



asceni  - on

Life Sciences into Business

**Challenges of Technology Transfer in the
Life-Science Sektor Area**

Peter Ruile, December 2006

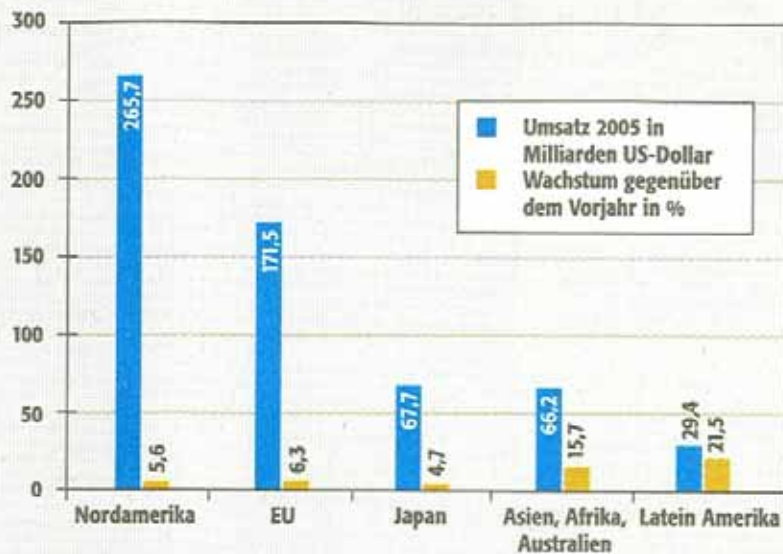
- Key numbers of research and development in pharma and biotech industry
- Challenges and prerequisites for area specific technology transfer
- Ascenion GmbH
- Technology transfer compared to international / european numbers
- Summary

Global Pharma Industry: a snapshot I

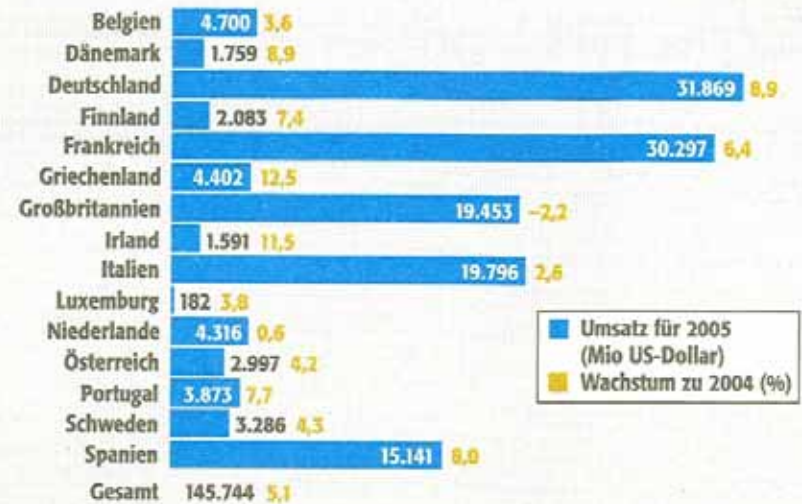
- Pharmaceutical industry total revenue: \$ 350-400 billion/year
- Profit margin of industry as a whole: 15% – 18 %
- One of the highest margins among all major industries (Compare: IT software: 6% – 8%, hardware: 1% – 2%)
- Pharma R&D: \$ 60-70 billion/year
- Biotech/Biopharma total revenue: \$ 45-50 billion/year
- Biotech R&D: \$ 15-20 billion/year
 - Cost of discovering a drug (defined as total R&D spend divided by number of licensed NCE's): \$ 800- 1,000 Mn
 - Average development time: 10 – 15 years
 - Only 250 of 5.000 screened compounds enter the preclinical phase
 - Only 5 of them enter the clinical phase
 - Only 1 of them will get FDA or EMEA approval"

Globaler Pharmamarkt

Weltpharmamarkt nach Regionen



Pharmamarkt der EU-15*



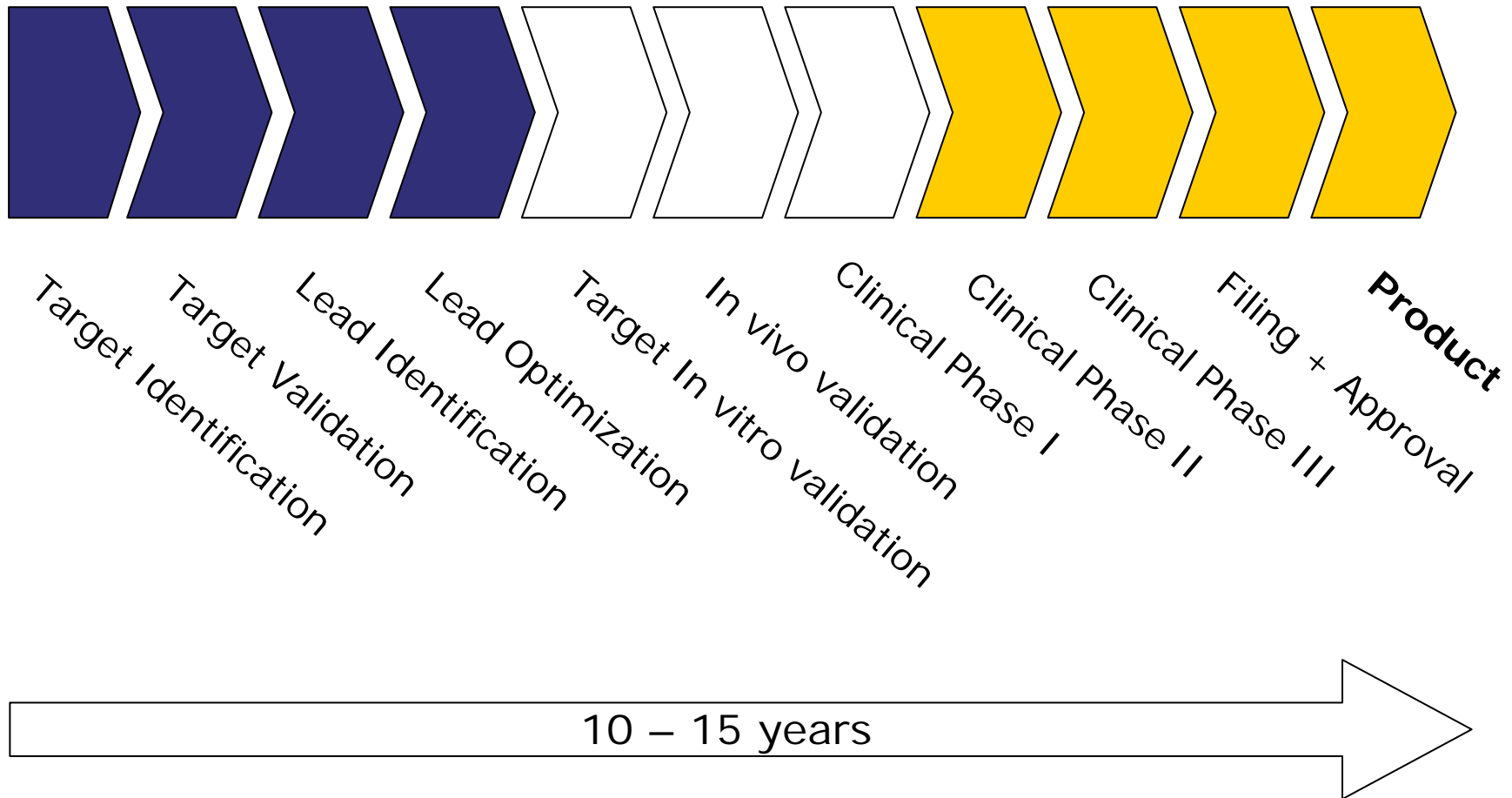
* Umsätze aus beobachteten Märkten plus Schätzung der nicht beobachteten Teilmärkte ergeben den Umsatz eines Landes; Wachstum ist bezogen auf LCD: Local currency Dollar (für US-Dollar) - Währungsschwankungen im Land sind nicht berücksichtigt

