

„Genetic Inventions and Patents - A German Empirical Survey“*
BMBF & OECD Workshop
„Genetic Inventions, Intellectual Property Rights and Licensing Practices“
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Joseph Straus, Max-Planck Institute, Munich

- **Reasons for and Concept of the Survey**
- **Target Groups**
- **Findings:**
 - as to the impact of patents in genomics on: e.g., overall financial micro-environment – cooperation - research and publication - patent litigation
 - as to specific patent law problems, e.g.: relevance of patent disclosure - Reach-through claims - Product claims on DNA sequences - Differences in law and practice - Lack of a community patent
- **Is a special regime needed?**

* Performed by H. Holzapfel and M. Lindenmeir, MD.

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Reasons for the Survey

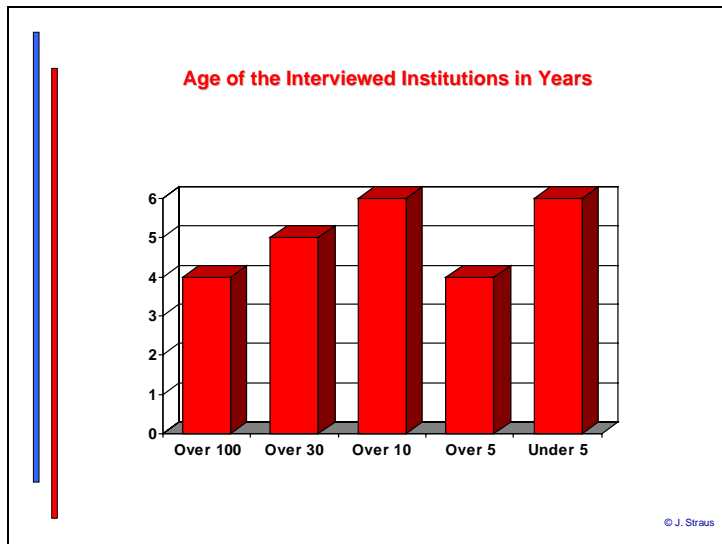
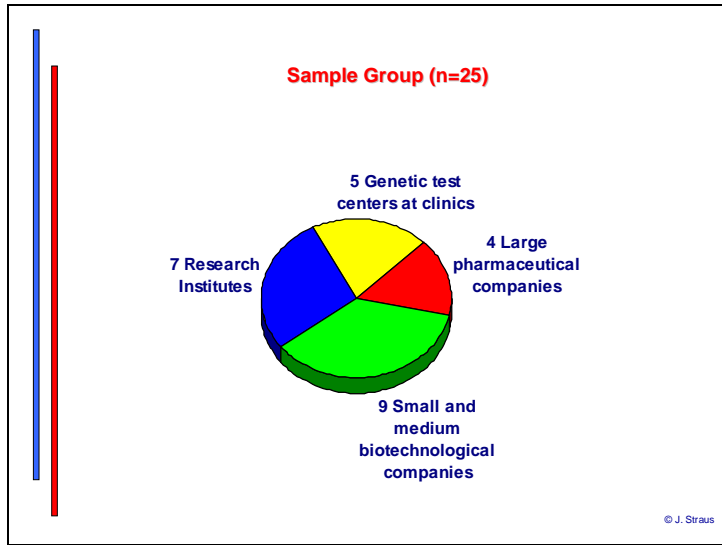
- To **verify** concerns expressed on negative impact of patents in genomics as set forth in the EU Biotech Directive 98/44 – in particular related to:
- Dependency resulting from DNA patents in general and from undue broad claims specifically
- Reluctance of researchers to enter fields with already patented genes
- Genetic testing
- Monopolistic genetic testing practices
- Royalty stacking
- Explosion of legal disputes

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Concept of the Survey

- **Personal interviews, based on**
- **Extensive questionnaires, adapted to the targeted groups**
- **Target groups: pharmaceutical companies (4), biotech companies (9), publicly funded research institutes (7), clinical genetic test centers (5)**
- **July 2001 – January 2002**

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Specialization of the Interviewed

Interview partner	specialization
pharmaceutical companies	development and marketing of medical drugs
biotechnological companies	development of medical drugs (no marketing yet); partially services like purification, sequencing, target identification, screening, expression analysis, development of expression systems
research institutions; unit for exploitation of research results	tumor immunology, molecular biochemistry;
clinical institutions	genetic consulting, basic research in anti-retroviral therapy, molecular cytogenetics, gene therapy

