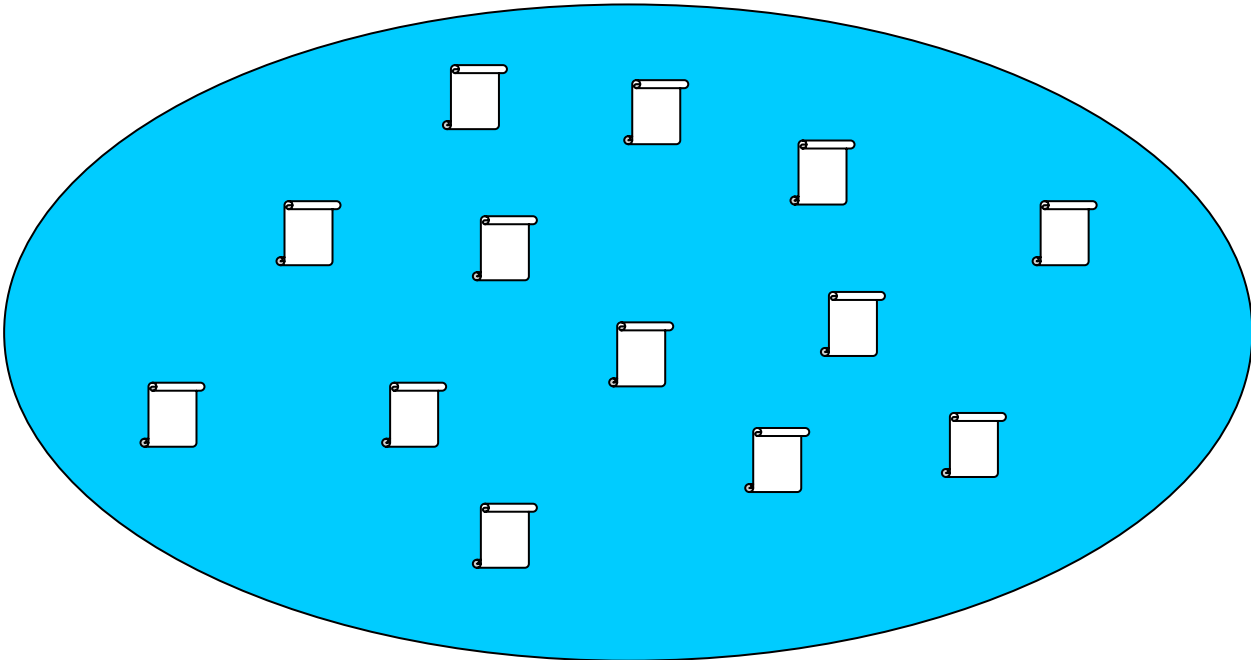
www.oecd.org/sti/biotechnology/licensing



Collaborative Mechanisms

- Patent Pools
- Patent Clearing-houses
- Other Mechanisms

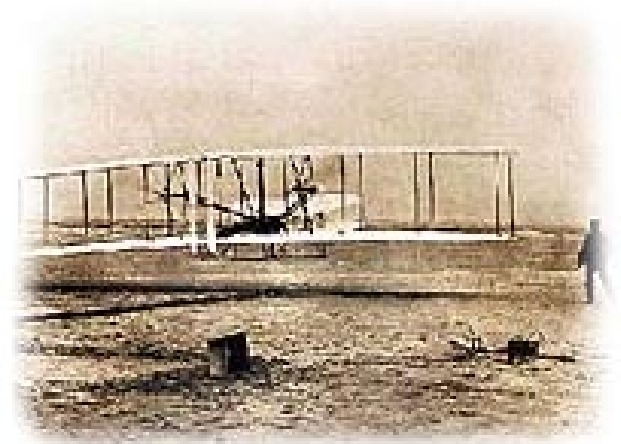
Patent Pools



Patent Pools

● Historical

- *Aircraft Manufacturer's Association*
 - Blocking patents prevented each other and others from use and commercialisation
 - Government imposed pool
- *Radio Corporation of America*
 - Volunteer coming together of 4 leading companies
 - Led to standardisation of radio parts, frequency locations, and TV transmission standards.