Quellen: BPI, IMS World Review 2006

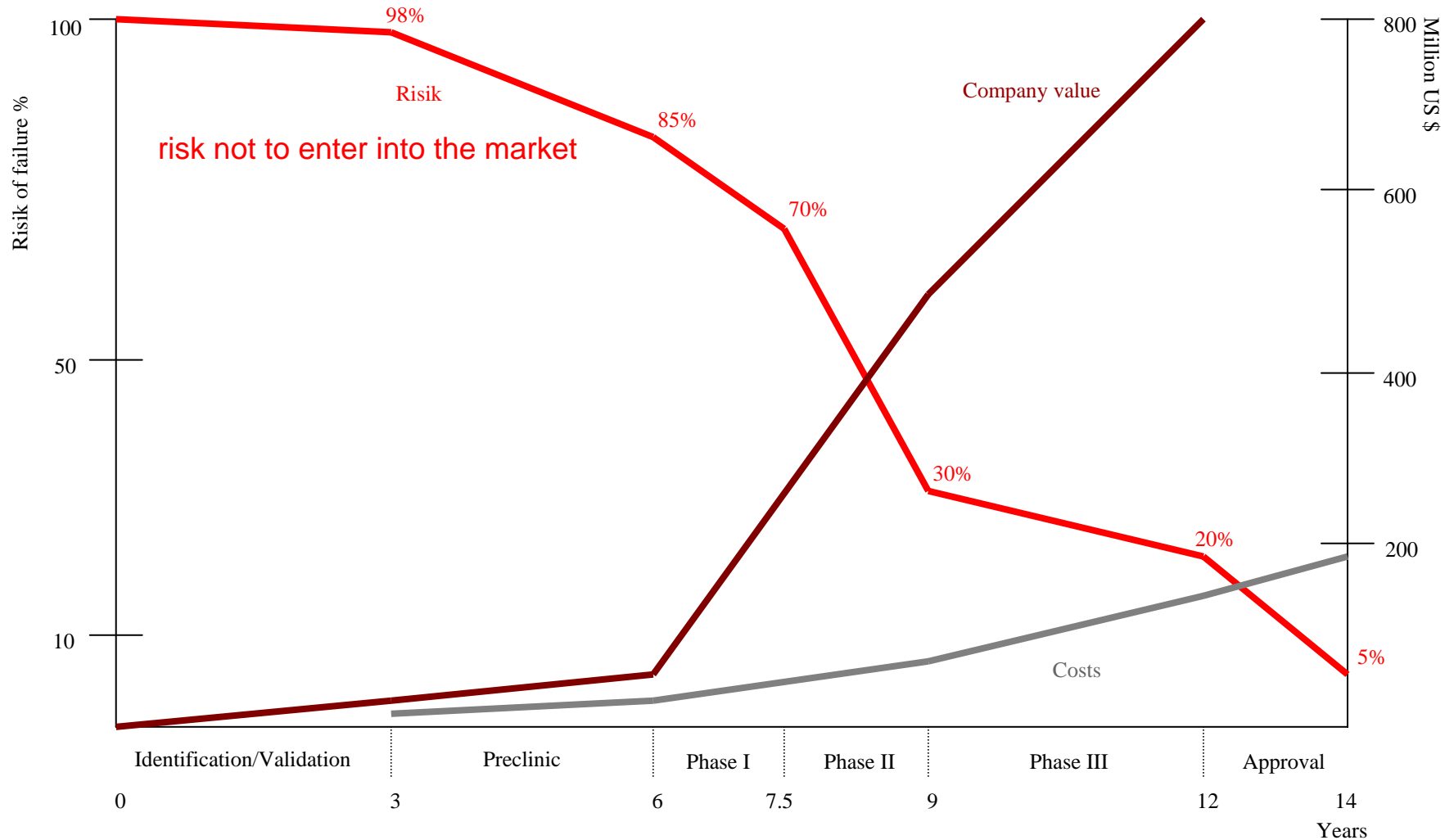
© GIT VERLAG

© GIT VERLAG

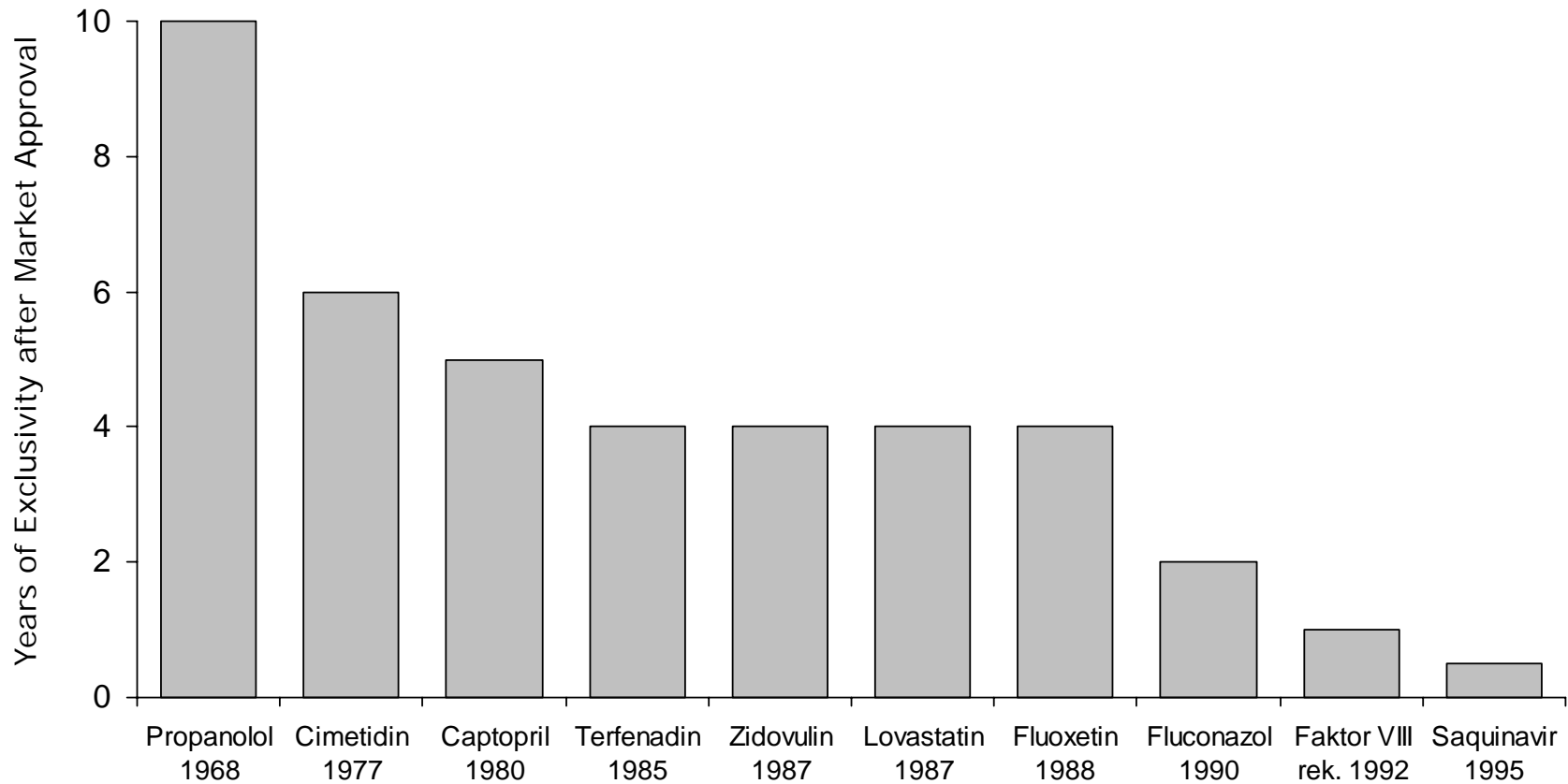
