



How effective are Research Exemptions in Patent Law? The German Experience

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Research Use of Patented Inventions
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- **The rationale of the patent system**
- **Common European Statutory Roots**
- **German Statutory and Case Law**
- **Limits of the exemption**
- **Experience / Some Final Thoughts**



The Rationale of the Patent System

„The ground for granting a patent to the inventor is ultimately the public interest in scientific and technological progress. Therefore the unlimited protection of the patent is not justified in a case where the further development of technology is hindered. The patent right – in the national sector as well as in principle in foreign law is aimed at promoting technological progress and stimulating the spirit of invention in the industry in a profitable manner.“

German Federal Supreme Court [1998]

R.P.C. 423 (435) – Confirmed by the

German Federal Constitutional Court in 2000



Common European Statutory Roots

Article 27 (b) Community Patent Convention (CPC) 1975 as reaffirmed in 1989

- **The right conferred by a Community Patent does not extend to**

„Acts done for experimental purposes relating to subject matter of the patented invention.“
- **All EU Members, except Austria followed suit – the Netherlands adopted somewhat narrower wording**



German Statutory Law

Section 11 Patent Act

The Effects of the Patent should not extend to:

...

- 2. Acts for experimental purposes relating to the subject matter of the patented invention**
 - 2a. The use of biological material for the purpose of breeding, discovery and development of new varieties of plants**
 - 2b. Studies and trials... necessary for obtaining pharmaceutical marketing authorization...**

Case Law: Germany Clinical Trials I

- Experiment under Sec. 11 No. 2 Patent Act
 - “... any planned act for the acquisition of knowledge, independent of the purpose for which the acquired knowledge is intended to serve eventually.”
- The subject matter of the invention must be the object of the test activity for the **purpose of gaining knowledge**
- Covers acts performed to determine the **effects** of a substance or **new previously unknown applications – further medical uses**
- Test may, eventually, serve commercial interests

Federal Supreme Court (1997) 107 IIC – *Clinical Trials I*

Case Law: Germany Clinical Trials II

- Clinical trials with substances of same indication **allowed** as long as not solely aimed at clarifying commercial facts, such as market needs, price acceptance and marketing possibilities but not at further clarifying properties, effects, possible uses and production possibilities of the subject matter of an invention
- Even if introduced and carried out with the commercial goal of obtaining marketing authorization with the data obtained

Federal Supreme Court [1998] R.P.C. 433 (434) – *Clinical Trials II*

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Limits of the Experimental Use Exemption

- **Yardstick: activity aimed at gaining new knowledge – enriching the state of the art**
- **Not covered: use of the invention as research tool (PCR, ESTs), i.e. for the patented purpose**

Impact of Patents on Research Activity

- Tests for testing novelty, disclosure and functioning of competitor's patented invention
- Tests for comparing own products under development to already marketed patented products
- Reluctance to search for new uses of products (e.g. DNA sequences) patented for others
- Use of research tools – not a real problem: available as staple goods, takes place behind lab doors, no economic incentive to sue until no turnover generated

Experience with the legal status quo

- Pharmaceutical industry offered strong opposition but gave up after the German Federal Constitutional Court confirmed the case law
- Instrumental for the acceptance of patents on biological material, such as genes, cell lines, plants and animals
- No economic negative impact reported
- Academic scientist (DFG) at time pleaded for a broader scope covering research tools, too
- No single compulsory license applied for



Some Final Thoughts

- **A balanced system – highest priority**
- **Sustained generation of new research tools essential – thus respective incentives necessary**
- **Simple extension of research exemption to research tools – counterproductive**
- **Legal license – may be a solution – but not without problems: for whom, compensation, impact on competition, etc.**