Patent Pools (cont'd)

● Modern

MPEG & DVD

- Limitation of portfolio to technically essential patents
- Portfolio patents clearly identified
- Portfolio patents can be licensed individually as well as in package.
- Issue of worldwide non-exclusive licences.
- Royalty payment conditioned on actual use of patents
- Freedom of licensees to develop and use alternative technologies
- Grant-back requirements.



Patent Pools (cont'd)

● Beneficial Aspects

- Pools promote licensing and cut through patent thicket – “one stop shopping”
- Provide pro-competitive benefits by:
 - Integrating complementary technology
 - Reducing transaction costs
 - Clearing blocking positions
 - Removing infringement uncertainty and creating FTO
 - Enable usage and production of complementary technology
 - Create new commercial opportunities by pooling implementation technologies or others

Patent Pools (cont'd)

● Key Challenges

- Motivation
 - Pool must bring together sufficient IPRs to create incentive.
- Establishment
 - Governance, legal structure, allocation
- Standardisation
 - Few standards in life sciences
 - Necessity?
- Competition/Anti-Trust Law
 - Pools must not fall afoul of competition / anti-trust law – biggest challenge

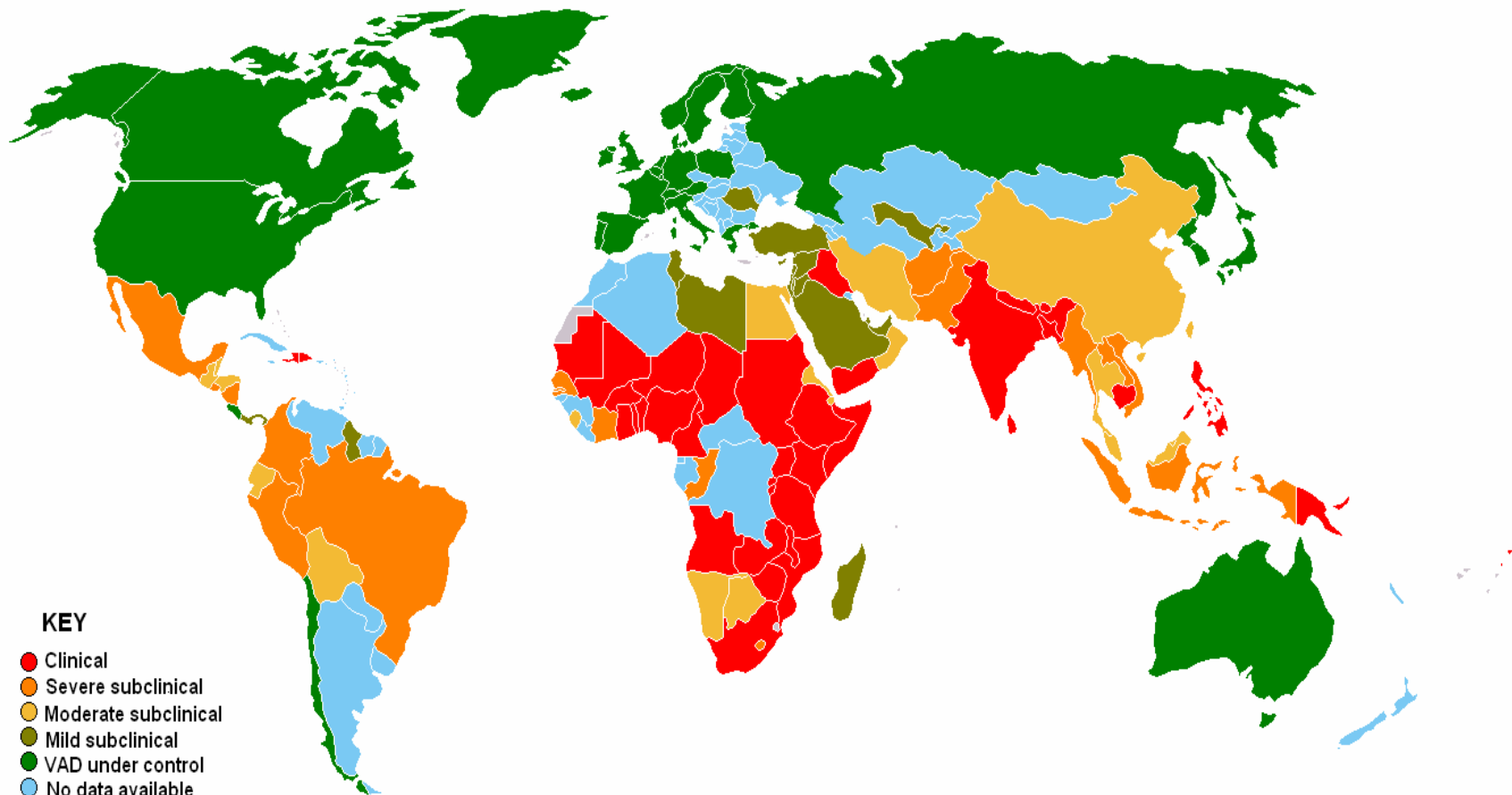
DG Competition



Government
of Canada

Gouvernement
du Canada

Pools in Life Sciences: Golden Rice



KEY

- Clinical
- Severe subclinical
- Moderate subclinical
- Mild subclinical
- VAD under control
- No data available

Pools in Life Sciences: Golden Rice



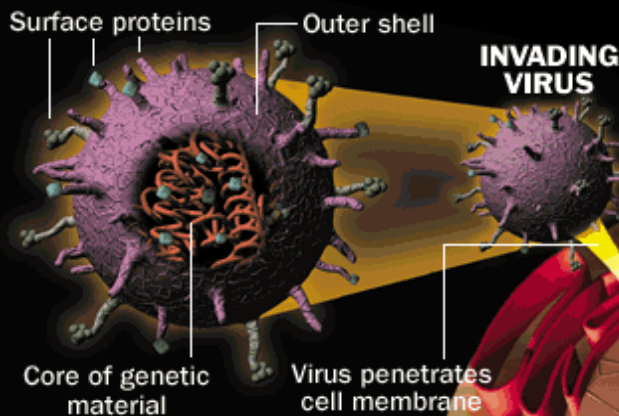
Pools in Life Sciences: SARS

HOW A CORONAVIRUS SPREADS

TIME asia Close

STAGE 1

Experts believe a deadly cousin of the common cold virus is behind the mystery illness that has killed at least 55 people and infected more than 1,500 worldwide. Tests on infected patients suggest the disease is caused by a never-before-seen member of the coronavirus family



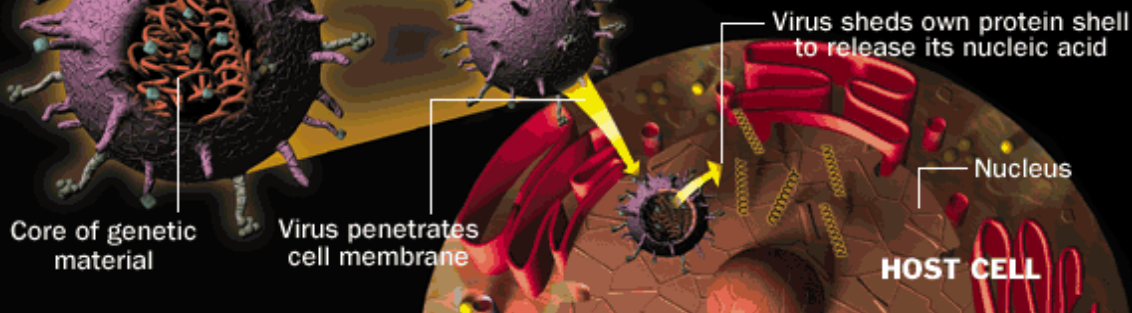
STAGE 2

What is a virus?