The Drug Discovery Process



Value/Cost/Risk-Scenario

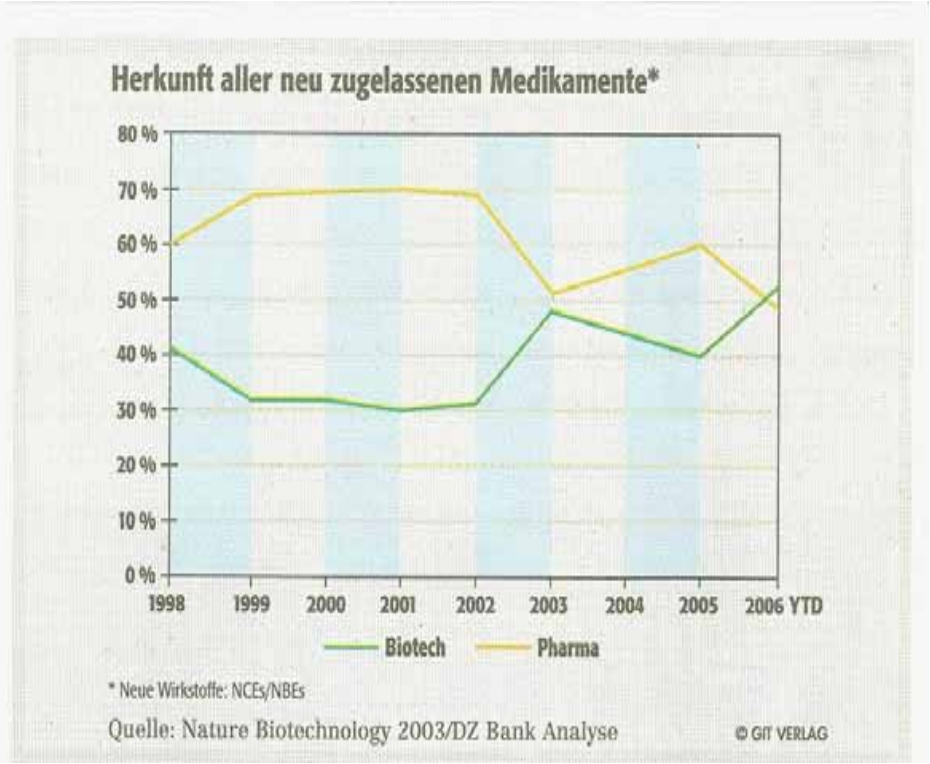
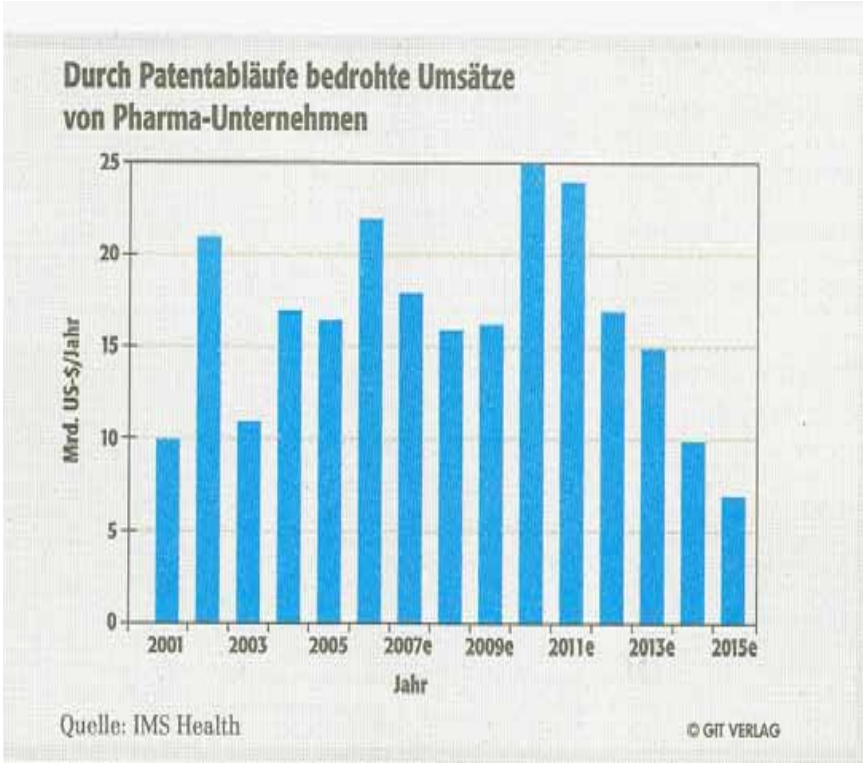