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Age of the Interviewed

Interview partner	foundation year
pharmaceutical companies	prior to 1900
biotechnological companies	2001: 1 2000 - 1998: 2 1997 - 1994: 3 1992; 1988; 1985
research institutions, unit for exploitation of research results	1964 (genome research since 1987); 1970; 1970; 1975; 1990
clinical institutions	1970; 1970; 1972; 1976; 1985 genome research since mid-80'

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Number of Patent Applications for Genetic Inventions

interview partner	patent applications
pharmaceutical companies	about 100*
biotechnological companies	25 – 180**
research institutions, unit for exploitation of research results	50 – 100**
clinical institutions	1 – 20**

* per annum
** total number

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Number of Granted Genetic Patents

interview partner	100	granted patents
pharmaceutical companies		500 - 1100
biotechnological companies		0 – 55
research institutions, unit for exploitation of research results		30 – 110
clinical institutions		1 – 6

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Number of Granted and Obtained Licenses

interview partner	granted licenses	obtained licenses
pharmaceutical companies	n. a.	n. a.
biotechnological companies	0 – 28	1 - multiple
research institutions, unit for exploitation of research results	0 – 83	0 - 10
clinical institutions	0 – 3	0

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Number of Co-operations

interview partner	co-operations
pharmaceutical companies	many
biotechnological companies	0 - many
research institutions, unit for exploitation of research results	2 - 91
clinical institutions	0 - 5

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Number of Lawsuits on Genetic Inventions

interview partner	Lawsuits
pharmaceutical companies	0 – 2
biotechnological companies	0 – multiple
research institutions, unit for exploitation of research results	0 – 4
clinical institutions	0 – 1

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Financial dependency on Patents and Lawsuits

- Pharmaceuticals companies: not affected, even with great proportion of turnover by biotechnological products
- Biotechnological companies: in general greatly affected,
 - Start-ups more
 - Established companies less
- No accumulation of law suits observed (one exception); dispute settlement as a solution
- Defensive strategy of enforcing patent rights prevailing

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Significance of Patents for Co-operation and Merging

- Limited significance for intermediate products, production assets and services like purification; know-how equally important
- Great significance for research tools like ESTs, SNPs (further innovation activity)
- Flexible agreements on the ownership of inventions emerging from co-operation

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Impact of Patents on Research Activity

- Tests for testing novelty, disclosure and function of patents owned by competitors
- Tests for comparing own products still under development to products already marketed
- Reluctance to search for new uses for alien inventions
- Use of research tools was not seen as problematic: available as staple goods, use remained behind closed laboratory doors, no economic incentive to sue until turnover generated

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Impact on Patents on Publication Activity

- Companies established pre-publication procedures in order to prevent publications precluding novelty
- Publications in scientific journals no problem due to time-consuming peer-review process
- However, academic institutions deplore lack of grace period

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Licensing

- No specific problems: Licenses are available. Royalty seen by some as a problem, but royalty stacking clauses could be included in license contracts
- Patent pooling and cross-licensing not common
- Compulsory Licenses - a more hypothetical alternative

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Defficiencies of Patent Documents and Patent Examination

- Language barrier between scientists and lawyers
- Broadest claims sometimes hidden in applications
- Patent documents often not very substantial compared to scientific papers. Suggestion made: peer-review program
- Difficult patent search because of claims like "hybridizing with", and whole sequence families in single applications
- Too long lasting patent granting proceedings

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Identified and Not Identified Problems

- Reach-through claims: Controversy on problems and how often they occurred
- Absolute Protection of Gene Sequences: Favored by majority in order to not discriminate against chemical inventions
- Problem: Examination guidelines still vary in detail between different countries
- Problem: in Europe uniformly granted patents split up in various national patents, each treated according to national legislation – lack of Community patent deplored!
- Problem: Ethical debate, distorted perception of the impact of patenting genetic inventions; however, political environment has improved since the amendment of genetic engineering law in Germany

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Special Regime for Genetic Inventions?

- Not supported: could prove outdated, no discrimination against chemical inventions
- Specificities of genetic inventions could diminish or even disappear in future, when e. g. function of a gene is analyzed automatically

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