Viruses cause diseases such as the common cold and AIDS, often forcing the host's immune system to turn on itself and kill healthy cells. Since viruses cannot procreate, they attack living cells to survive and replicate

Stage 1 Virus invades host

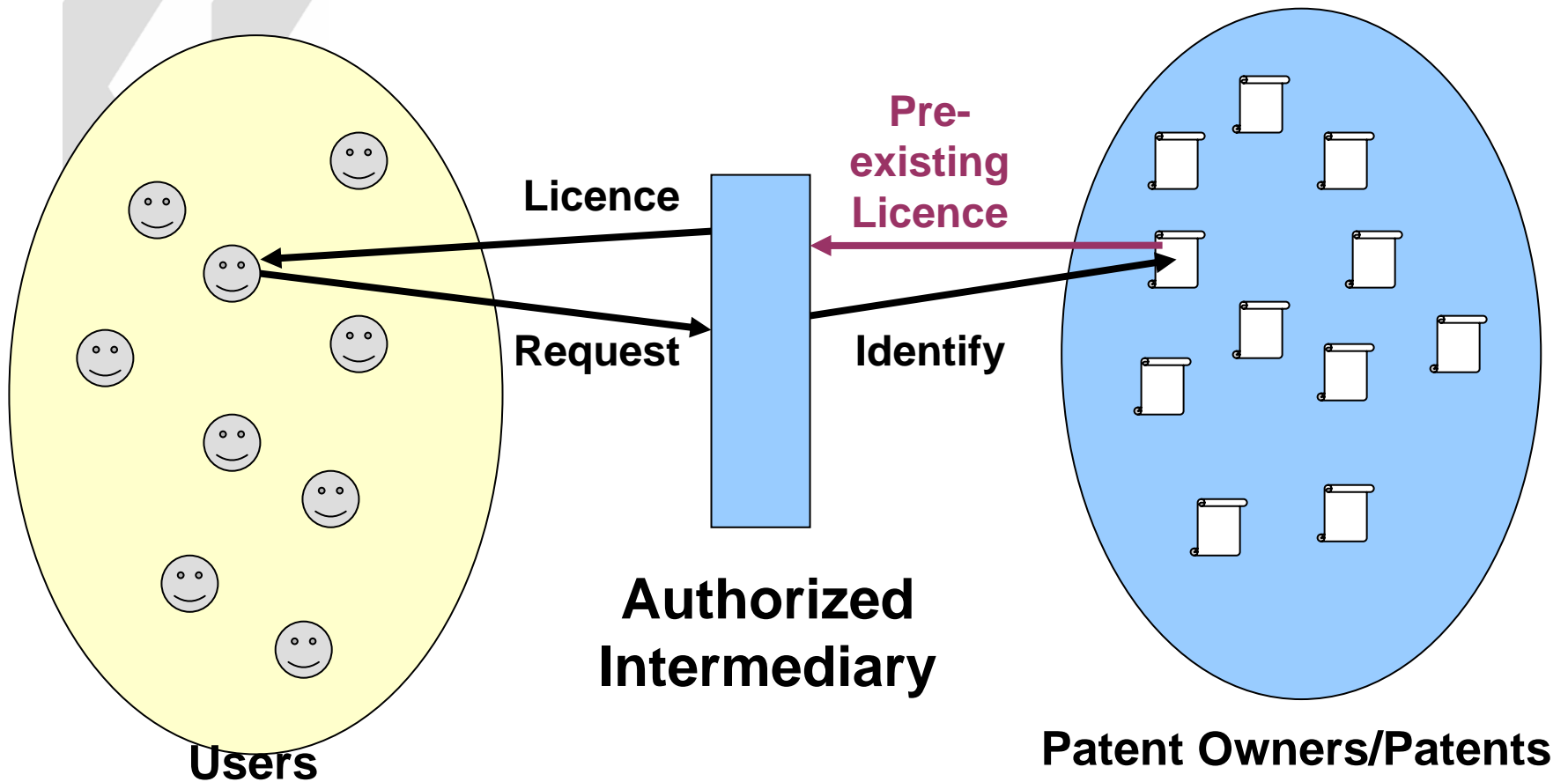
In order to subvert a host's genetic material and continue to thrive, a virus attaches to a host cell's outer membrane, injects itself into the cell and then discards its own outer shell, flooding the host with viral material