Selected Examples



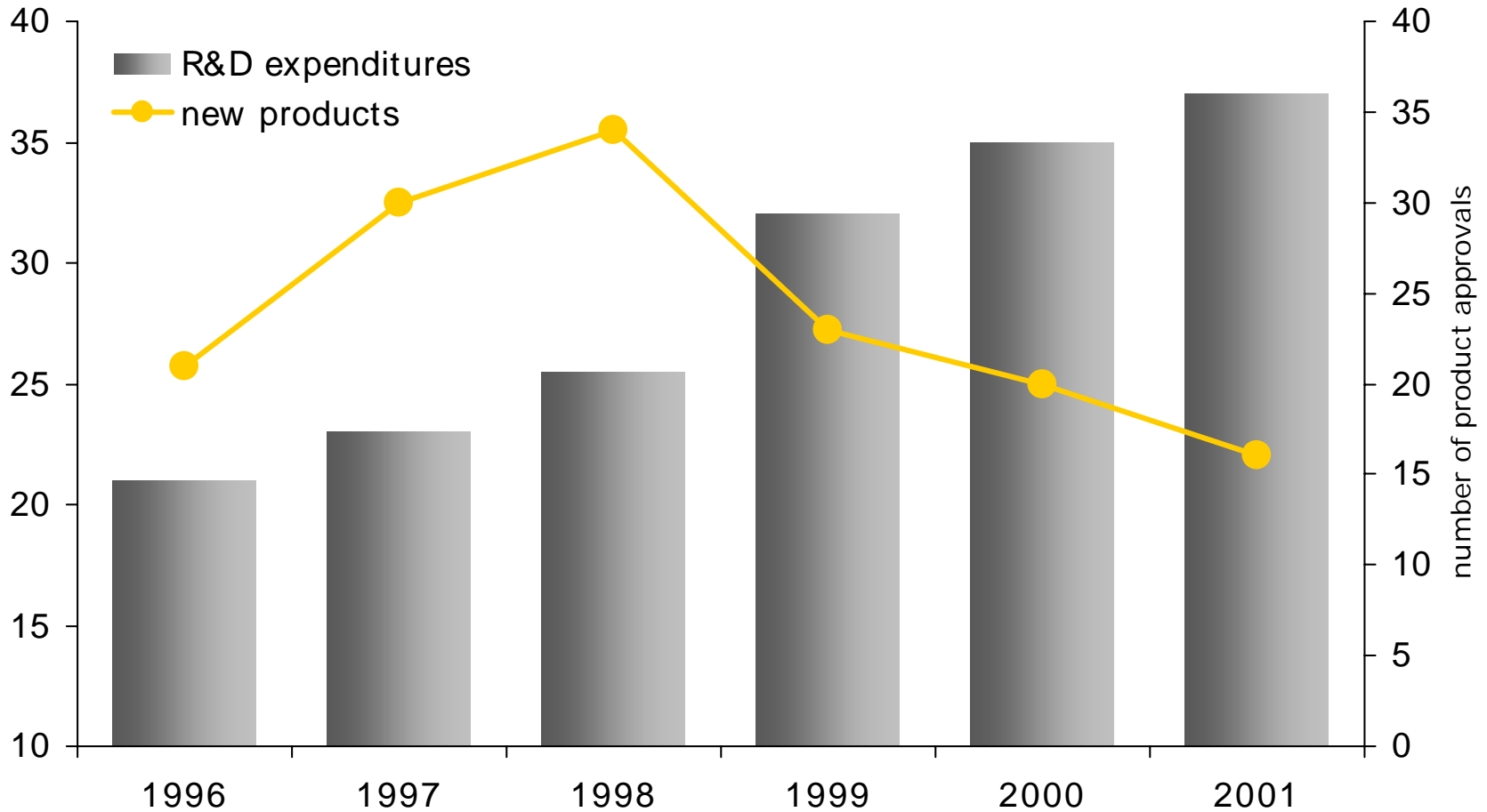
Exclusivity of the first representative of a substance class

Quelle: CMR



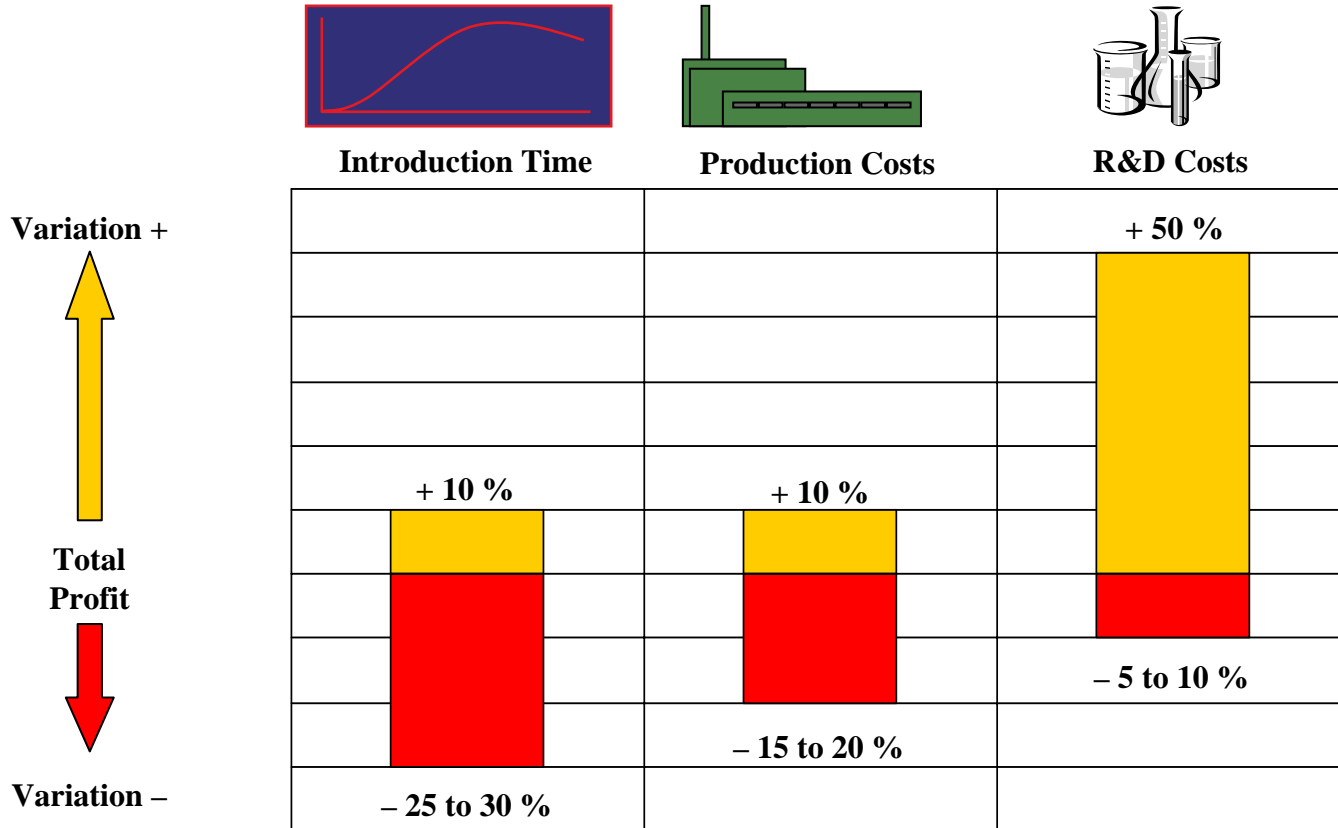
Quelle: CHEManager 22/2006

R&D Expenditures vs. productivity of the 20 biggest Pharma Companies



Quelle: Renfrey & Featherstone, Nature Genetics 2002

Late product launch is responsible for the biggest profit loss



Quelle: Arthur D. Little

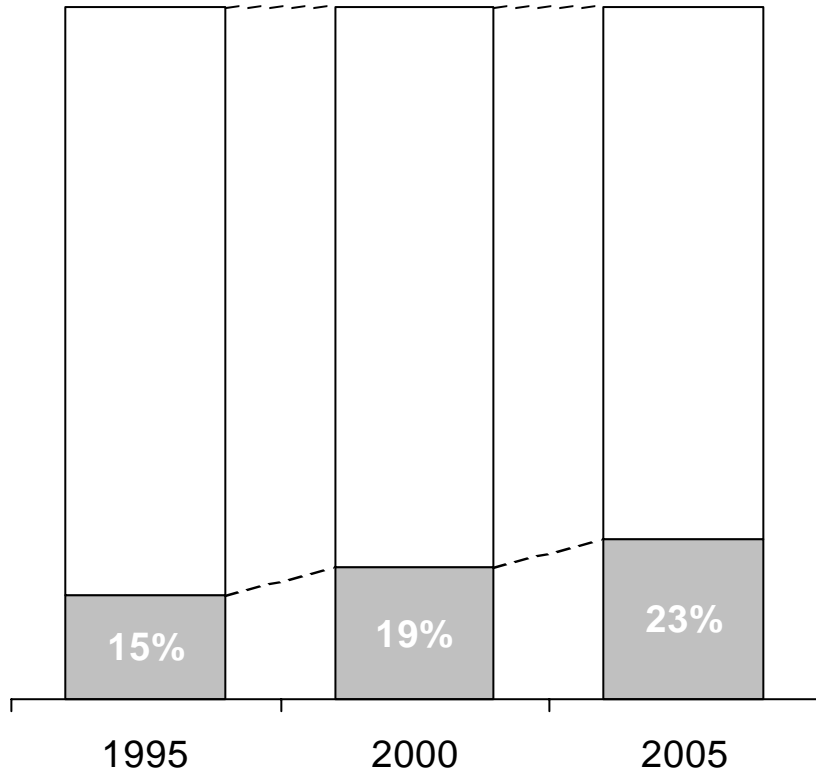
Ideas have to be translated very fast

- R&D spending has doubled in past seven years
- Loss of patent protection for drugs with a total turnover of more than 20 Bn US \$ per year for the next 5 years
- But nevertheless pipelines of new drug candidates drying up
- Inlicensing of R&D projects from other companies and academic research institutes is now a serious option,

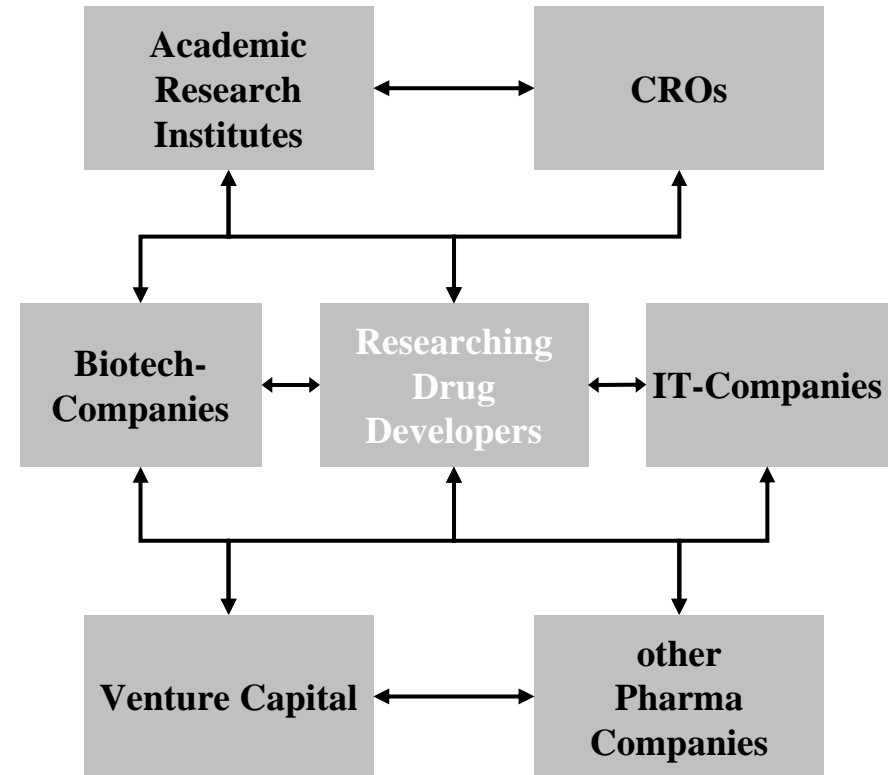
!! But only if
market is commercially interesting and
technology is patent protected !!