Clearinghouses



Patent Clearinghouses



Other Mechanisms & Considerations

- Public-Private Partnerships/ Product Development Partnerships
- “Open” Innovation”
- Advanced Market Commitments
- CAMBIA
- PIPRA
- Consortia





Biotechnology, Innovation & Health

For info: benedicte.callan@oecd.org



Biotechnology, Innovation & Health

This work has two objectives:

- To understand how the policy environment and business practices may need to change in order to capture the benefits of advances in biotechnology.
- To understand how advances in the biosciences – especially genetics and genomics – are changing the climate for innovation in health.

Emerging Research Models Project

- New health technologies will not automatically result in improved products and processes, if the current R&D process is too costly, unpredictable or inefficient.
- Problem areas include:
 - Tech transfer from public research organisations
 - The valley of death – preclinical research financing
 - Pharmaceutical industry productivity – drug discovery
 - Clinical research cost, duplication, loss of knowledge
 - Regulatory environment – slow adaptation to new technologies

Emerging Research Models Project

- Throughout the innovation cycle, many policies are being put in place to try to accelerate the translation of biomedical research into innovations that reach the patient.
- ERMs described these alternative systems for discovery, research, development and delivery.
- **Q:** Together, do these new policies and strategies add up to a new model for health innovation?

ERMs: Bold Visions for Health Innovation

- Despite some high profile attempts to create a holistic vision of how health innovation must change...
 - *NIH Roadmap*
 - *FDA Critical Path*
 - *EC Innovative Medicines Initiative*
 - *EMA Roadmap to 2010*
- Most of the policies and strategies being put in place now remain focused on particular segments of the innovation cycle:
 - *Biomedical clusters: Tech transfer*
 - *Innomed: drug discovery*
 - *UKCRC: clinical research*

ERMs Workshop and Report

- Familiarize policymakers with the range of new initiatives and policies for discovery, research, development and delivery to bring biomedical innovations from invention to market.
- Organise policies into a typology to allow comparisons -- identify the characteristics of similar approaches, including their strengths and weaknesses; clarify how these approaches differ from business-as-usual.
- Recommend areas in which measures, policies or intergovernmental cooperation might increase the speed and efficiency with which safe advances in health-related research are translated into innovative goods and services.
- Identify available tools and good practices.
- Publication – Fall 2007



ERMs Recommendations and Future Work

- Articulating a vision of the future of health innovation
- Creating “Knowledge Markets”
- Regulatory regime reforms
- Research infrastructures
- IP management



Medicines for Emerging and Neglected Infectious Diseases: Enhancing their Availability

High Level Forum

June 20-21, 2007

Noordwijk-aan-Zee, Netherlands



Incentivising R&D for infectious diseases?

- Slow development of new medicines for infectious diseases that primarily affect developing countries due to, amongst others, weak incentives – small markets, and uncertain demand.
- How can we incentivise firms to invest in R&D on neglected and emerging infectious diseases?



Policy Levers and New Research Paradigms

- Push mechanisms
 - Direct R&D support
 - Tax breaks
- Pull mechanisms
 - Advanced market commitments
 - Prizes
- **New technologies and approaches to organising drug R&D could reduce costs and make small markets more attractive**

Conclusion





THANK YOU!!

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www.oecd.org/sti/biotechnology