Pharmaceutical Research embedded in a network of external partners

Proportion of external Co-operations of global research budgets



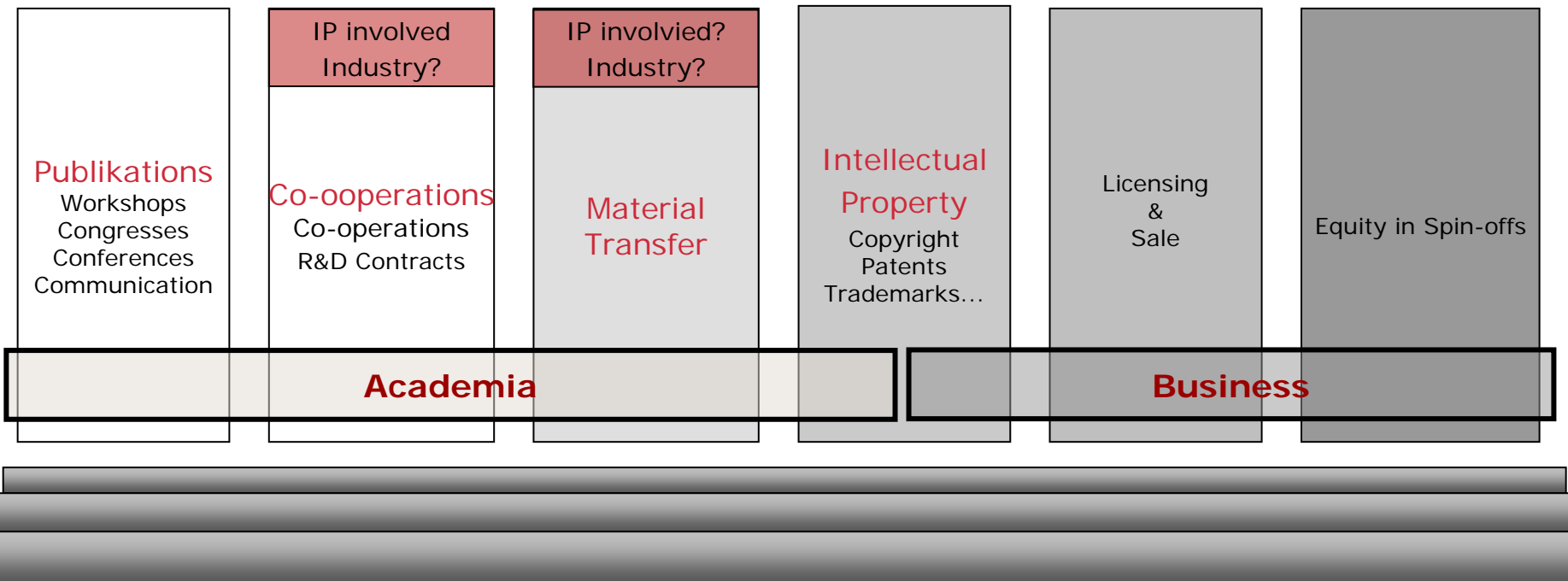
Development of a Co-operation network



- Early patent protection of inventions is essential
- High costs of patent protection have to be paid by research institutions
- Potential and chances of an invention are hard to evaluate in a very early stage of development
- Very long periods of development in the Life-Science area of up to 15 years
- Very high costs of development, especially in the later stages
- High risk of project failure over the time of development
- Development of projects within academic institutions mostly only up to the preclinical stage
- Interest of industry especially in late stage projects in clinical phases

- Critical mass (diversification of risk)
- Competence
- Regional versus area specific technology transfer
- Sustainability and long-term oriented
- Creation of self-interest
- Entrepreneurial freedom

Technology Transfer



- Founded in 2001
- Fully owned subsidiary of the Life-Science Foundation for the Promotion of Science and Research
- Focus on life sciences
- Marketing over **550 technologies** and materials of public research institutions
- Team of 16 specialists with multiyear experience and sector specific expertise
- Offices in Munich, Berlin, Brunswick, Hamburg, Hanover Neuherberg



Helmholtz
and Leibniz
Associations

IP Asset
Management

Medical Schools

IP Asset
Management

NGFN-2

Coordinating
Technology Transfer

Industry /
Free Inventors

Consulting



T. Jessen, H. Schühslser, E.-G. Afting

CEO: Dr. C. Stein, COO: Dr. P. Ruile

Team of analysts, technology managers, legal / tax advisors, IT, office manager / accounts

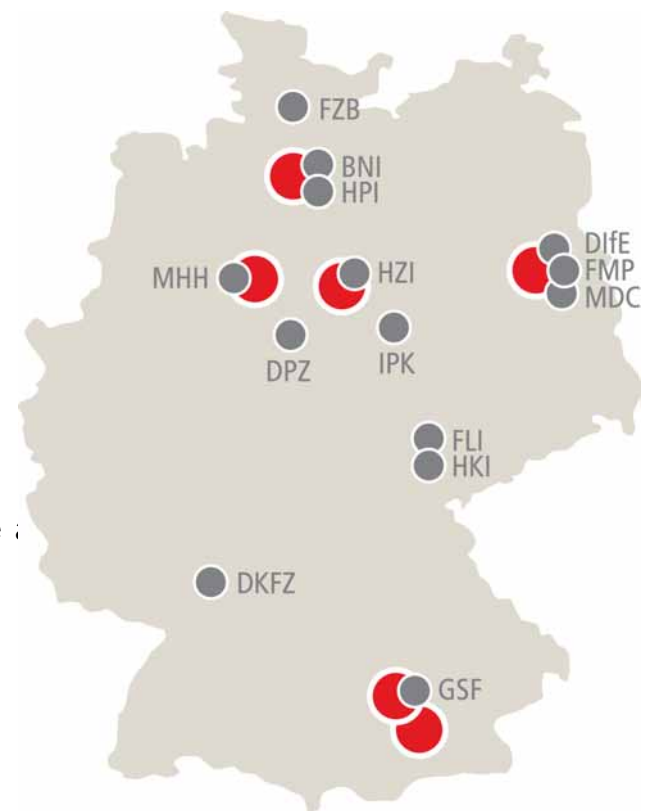
Technology scouts, technology managers

Helmholtz Association

- DKFZ, German Cancer Research Centre (NGFN only)
- GSF, National Research Centre for Environment & Health
- HZI, Helmholtz Centre for Infection Research
- MDC, Max Delbrück Centre for Molecular Medicine

Leibniz Association

- BNI, Bernhard Nocht Institute for Tropical Medicine
- DIfE, German Institute of Human Nutrition
- DPZ, German Primate Center
- FMP, Leibniz Institute for Molecular Pharmacology
- FLI, Leibniz Institute for Age Research – Fritz Lipmann Institute
- FZB, Research Center Borstel - Leibniz-Center for Medicine & Biosciences
- HKI, Leibniz Institute for Natural Product Research and Infection Biology - Hans-Knoell-Institute
- HPI, Heinrich Pette Institute for Experimental Virology and Immunology
- IPK, Leibniz Institute of Plant Genetics and Crop Plant Research



Medical Schools

- MHH, Hanover Medical School

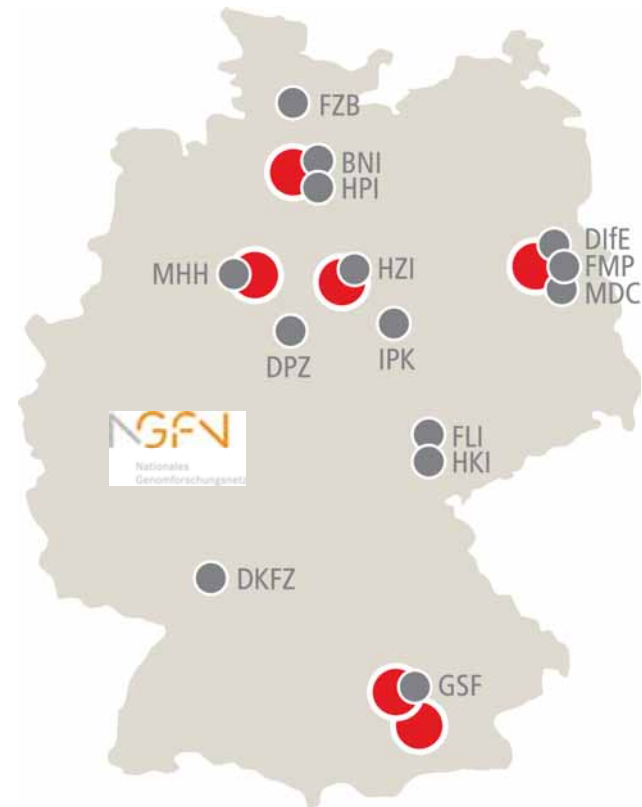
Coordination of technology transfer in the NGFN

- Large-scale research project linking various teams across Germany

➡ Total Potential *

- Approx. 6,500 employees
- Approx. € 480 mn budget p.a.
- Over 550 patent families
- Broad portfolio of know-how and research tools

* NGFN not included

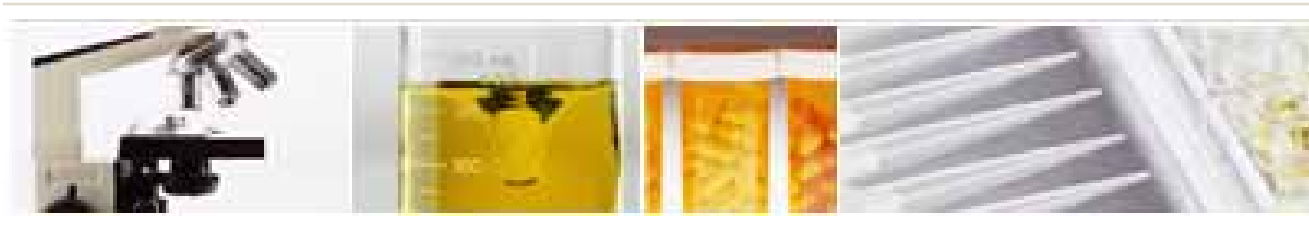


Over 550 patent families in 18 areas, including

- Oncology
- Infection
- Bioinformatics

Commerically attractive materials and research tools

- Antibodies
- Animal models
- Vectors



Full range of services:

- Scouting, identification, valuation of assets
- Developing IP strategy
- Developing options for exploitation
 - Licensing
 - Collaboration
 - Spin-off
- Marketing
- Structuring and negotiating agreements
- Coaching entrepreneurs, equity management
- Consistent follow-up
- Portfolio management
- Educating researchers

- **Activaero** - highly efficient aerosol technology and inhalation systems
- **Biomax AG** – identification of gene sequences and prediction of protein structure und function
- **Encepharm GmbH** – tailored research services and preclinical studies in the fields of mental illness (Depression) and neurodegenerative disease (MS and Parkinson)
- **Genomatix GmbH** – bioinformatics for functional genome analysis
- **IBA Biologics GmbH** – process development, GMP-production, cell banks
- **Inamed Research GmbH & Co KG** – contract research in the field of medical, technical and other aerosols
- **Ingenium Pharmaceuticals AG** – mouse model for human genetic diseases
- **IsoDetect GmbH** – analysis and monitoring of hazardous waste subject to compulsory cleanup
- **KeyNeurotek AG** – molecular design of active ingredients in the development of small-molecule drugs
- **NanoRepro GmbH** – male fertility and stem cell kryoconservartion
- **R & D Biopharmaceuticals GmbH** – development of therapeutics in oncology
- **Trion Pharma GmbH** – tumour therapy with bi-specific antibodies
- **Vaecgene GmbH** – recombinant Epstein–Barr virus as a tool in vaccine development and gene therapy



Over 180 revenue carrying agreements since 2002 and equity stake in 13 spin-offs

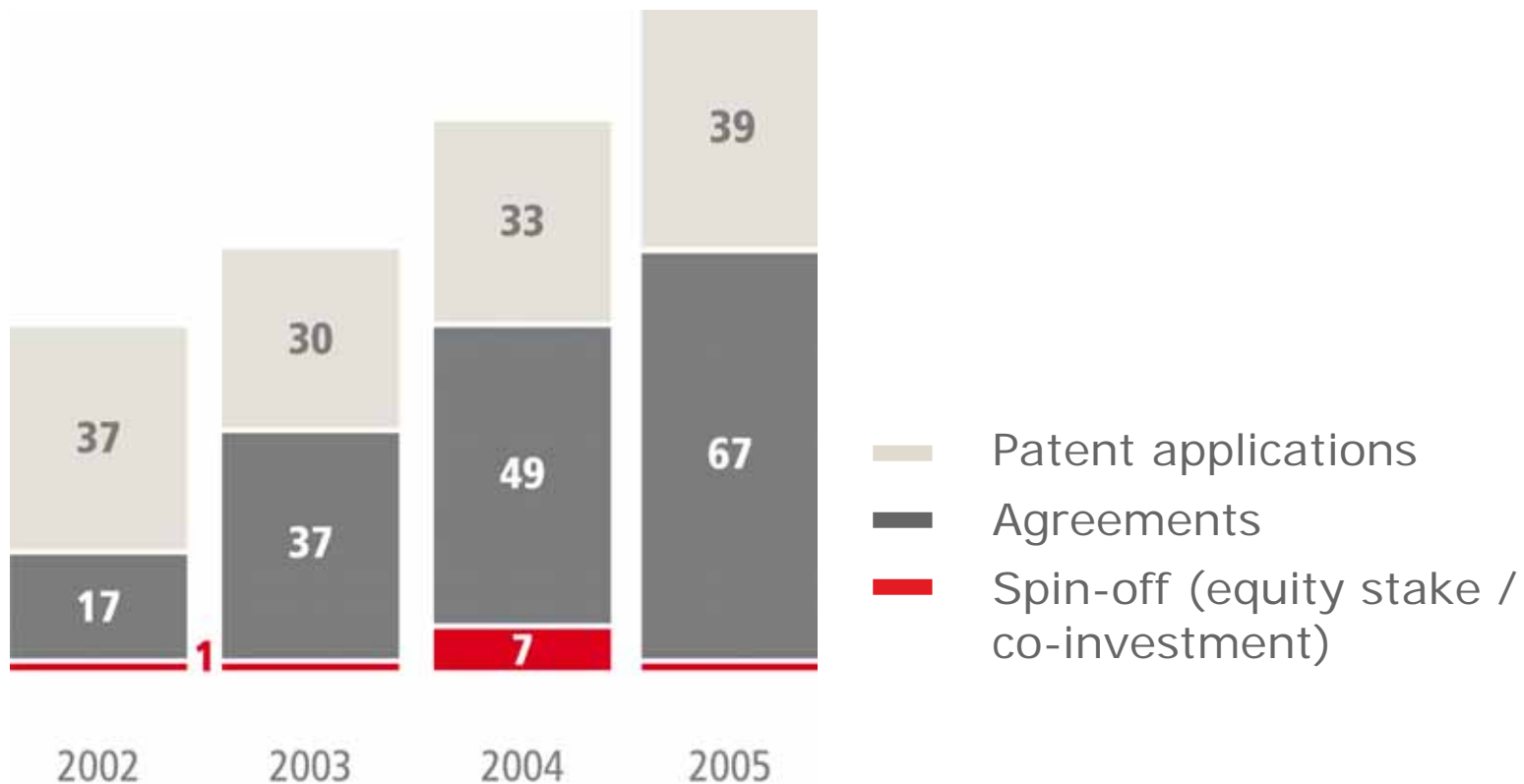
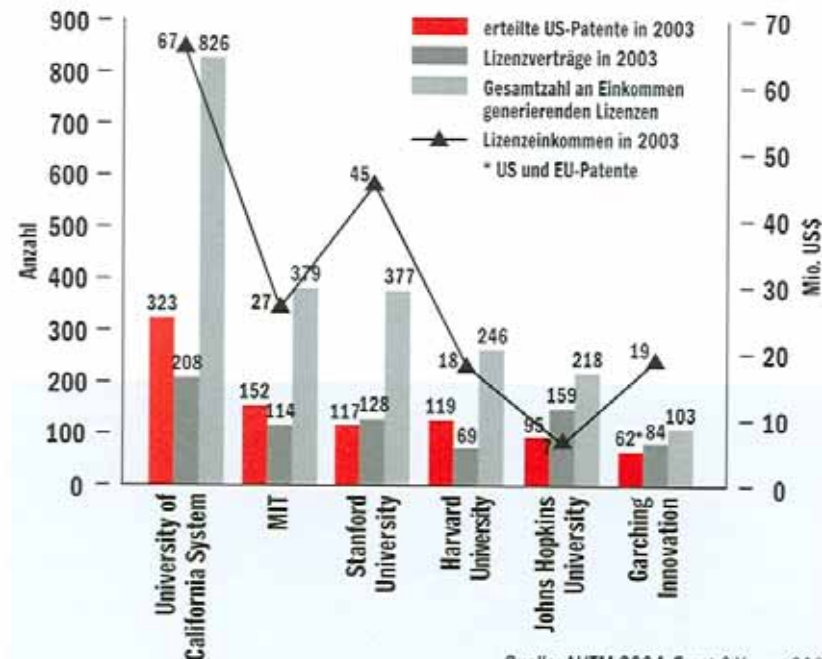


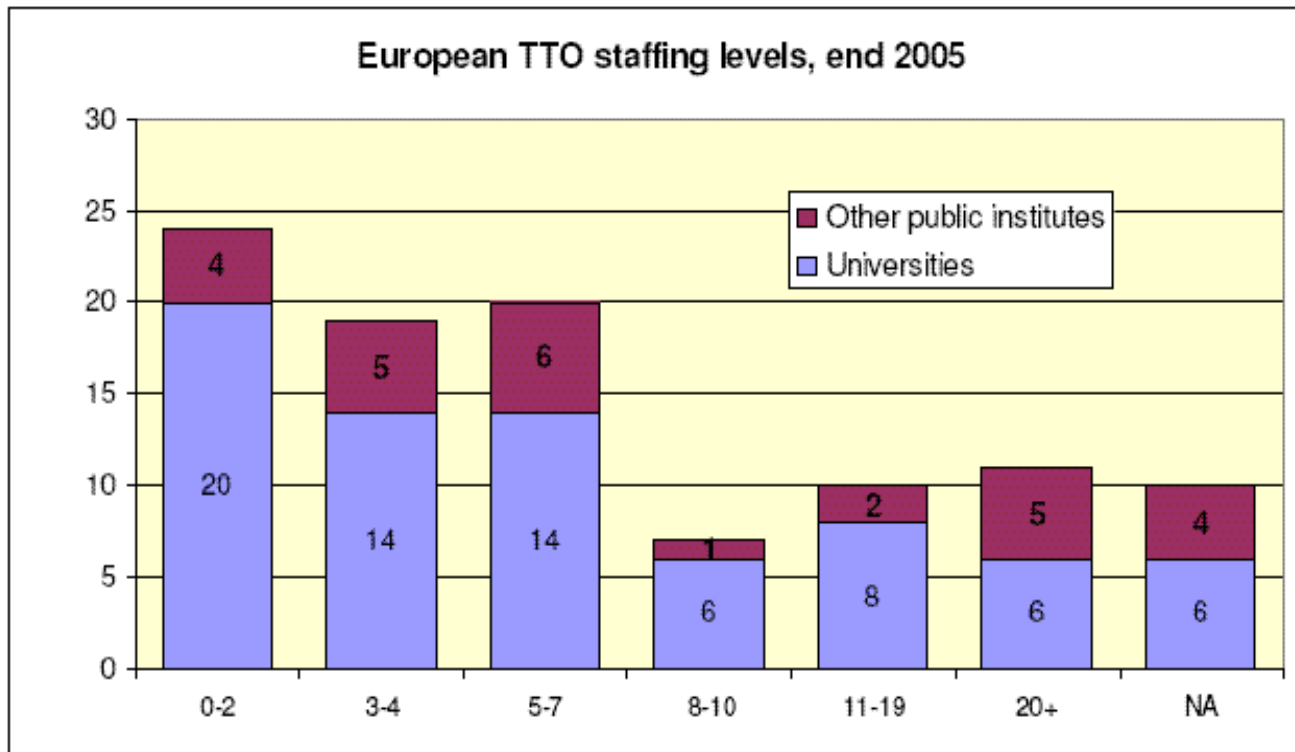
Abbildung 5-5:

Technologietransfer im internationalen Vergleich (Stand 2003)



Quelle: AUTM 2004, Ernst & Young 2005

Quelle: Ernst & Young, Deutscher Biotechnologie-Report 2005



NA = Not Available (respondent did not report results).

AUTM equivalent results: Figures US-3 and US-4 page 13 & 14, AUTM report.

Quelle: The 2006 ASTP Survey

- **One point of access** to an outstanding life-science IP portfolio (excellent academic research + critical mass)
- Experienced and interdisciplinary **team of specialists** (early patent protection + commercialisation strategy for promising technologies)
- **Extensive network** to the international industry, investors, experts
- Flexibility to structure deals **tailored** to the specific needs of the respective partners
- **Financial incentive** to go for the best deal
- **Entrepreneurial freedom** based on shareholder structure
- **But also: proceeds** are channeled back to research institutions

- Necessary prerequisites: **time, patience** and **money!!!**